Bundesverband Medizintechnologie e.V.

Stellungnahme

Gezielte Überarbeitung der EU-Vorschriften für Medizinprodukte und In-vitro-Diagnostika

6. Oktober 2025

Vorbemerkung

Der Bundesverband Medizintechnologie e.V. (BVMed) begrüßt vollumfänglich das Bestreben der Europäischen Kommission, den Rechtsrahmen durch eine Verringerung des Verwaltungsaufwands und eine Steigerung der Berechenbarkeit und Kosteneffizienz bei gleichzeitiger Wahrung eines hohen Maßes an öffentlicher Gesundheit und Patientensicherheit zu straffen und zukunftssicher zu gestalten und so zu den ursprünglichen Zielen der Verordnungen beizutragen.
Die Stellungnahme wird sich vornehmlich auf die europäische Medizinprodukteverordnung (Verordnung 2017/745, nachfolgend MDR) beziehen und basiert auf allen bisherigen Papieren und Stellungnahmen des Verbandes.

Wir beobachten unter anderem Folgendes:

> Die Gesamtkosten und die Dauer der Konformitätsbewertungsverfahren bis zur Zertifizierung von Medizinprodukten sind für die Hersteller unvorhersehbar, nicht planbar und haben erheblich zugenommen;
> Die Auslegungen der Vorschriften und die Anwendung der MDCG[1] Leitfäden durch Benannte Stellen und Behörden gehen oft über das Gesetz hinaus und sind europaweit unterschiedlich, was dem Ziel der Harmonisierung im Binnenmarkt widerspricht;
> Produkte und insbesondere Innovationen werden nicht mehr in der EU sondern anderen Märkten (insbesondere USA) initial zugelassen.
> Einige Medizinprodukte sind auf dem Markt nicht mehr erhältlich und Unternehmen verschwinden, weil die Wirtschaftlichkeit nicht mehr gegeben ist.
> Kleine und mittlere Unternehmen (KMU) sind überproportional betroffen.

1. Lösungsansätze

Der BVMed hat mit dem deutschen Partnerverband für IVD (VDGH) bereits 2023 ein Whitepaper zur Weiterentwicklung des regulatorischen Rahmens veröffentlicht, in dem die Problemstellung im Zuge der MDR und IVDR-Implementierung aufgezeigt worden sind und konkrete Vorschläge zur Verbesserung gemacht (Anlage 1).

Neue Erhebungen[2] zeigen, dass die Innovationsfähigkeit der Unternehmen in Deutschland drastisch abgenommen hat und Innovationen zunächst in anderen Märkten, insbesondere in den USA, eingeführt werden.

[1] Medical Device Coordination Group, gemäß Art. 103 MDR
[2] Verbändeumfrage Sommer 2025 der dt. Verbände BVMed, SPECTARIS und VDGH sowie dem Medizintechnik Cluster Medical Mountains, Publikation folgt

Die besonderen Herausforderungen von Medizintechnik KMUs haben wir in einem Papier zusammengefasst (Anlage 2). Auch wenn sich die Herausforderungen oftmals mit denen großer und multinationaler Unternehmen decken, sind die Auswirkungen jedoch sind andere. Ein Grund dafür ist unter anderem die geringere Verfügbarkeit von finanziellen und auch personellen Ressourcen.

Der BVMed begrüßt die Ambitionen der Europäischen Kommission, bereits 2025 gesetzliche Vorschläge zur Änderung der Rechtstexte vorzulegen. In Anbetracht der Dauer dieser gesetzlichen Änderungen im Trilog-Verfahren, möchten wir wie bereits in den vorhergehenden Konsultationen eingehend darauf hinweisen, dass darüber hinaus kurzfristige Bürokratieentlastungsmaßnahmen und untergesetzliche Änderungen zwingend und zeitnah notwendig sind. Auch hierzu hat der BVMed gemeinsam mit weiteren Verbänden aus der DACH Region umfangreiche Beispiele vorgelegt (Anlage 3 und Anlage 4).

Wir bitten Sie, diese Vorschläge entsprechend zu berücksichtigen und stehen für Rückfragen gerne zur Verfügung.

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Anhang I
Anhang II

WHITEPAPER
zur Weiterentwicklung der MDR und IVDR

Die Ausgangslage

- komplexe und intransparente Vorschriften
- fehlende Regelungen für Orphan Devices, Nischenprodukte und Fast-Track
- erschwerte Entwicklung und Markteinführung neuer Produkte in Europa
- sinkende Attraktivität der CE-Marke
- absehbare Verknappung von Medizinprodukten
- gedrosseltes Innovationstempo

Unser Ziel mit der Weiterentwicklung

- solider, transparenter und berechenbarer Rechtsrahmen für das Inverkehrbringen von Medizinprodukten und In-vitro-Diagnostika
- hohes Maß an Sicherheit und Gesundheitsschutz
- Förderung von Innovationen
- eine Struktur, die die Gesamtverantwortung übernimmt
- Einhaltung der Grundsätze guter Verwaltungspraxis

5 Maßnahmenbereiche

1 ERGÄNZUNG DES DERZEITIGEN REGULIERUNGSSYSTEMS

Fast-Track-Verfahren (beschleunigte Verfahren) analog zu anderen Rechtsbereichen für

- innovative Produkte
- Orphan Devices und Diagnostics for rare diseases
- Nischenprodukte mit nachgewiesener Erfolgsbilanz

2 STEIGERUNG DER EFFIZIENZ DES SYSTEMS

Konsequente Umsetzung der Grundsätze guter Verwaltungspraxis

- planbare Fristen und berechenbare Kosten der Regulierungsverfahren
- gleicher Zugang für alle zum Regulierungssystem
- erhöhte Transparenz der Zertifizierungsprozesse auch durch Digitalisierung
- wirksame Rechtsmittel gegen Marktzugangsentscheidungen
- bessere Koordinierung paralleler und nationaler Gesetzgebungen

3 REFORM DES FÜNFJÄHRIGEN RE-ZERTIFIZIERUNGSZYKLUS

- begrenzte Gültigkeitsdauer der Zertifikate von fünf Jahren abschaffen
- effizienterer und stärker risikobasierter Zertifizierungszyklus, basierend auf Post-Market Daten
- IVDR: Selbstzertifizierung von Produkten niedriger Risikoklasse (Klasse B) zur Systementlastung und Wegfall bürokratischer Berichte ohne Patient:innenutzen

4 VERBESSERUNG DER INTERNATIONALEN ZUSAMMENARBEIT

- internationales Ansehen der CE-Kennzeichnung wiederherstellen
- verstärkte Einbindung der EU in das MDSAP-Programm für QM-Systeme
- MRAs (Mutual Recognition Agreement) der EU mit der Schweiz und UK

5 ZENTRALISIERUNG DER VERANTWORTUNG

- zentrale rechenschaftspflichtige Verwaltungsstruktur einführen
- Notifizierung und Überwachung der Benannten Stellen europaweit harmonisieren und zentralisieren
- KMU-Büro auf EU-Ebene einrichten

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Vollständiges Whitepaper
bvmed.de/whitepaper
vdgh.de/whitepaper

BVMed Die Stimme der deutschen MedTech-Branche

VDGH Verband der Diagnostica-Industrie

BVMed and VDGH White Paper on the Future Development of the MDR and IVDR

In cooperation with Erik Vollebregt – Axon Lawyers

9th June 2023

1 Introduction

Europe is at a crossroads with its market access system for medical devices. By now it is becoming clear that the MDR and IVDR risk not delivering on its promise of a "sound, transparent, predictable and sustainable regulatory framework" that "ensures a high level of safety and health protection" and "at the same time promotes innovation".[1]

In 2012 the Commission found that the medical devices regulatory system was "considered as not sufficiently efficient and effective".[2] This has not improved since. The functioning of the MDR and IVDR still compromises patient and user safety as well as the good functioning of the internal market. Severe and persisting issues relating to the MDR and IVDR transitional regime and application of new procedures lead to shortages of medical devices and IVDs. Many manufacturers have had to rationalize product portfolios as a result of costs for MDR and IVDR compliance, adapt devices to meet MDR and IVDR requirements and experienced significant changes in their supply chains as a result of required changes to devices. Many manufacturers are struggling to find notified body capacity available to re-certify devices again under the MDR and IVDR criteria, which were already safe and effective. As a result of lack of direction of notified bodies the emphasis in conformity assessment is put on procedural minutiae and requirement box-ticking, rather than assessment of the manufacturer's ability to reliably manufacture the device(s) concerned in his QMS.

The current system slows the pace of innovation. The MDR and IVDR rules are experienced as complex and unpredictable, making it less appealing to develop and launch novel products in Europe.[3] This is compounded by other factors, including Brexit and intense reimbursement pricing pressure, which may also reduce the attractiveness of pursuing the CE mark. This has resulted in a situation where the US market has emerged as the preferred launch site for new medical technology while, historically, medtech companies preferred to launch in Europe because they viewed EU product registrations as more straightforward.[4]

The governance of the medical devices system in the Union is fragmented, as a result of which there is no concentration of responsibility for the functioning of the system in one place, resulting in many parties taking part in the system but none of them

[1] Recital 1 MDR and IVDR
[2] Impact Assessment, Executive Summary (SWD(2012) 274 final), p. 4
[3] Boston Consulting Group, "Interstates and Autobahns: Global Medtech Innovation and Regulation in the Digital Age", March 2022, p. 5
[4] Boston Consulting Group, "Interstates and Autobahns: Global Medtech Innovation and Regulation in the Digital Age", March 2022, p. 5

taking responsibility for its overall functioning and performance. Industry welcomes the established system based on certification by Notified Bodies as third-party, independent institutions, which has functioned very well for decades and has proven its legitimacy and efficiency under the Directives. Like the other stakeholders notified bodies have invested massively in MDR and IVDR implementation and are facing problems related to lack of harmonized policy and delayed MDR / IVDR roll-out.

In the meantime at national levels health institutions find themselves in the situation that medical devices are often not available to the market. Data from April 2022 show that more than 50% of the medical devices companies are planning portfolio reductions, affecting 33% of these companies' devices as planned for discontinuation.[5] For IVDs 17% of today's IVD total market will be discontinued, of which 50% is discontinued by small and medium sized enterprises (SMEs).[6] SMEs turn out to be impacted more by the MDR[7] and IVDR[8] than larger companies, although they represent 95% of the medical devices and IVD manufacturers in Europe. Discontinuation decisions taken by many SMEs largely are based on the expectation that the IVDR remediation cost will outweigh the product revenue.[9] This happens on top of the devices that have already been discontinued since the entry into force of both regulations on 26 May 2017 and regardless of the additional legacy devices expected to be discontinued by the end of the grace periods for the MDR and IVDR in case their transition to the MDR or IVDR is unsuccessful. This will have a significant impact on healthcare systems. National parliaments are putting more and more pressure on local government to intervene in the excesses and shortages caused by a regulated market driven approval mechanism for medical devices.

At the moment we have not achieved the robust regulatory framework promised in the Impact Assessment for the MDR and IVDR that would be adapted to present and future technical and scientific progress, would contain clearer rules, more easily to be followed by economic operators and to be implemented by national authorities, and would provide the necessary instruments for a sustainable, efficient and credible management at EU level.[10] The regulated commercial partnership between notified bodies and manufacturers based on a civil law certification agreement is currently not calibrated under the MDR and IVDR to the efficiency with which it functioned under the Directives preceding the MDR and IVDR. Notified bodies struggle with the

[5] MedTech Europe Survey Report analysing the availability of Medical Devices in 2022 in connection to the Medical Device Regulation (MDR) implementation, 14 July 2022, p. 3
[6] Transition to the IVD Regulation, MedTech Europe Survey Results for October 2022, February 2023, p. 8
[7] MedTech Europe Survey Report analysing the availability of Medical Devices in 2022 in connection to the Medical Device Regulation (MDR) implementation, 14 July 2022, p. 7
[8] Transition to the IVD Regulation, MedTech Europe Survey Results for October 2022, February 2023, p. 8
[9] Transition to the IVD Regulation, MedTech Europe Survey Results for October 2022, February 2023, p. 8
[10] Impact Assessment, Executive Summary (SWD(2012) 274 final), p. 12

additional responsibilities under the MDR and IVDR and the restrictions on possibilities for meaningful dialogue with manufacturers.

With the January 2022 amendment to the IVDR[11] and the March 2023 amendments to the MDR[12] transitional regimes the EU has bought more time for notified bodies to complete conformity assessment of the enormous reservoir of applications clogging the system. Manufacturers are obliged to delay introduction of innovations to the European market where they can already apply make them available in other markets. This results in a situation where European patients are worse off, and manufacturers will need to incur additional costs in supporting older versions of devices for the European market only.

Furthermore, structural issues that create compounding inefficiencies in the system or violate principles of good administration that could have been resolved before the initial entry into force of the MDR and IVDR still persist. The principles of good administrative practice developed in the case law under the European Convention of Human Rights and the EU's own Human Rights Charter are incorporated in the MDR and IVDR by reference but none have been operationalised.[13] In short, the overall objectives of the MDR and IVDR have not been met at this stage.[14]

This paper occasionally refers to the EU medicinal products framework as a reference point for implementation of good administrative practice for market access of healthcare products. Given the fact that medical devices and IVDs fulfil an essential role in the healthcare system like medicinal products do there is no objective justification why medical devices and IVDs should be treated differently when it comes to application of principles of good administration.

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[11] Regulation (EU) 2022/112 of the European Parliament and of the Council of 25 January 2022 amending Regulation (EU) 2017/746 as regards transitional provisions for certain in vitro diagnostic medical devices and the deferred application of conditions for in-house devices, OJ 2022 L19/3

[12] Regulation 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices, OJ 2023 L080/24

[13] See recital (89) MDR and IVDR: "This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter and in particular human dignity, the integrity of the person, the protection of personal data, the freedom of art and science, the freedom to conduct business and the right to property. This Regulation should be applied by the Member States in accordance with those rights and principles."

[14] Impact Assessment, Executive Summary (SWD(2012) 274 final), p. 6: "This revision pursues three overall objectives:

- Overall objective A: To ensure a high level of protection of human health and safety
- Overall objective B: To ensure the smooth functioning of the internal market
- Overall objective C: To provide a regulatory framework which is supportive for innovation and the competitiveness of the European medical device industry"

This White Paper does not aim to provide fixed solutions but aims to a start discussion on how to make the MDR and IVDR future-proof beyond the quick fixes and 'delays' by proposing potential options for the further development of the regulatory system for medical devices after the final transition from the Directives to MDR and IVDR and ensure their full implementation, in the short, mid and long term:

Option	**Short term (1 year)**	**Mid term (2-4 years)**	**Long term (>5 years)**
3.1 Fast Track Procedure for Innovations		X	
3.2 Orphan Devices and diagnostics for rare diseases regime	X	X	
3.3 Niche products regime	X	X	
4.2 Predictability of deadlines	X	X	
4.3 Calculability of the costs	X		
4.4 Access to the system	X	X	
4.5 Transparency of notified body procedure and surveillance	X		
4.6 Substantial Change definition	X		
4.7 System-inherent possibility to complain	X		
4.8 Legal review of decisions	X (option 2)	X (option 1)	
4.9 Overlapping legislation and national legislation	X		
5.1 Reform of re-certifications of MDR and IVDR products	X	X	X
5.2 Post market surveillance more pragmatic	X	X	
6.1 EU participation in the MDSAP	X	X	
6.2 International reliance		X	
7.1 Structuring of certification procedures and self-certification		X	X

2 Executive summary

While there is broad agreement that the foundations of the EU system are sound, all stakeholders seem to agree at the moment that the EU system for medical devices and IVD policy, market access and oversight is structurally underperforming and does not deliver on the promise of a future proof and state of the art regulatory system for medical devices and IVDs. This affects confidence and trust in the system, its stakeholders and the reliability of medical devices approved under the system. As a result of the continued fragmentation and under-resourcing of the system on both EU and Member State level structural problems such as timely notified body designation, pragmatic implementation of the MDR and IVDR, development of guidance and adaptation of the system to specific needs (e.g. orphan devices) are not addressed adequately except with repeated moving of transitional period deadlines in several amendments and corrigenda. BVMed and VDGH believe that more structural measures are needed to make the market access process more reliable and predictable and enable notified bodies to function more effectively. BVMed and VDGH further believe that the EU should step up international harmonisation efforts in the IMDRF and on bilateral basis. Finally, BVMed and VDGH believe that one of the core issues that makes Union devices policy underperform is the lack of central responsibility for the functioning and performance of the system, which could be centralised in a European level structure to be determined.

3 Supplement missing regulations

3.1 Fast Track Procedure for Innovations

3.1.1 Issue

The EU medical devices system has no dedicated pathway for innovative devices for which there is a specific need in society. Innovative devices comprise medical technology that, whether incremental or not, offers meaningful advantages over alternatives for users, patients, health institutions, reimbursement systems and/or society. Small and medium sized manufacturers, which comprise the majority of EU (in vitro diagnostic) medical device manufacturers, are the engine of innovation in medical technology, are treated the same as the largest manufacturers in terms of fees, timelines and cost of compliance.

As a result of this one-size-fits all approach, medical innovations that significantly improve outcomes and/or raise the standard of care take unnecessarily long to become available to patients.

3.1.2 Background

Where other jurisdictions have accelerated pathways to bring medical devices to the market (e.g. the FDA breakthrough devices program[7], Japan's fast-track review process for pioneering devices), the regulations only provide for emergency authorization under article 59 MDR / 54 IVDR.

By contrast, the EU pharmaceutical law framework contains a number of accelerated or abbreviated pathways for medicinal products that are of major interest to public health.

Given the presence and success of abbreviated and accelerated pathways in other jurisdictions (e.g. the FDA breakthrough devices program) and the EU's intention to have the medical devices regulatory framework converge more with the medicinal products framework there is no objective reason why there would not be similar options for medical devices in the Union. Without an accelerated pathway for medical technology innovations in the EU, European patients with unmet medical needs, life-threatening or highly debilitating diseases have delayed options for treatment compared to other countries.

Abbreviated and/or accelerated procedures for innovations are available in several jurisdictions and in the EU under the medicinal products framework as these procedures serve public health goals. At Union level choices will need to be made who decides which devices and/or manufacturers are eligible for these procedures and who is responsible for this.

3.1.3 Solutions for discussion and opportunities

Solutions to this problem are readily available because several jurisdictions have developed successful local procedures. These procedures can be adopted for administration and application under the EU system. Procedures that can be envisaged are (in addition to orphan and niche devices discussed in sections 3.2 and 3.3 respectively) are:

- A fast-track procedure for devices that are innovative (e.g. by analogy to the FDA breakthrough devices program[15]);
- A conditional approval procedure for devices that address an unmet medical need (by analogy to medicines procedure). This could be available where the benefit of immediate availability of the device outweighs the risk inherent in the fact that additional data are still required. The additional data requirements could be set out in a PMCF/PMPF program to which the

[15] https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program

manufacturer commits. This procedure should be distinguished from article 59 MDR / 54 IVDR, which provides for a pathway based on interests of public health or patient safety or health for devices that are not CE marked and do not need to be CE marked.

BVMed and VDGH see the following options to implement these procedures.

Option 1

Annex VII of the MDR / IVDR could be amended based on the delegation in article 36 (3) MDR / 32 (3) IVDR to include additional accelerated and/or abbreviated procedures. Member State competent authorities and/or the European accountable managing structure would have oversight over the application procedures based on articles 44 and 45 MDR / 40 and 41 IVDR.

Option 2

Alternatively, these procedures could be administrated by Member States. It would be possible to provide for a procedure under which either a Union level article 59 (3) MDR / 54 (3) IVDR derogation or a Union level article 97 MDR / 92 IVDR exemption[16] is granted for the duration of the conformity assessment of the device.

Option 3

A third option would be to set up an EU level expert panel that provides an advice about eligibility for one of the fast track procedures mentioned above, after which the accountable managing structure takes a formal decision to award the procedure benefit. After that decision, the notified body concerned would apply the conformity assessment procedure.

In the US the services of the FDA decide if a device is eligible for breakthrough designation. In the Union it would need to be decided where the decision for eligibility is made. Since the designation of special status for public health purposes is a Member State decision, it would seem appropriate to attribute this decision to the Member States or to a specific EU level expert panel, because accelerated or abbreviated procedures serve a goal of public interest.

[16] By analogy to the procedure in MDCG 2022-18 MDCG Position Paper on the application of Article 97 MDR to legacy devices for which the MDD or AIMDD certificate expires before the issuance of a MDR certificate

3.2 Orphan Devices and diagnostics for rare diseases

3.2.1 Issue

Currently the MDR and IVDR are lacking a specific regulatory pathway for orphan devices such as paediatric devices or diagnostics for rare diseases (see under 3.3 below for niche products). Developing medical devices and diagnostics intended for small numbers of patients has little commercial incentive under normal market conditions, which is exacerbated by the conformity assessment pathways and regulatory burden for the lifetime of the device that adds to this cost. Manufacturers of orphan devices will focus their efforts on jurisdictions with orphan device and niche device regulations, where the orphan device reaches the market earlier, depriving Union patients of (early) access to these devices.

3.2.2 Background

The Commission and industry seem aligned on the need of a solution for orphan devices or diagnostics for rare diseases under the MDR and IVDR.[17] The MDCG has stated in MDCG 2022-14 that sustainable solutions are needed in the mid- and long-term for orphan devices.[18] The Commission has indicated to the Council that it considers that a solution for orphan devices should be tackled before the end of the extended transitional periods.[19] Orphan medical devices are also addressed in the EU4HEALTH program 2022, targeting paediatric patients specifically.[20]

Currently the Commission is gathering further evidence for the comprehensive evaluation of the MDR and IVDR due by May 2027 pursuant to Article 121 MDR / 111 IVDR.[21] The findings of the Commission are that costs related to market access, in particular clinical evaluation and conformity assessment, often render the development of paediatric devices economically not interesting. Innovation for paediatric patients therefore lags behind the advances made in relation to non-orphan devices.

The Commission is currently considering an orphan devices policy of supporting non-profit organisations or consortia that provide a platform for academic bodies, scientific societies, developer of devices, in particular SMEs, and NGOs with a specific interest in innovative paediatric devices. The intention is to help foster and guide the development of orphan devices this way, for paediatric patients, in particular in areas

[17] Information note from General Secretariat of Council, Brussels, 8 March 2023 6484/23, p. 7
[18] MDCG 2022-14, point 18
[19] Information note from General Secretariat of Council, Brussels, 8 March 2023 6484/23, p. 7
[20] See HS-g-23-65 Call for proposals for a program on orphan medical devices, in particular targeting paediatric patients (https://health.ec.europa.eu/system/files/2022-11/wp2023annexen.pdf)
[21] Information note from General Secretariat of Council, Brussels, 8 March 2023 6484/23, p. 7

of unmet medical needs in the EU4HEALTH programme.[22] This takes inspiration from the Paediatric Device Consortia Grants Program of the US Food and Drugs Administration (FDA).[23] However, a number of other jurisdictions also have successful orphan device programs that may serve as source of inspiration, such as Brazil, China and Japan.

Arguably support of consortia or platforms that support development of orphan devices is not the same as adoption of a regulatory pathway for orphan devices like available for medicinal products. This seems to be missing in the Commission's actions under the EU4HEALTH framework. Jurisdictions like Brazil, China and Japan do have specific orphan devices pathways.

The MDCG, for its part, has indicated that it "will pursue work with a view to providing a definition for 'orphan devices' and suggesting specific guidance or other means of assistance for those products to be able to meet the legal requirements."[24]

3.2.3 Solutions for discussion and opportunities

BVMed and VDGH believe the MDCG's work on definition of orphan devices and diagnostics for rare diseases and means of assistance must be developed in close cooperation with all stakeholders in order to arrive at solutions that will be viable in the middle and long term and will have the intended effect.

An orphan designation for medical devices and diagnostics for rare diseases could be modelled on the orphan designation criteria for medicinal products of rarity, severity and unmet medical need for the device.[25] At EU level a much looser working definition is used: "medical devices, that benefit a relatively small group of patients in the treatment or diagnosis of a disease or condition"[26]. The definition can be incorporated in article 2 MDR / IVDR to ensure legal certainty. Alternatively, specific orphan medical conditions can be listed on a rolling basis an EU level by the accountable managing structure discussed in section 7.1 after SCHEER advice. They may also be included as an annex to the MDR or IVDR subject to amendment by the Commission after e.g. SCHEER advice based on delegation with a mechanism of

[22] See HS-g-23-65 Call for proposals for a program on orphan medical devices, in particular targeting paediatric patients (https://health.ec.europa.eu/system/files/2022-11/wp2023annexen.pdf)
[23] HS-g-23-65 Call for proposals for a program on orphan medical devices, in particular targeting paediatric patients (https://health.ec.europa.eu/system/files/2022-11/wp2023annexen.pdf)
[24] MDCG 2022-14, point 18
[25] https://www.ema.europa.eu/en/human-regulatory/overview/orphan-designation-overview
[26] HS-g-23-65 Call for proposals for a program on orphan medical devices, in particular targeting paediatric patients (https://health.ec.europa.eu/system/files/2022-11/wp2023annexen.pdf)

periodic revision. Any devices with diagnosis or treatment of these conditions as intended purpose could qualify as orphan devices diagnostics for rare diseases.[27]

Orphan status qualification could be done based on application of a definition alone, by a notified body, or by the accountable managing structure.

Appropriate elements of a devices orphan designation would be:

- Scientific advice for orphan devices and diagnostics for rare diseases analogous to protocol assistance for orphan medicinal products (to be implemented by means of a change to article 61 (2) MDR / 56 (2) IVDR);
- Fee reductions, grants (e.g. via EU4HEALTH program) or tax reduction[28]; and
- Optional national incentives in Member States.

Conformity assessment of orphan medical devices or diagnostics for rare diseases could take place by means of a specifically described conformity assessment pathway set out in article 52 MDR / 48 IVDR and Annex IX, section 5, e.g. in a new section to be added this section. This conformity assessment pathway should be expedited, with shortened time periods for the different stages of the conformity assessment[29] and a fixed duration for the whole procedure as to ensure predictability of the process for the manufacturer in case of an orphan device.

3.3 Niche products

3.3.1 Issue

The current medical devices regulatory system does not provide for incentives to stimulate economically unsustainable niche (in vitro diagnostic) medical devices for specific conditions, where there may be unmet medical needs. Examples would be rare autoimmune diseases or allergies.

3.3.2 Background

Niche devices are devices that are designed to treat or diagnose a specific medical condition or used in a specific procedure and may be used in a specific medical field or be intended for a specific subset of patients. The main feature and at the same time problem of niche devices is that they have a limited market, and that their development and commercialisation are justified by the clinical need of a small but

[27] This model is used in China and Japan currently, see RegIntA report "Orphan Devices & Niche Products – Global Approaches", June 2022, sections 2.3 and 2.4

[28] Certain jurisdictions (China and Japan for example) with orphan device programs provide tax reduction and government funding for R&D activities in the field of orphan medical devices, see RegIntA report "Orphan Devices & Niche Products – Global Approaches", June 2022, sections 2.3 and 2.4

[29] Analogous to the HDE application for Humanitarian Use Devices (HUDs) in the US, which takes 75 days instead of 180 days, see RegIntA report "Orphan Devices & Niche Products – Global Approaches", June 2022, section 2.6

identifiable group of patients, while not meeting requirements for an orphan device. Niche devices are often not profitable or may become not profitable if the investment in regulatory clearance and clinical data for the clearance process outweighs the expected profits.

They are distinguished from orphan devices by the fact that they are not intended for a specifically indicated orphan medical indication or do not meet the population size criteria for orphan device.

The small size of the target patient population makes it more difficult to conduct clinical or performance studies and generate sufficient clinical evidence to support regulatory approval for niche devices. Additionally, since the market for these devices is small, they face challenges in obtaining reimbursement from payers. This leads to a combination of relatively low turnover of the device combined with relatively high costs for clinical evidence and market approval.

3.3.3 Solutions for discussion and opportunities

Definition

The definition of the concept of niche (medical) devices can be fitted within the existing definition of medical devices. A definition can be provided in article 2 MDR or IVDR, or a solution can be chosen of listing categories of niche devices in an Annex to the MDR or IVDR (like with the Annex XVI devices – the Annex can be implemented by implementing act) or in an implementing act. Listing of categories of devices has the advantage of increased legal certainty.

A definition of niche device for inclusion in article 2 MDR / IVDR could consist of the following elements:

1. The device is intended for a specific patient group or specific medical application or diagnosis;
2. The device is commercially not viable if made available for the niche intended purpose alone; and
3. The device offers a significant clinical benefit or other advantage over CE marked alternatives with an intended purpose that does not include the niche patient group or niche application.

Conformity assessment pathway

Devices that meet the qualification criteria for a niche device are eligible for the niche devices conformity assessment pathway, which would be characterised by a number of elements. The manufacturer of the niche device can indicate in the conformity assessment application that the application concerns a niche device, which would be validated by the notified body against the qualification criteria for niche devices.

In order to make the regulatory pathway more predictable for niche medical devices article 61 (2) MDR should be amended as to include niche medical devices in its scope to obtain certainty at an early stage about the clinical development strategy for the niche device. There should be dedicated expert panels for niche devices. A similar solution can be considered for IVDs by adding a provision similar to article 61 (2) MDR into article 56 IVDR.

The conformity assessment pathway after scientific advice should be expedited, with shortened time periods for the different stages of the conformity assessment[30] and a fixed duration for the whole procedure as to ensure predictability of the process for the manufacturer in case of a niche device that is intended for an unmet medical need.[31]

Account should be taken of regulatory approvals elsewhere in the world, where available.

Gaps in clinical data (provided that the device has a demonstrable positive risk/benefit ratio) can be filled in by means of PMCF / PMPF.[32]

Funding

Like orphan devices or diagnostics for rare diseases[33], niche devices should be able to profit from funding for the purpose of collecting clinical data, for example under the EU4HEALTH program, and be subject to tax reductions for R&D activities.

4 Measures to increase efficiency and implementation of principles of good administration

4.1 Introduction

The increased obligations for notified bodies and administrative formalities required under the MDR and IVDR have upset the historic partnership between manufacturers and notified bodies. This has led to several common challenges that are compounded by the inefficient notification designation process for notified bodies under the MDR and IVDR. Notified bodies take decisions with respect to the rights and obligations of private parties by granting, suspending, limiting and revoking certificates. BVMed and

[30] Analogous to the HDE application for Humanitarian Use Devices (HUDs) in the US, which takes 75 days instead of 180 days, see RegIntA report "Orphan Devices & Niche Products – Global Approaches", June 2022, section 2.6

[31] The criterion of unmet need could be copied from the orphan designation criteria for medicinal products: there must be no satisfactory method of diagnosis, prevention or treatment of the condition in the EU, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

[32] This solution is adopted in Japan, see RegIntA report "Orphan Devices & Niche Products – Global Approaches", June 2022, section 2.4

[33] See above under section 3.2.3

VDGH believe that consistent implementation of the principles of good administration in MDR and IVDR procedure is needed to ensure that the CE certification system under the MDR and IVDR continues to operate in a fair, transparent and predictable manner under administrative accountability.

4.2 Predictability of deadlines

4.2.1 Issue

At the moment there are no deadlines for conformity assessment procedure and quality system review, neither as regards (basically any of) the respective procedural steps, nor for the whole process. This makes it impossible for the manufacturers to plan their business reliably which defers investment in new and innovative devices. This insecurity and ensuing inability to plan affects SMEs the strongest.[34]

4.2.2 Background

The lack of deadlines for taking market access decisions is prevalent in the EU medical devices framework. Notified bodies can define their own deadlines and these may differ between notified bodies.[35] Only in exceptional cases is there a specific harmonised procedural deadline (e.g. for the clinical evaluation consultation procedure under article 54 MDR or the scrutiny procedure under article 50 IVDR). As a result, manufacturers have no reliable way of knowing when the CE certificate for a device will be granted. Notified bodies can only provide rough estimates, which they may not be able to guarantee in practice as a result of the slowdown in the system and the bottleneck caused by the stunted implementation of the regulations. Not only are notified bodies confronted with an enormous spike in the number of conformity assessments, but also with a more extended review in the individual conformity assessments as a result of new requirements under the MDR and IVDR. This is exacerbated by the significantly increased bureaucracy and monitoring of notified bodies, which compound to such inefficiencies that this leads to a massive slowdown of the individual conformity assessments.

In addition, where manufacturers agree audit dates and time slots with notified bodies these are often moved in practice due to the capacity bottleneck affecting notified bodies themselves. In practice this leads to a situation where a notified body may use internal deadlines for planning purposes, but could not commit to a deadline

[34] Transition to the IVD Regulation, MedTech Europe Survey Results for October 2022, February 2023, p. 8; MedTech Europe Survey Report analysing the availability of Medical Devices in 2022 in connection to the Medical Device Regulation (MDR) implementation, 14 July 2022, p. 7

[35] See Annex VII 4.5.1 MDR and IVDR requirement for notified body conformity assessment activities: “specify the rationale for fixing time limits for completion of conformity assessment activities”

for the conformity assessment process (even when this includes clock stops) like a medicinal products agency must in Europe.

It is a principle of good administrative practice when exercising government authority that citizens are treated equally and that a degree of certainty about the process is provided.[36] This is the standard in the medicinal products marketing authorization framework, which includes fixed durations for the whole procedure and fixed durations for the procedural steps.[37] Only clock stops during which the applicant has to supplement data or answer questions can add to the duration of the procedure.[38]

4.2.3 Solutions for discussion and opportunities

The MDR and IVDR are already a blend of competent authority decisions and notified body decisions, which leads to a lack of predictability, resulting in business uncertainty and unknown availability of technologies for patient care.

There are several options for solutions to this issue. All options should preferably be combined with centralisation of policy and responsibility at EU level as discussed below in section 7.

Option 1 – defining procedures in Annex VII

Article 36 (3) MDR / 32 (3) IVDR provides for a specific legal basis for implementing acts for the uniform application of the requirements set out in Annex VII to the extent necessary to resolve issues of divergent interpretation and of practical application. An implementing measure defining specific procedures, fixing total duration of these specific procedures and providing specific procedural steps would fit in the scope of this attributed competence. In order to meet the principle of transparency the procedures' deadlines should be published by the notified body, in addition to the amendment of Annex VII. This option could be combined with Option 3 below (oversight of procedural deadlines).

The deadlines provided in Annex VII could be established with direct reference to the principles set out in the medicinal products framework:

- Fixed duration for the whole procedure, excluding clock stops;
- Fixed duration for procedural steps in relation to the procedure concerned, allowing for a transparent and reliable procedure;

[36] See article 41 Charter and European Parliament resolution of 15 January 2013 with recommendations to the Commission on a Law of Administrative Procedure of the European Union (2012/2024(INL)) (https://fra.europa.eu/en/eu-charter/article/41-right-good-administration#eu-law)
[37] https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/evaluation-medicines-step-step
[38] https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/evaluation-medicines-step-step

- Mechanism for change notifications that allows a manufacturer to proceed with the change if the notified body for example has not given notice of need to further investigate the change within two weeks after notification of the change by the manufacturer.

Article 56 (2) MDR / 51 (2) IVDR should be amended to include a rule that a certificate cannot expire as a result of the notified body not having scheduled audits timely or not completing conformity or QMS assessment before expiry date of the certificate. Good administration requires that citizens do not lose a right to market access just because the market access authority is unable to finish review in time before expiry of a license. The notified body should remain responsible for surveillance of the certificate if it cannot finish procedure in time before expiry of the certificate.

Option 2 – aligning all procedure legally with administrative procedural law in the notifying Member State

A quick win from a legal perspective would be to make notified body procedure subject to administrative law procedures in the notifying Member States. This may require a degree of definition of procedures in Annex VII for precision but would essentially be a blended model under which notified bodies are bound by administrative procedural law of the notifying Member State. This option relies on the theory that notified body decisions are exercise of state authority and should therefore be subject to the same administrative procedural controls as Member States licensing procedures. This would include standard review times for the whole procedure of license or steps in the procedure (such as a legal deadline for responding to a request for evaluation of a change as substantial or not). Where notified bodies do not meet deadlines, citizens have the normal administrative procedural remedies in the notifying Member State that they would have against the notifying Member States' administrative bodies.

Option 3 – oversight by specific auditing on meeting procedural deadlines

Option 1 could be combined with an option where the notifying Member State or another (EU) entity audits the notified body for meeting procedural deadlines and making service level measured in KPIs a criterion for redesignation of notified bodies. In addition, KPIs of notified bodies in this respect could be published periodically along with transparent pricing conformity assessment activities, allowing manufacturers to make an information decision as regards notified bodies.

4.3 Calculability of costs

4.3.1 Issue

The MDR and IVDR requires notified bodies to establish lists of their standard fees for the conformity assessment activities that they carry out and make those lists publicly available[39], as well as 'operate in accordance with a set of consistent, fair and reasonable terms and conditions, taking into account the interests of SMEs in relation to fees'.[40] While MDCG guidance has been provided with a template list of standard fees structure[41] that has been in place for several months without transitional period, in practice notifying competent authorities do not seem to enforce against notified bodies that do not meet these requirements.

Because the notified body system is based on competition between (regulated) market driven services providers, the theory is that notified bodies will compete on price and quality of service. In practice neither happens. Moreover, notified bodies can (and do) change their prices often as there are no MDR or IVDR controls to prevent this.

Furthermore, there is a considerable proliferation of fees and fee structures among the dozens of notified bodies: each notified body uses its own rate structure and generally does not publish it at all or at an easily accessible location on the internet, which makes it impossible for companies to meaningfully compare notified bodies regarding prices of specific actions and overall conformity assessment costs. In addition, because notified bodies charge for their services by the hour and may added additional procedure related costs the total costs of conformity assessment cannot realistically be planned by an applicant.

In addition, notified bodies do not differentiate in prices between bigger and small customers, leading to a situation where SMEs have difficulties affording conformity assessment in the Union and cannot afford special fast track assessment pathways offered by notified bodies such as expedited review at a higher service level (faster and/or more reliable planning) at considerably higher costs than normal conformity assessment service level, leading to unequal treatment of applicants based on available budget.

4.3.2 Background

The proliferation of fees structures even at a single agency has been marked as unwanted with regard to medicinal products. By way of example EMA fees structure

[39] Article 50 MDR / 46 IVDR
[40] Annex VII, 1.2.8 MDR / IVDR
[41] MDCG 2023-2

revision shows what a responsible public policy should look like, and how a transparent and equitable fee structure can be created for public law exercise of powers, yet based on cost-reflectiveness and taking into account vital public policy objectives such as predictability, administrative burden, position of SMEs, impact on research and innovation and functioning of the internal market.[42]

The guidance provided in MDCG 2023-2[43] is a first small but still ineffective step towards a degree of transparency of rates. It does not fix the problem because notified bodies can still decide what activities are invoiced on what basis (flat, hourly or daily) and provide a range for conformity assessment activities that the notified body may divert from where it thinks that is justified [44] and can diverge at will, relying on "factors not considered in a list of standard fees".[45] At present BVMed and VDGH are unaware of any notified bodies that actually use the model standard fee list provided in MDCG 2023-2.

MDCG 2023-2 requires notified bodies to provide a minimum-maximum range per separate activity, which can lead to a very wide bandwidth in total for the added items comprising the conformity assessment procedure. Currently, the only requirement in non-binding guidance is that "in case of substantial difference between the quotation and the final fee charged, notified bodies should notify manufacturers about the discrepancy and duly justify this adjustment."[46]

Market access of innovative medical devices is a matter of public health policy. BVMed and VDGH are concerned to see that especially for innovative devices the MDR and IVDR contain more complex and time consuming procedures that increase costs, such as the clinical evaluation consultation procedure for class III implantable devices and class IIb active devices intended to administer and/or remove a medicinal product, the scrutiny procedure for class D IVDs and the companion diagnostics procedure.

A significant proportion of innovations in medical devices comes from SMEs. There is an accepted definition of SMEs in the Union market that is used also for SME benefits

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[42] Proposal for a Regulation of the European Parliament and of the Council on fees and charges payable to the European Medicines Agency, amending Regulation (EU) 2017/745 of the European Parliament and of the Council and repealing Council Regulation (EC) No 297/95 and Regulation (EU) 658/2014 of the European Parliament and of the Council, COM/2022/721 final, sub 3 Impact Assessment (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52022PC0721)

[43] MDCG 2023-2 List of standard fees

[44] MDCG 2023-2, p. 3: "The quotation and fees actually charged, including individual items for an individual project, can be different for individual devices due to factors not considered in a list of standard fees. In case of substantial difference between the quotation and the final fee charged, notified bodies should notify manufacturers about the discrepancy and duly justify this adjustment."

[45] MDCG 2023-2, p. 3

[46] MDCG 2023-2, p. 3

under the medicinal products system that can be followed for the MDR and IVDR.[47] The market access system for medical devices should therefore not have unduly high financial barriers for SMEs as it currently has. Currently the only requirement is that the notified body should have 'fair' rates and should also indicate how the interests of SMEs are taken into account.[48] In medicinal products market access at the EMA provision has been made for SMEs in order to ensure that the central marketing authorization pathway is affordable for SMEs as well. Oversight of compliance of rates with the criteria in Annex VII, 1.2.8. (consistent, fair and reasonable) could be performed possibly by the accountable managing structure discussed in section 7.1 below.

4.3.3 Solutions for discussion and opportunities

EU harmonization of fees and fee structures would allow for transparency and possibility to compare between notified bodies and to arrive at fees that are indeed fair and reasonable as required under the MDR and IVDR.[49] The Commission could set fee bandwidths or fees for a specific conformity assessment activity or procedure. This way it can be ensured that the fees reflect the underlying costs of the notified bodies better. BVMed and VDGH believe that rate structures that allow for fast tracking, more reliable planning or other increased service levels at notified bodies in exchange for increased fees are not fair and reasonable as the effect is unequal treatment of applicants based on their ability to pay fees alone.

By analogy to the Commission's proposal to change the EMA's fee system, fixed fees or fee bandwidths for notified bodies set by the Commission by means of delegated[50] or implementing acts under the MDR and IVDR could be combined with a cost monitoring mechanism and a degree of flexibility to adjust fees to significant changes in costs. [51] It should under, all circumstances, be a principle that costs for the market access system can be, reliably recouped, and that for the scarcity of capacity should not be a justification for higher fees. Like with the revision of the fee structure for the

[47] Commission Recommendation 2003/361/EC
[48] MDCG 2023-2, p. 3
[49] Annex VII, 1.2.8.
[50] The EMA fees structure revision regulation uses delegated acts for the Commission competence, see Proposal for a Regulation of the European Parliament and of the Council on fees and charges payable to the European Medicines Agency, amending Regulation (EU) 2017/745 of the European Parliament and of the Council and repealing Council Regulation (EC) No 297/95 and Regulation (EU) 658/2014 of the European Parliament and of the Council, COM/2022/721 final
[51] https://health.ec.europa.eu/medicinal-products/legal-framework-governing-medicinal-products-human-use-eu/european-medicines-agencys-ema-fee-system-impact-assessment-and-commission-proposalen

EMA it could be considered to include fees for minor post-authorisation procedures (e.g. such as evaluating changes to devices) in the annual surveillance fees.[52]

In addition, SME benefits could be considered in specific cases given the increased time and cost of procedure under the MDR and IVDR. SME discounts are a normal phenomenon in e.g. the medicinal products framework, where SME get very substantial discounts for market access procedure fees at the EMA of up to 100% for certain procedures.[53] By analogy the MDR and IVDR could be amended for a central SME office at EU level that assigns SME status to a manufacturer and entitles the manufacturer to SME benefits awarded under the MDR and IVDR (see also in section 7.1). The SME office provide guidance for SMEs and certain public subsidies ,can also monitor that notified bodies and notifying competent authorities (when auditing their notified bodies) duly take SME interests into account.

4.4 Access to the system

4.4.1 Issue

The notified body certification system under the MDR and IVDR operates based on the principle of a regulated market. This leads to the situation that manufacturers experience the negative effects of markets and scarcity in the form of high fees for certification. At the same time manufacturers can legally only place products on the market by relying on a process that is not controlled by principles of good administration, such as equal access to certification and transparent and predictable procedures. In practice some manufacturers are refused access to notified bodies and are unable to obtain regulatory approval for their devices. This is especially the case for small and medium sized undertakings and first-time applicants.

4.4.2 Background

The MDR and IVDR rely heavily on commercial third party involvement in conformity assessment due to the policy choice to organise conformity assessment of medical devices this way. The commercial third parties involved are the notified bodies, while competent authorities of Member States generally limit their role to market surveillance. Notified bodies, as the commercial undertakings that they are, prefer to concentrate on customers with a relatively large amount of predictable work, as this

[52] See Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on fees and charges payable to the European Medicines Agency, amending Regulation (EU) 2017/745 of the European Parliament and of the Council and repealing Council Regulation (EC) No 297/95 and Regulation (EU) 658/2014 of the European Parliament and of the Council, COM/2022/721 final

[53] https://www.ema.europa.eu/en/human-regulatory/overview/support-smes/financial-advantages-sme-status

leads to economies of scale for the notified body, resulting in an improved profit margin. However, this also provides notified bodies with a potential incentive to refuse services to smaller and medium sized manufacturers that take up more time relative to possible turnover. The MDR and IVDR do not provide for a duty of notified bodies to accept customers or to not refuse them on arbitrary grounds, only that the notified body must have an onboarding procedure.[54] Accepting customers on a non-discriminatory basis is currently not a requirement under Annex VII MDR / IVDR.

The Commission has stated publicly that small manufacturers' access to notified bodies is a structural issue in the medical devices framework that needs to be tackled in the short term because it has a negative impact on patient safety, public health and medical innovation.[55]

The MDCG has published and suggested limited non-legislative measures by means of MDCG 2022-14 that features 19 points intended to improve the functioning of notified bodies and intends to free up capacity at notified bodies. Also the extra time afforded under the recent MDR and IVDR amendments for notified bodies to finalise conformity assessment in the period 26 May 2024 to 31 December 2027 or 2028 under the MDR and up to 26 May 2027 under the IVDR respectively is intended to free up capacity at notified bodies. However, these measures comprise funding of actions that are not expected to achieve any serious difference in the short term because they concern no concrete solutions other than 'a call for proposing solutions to facilitate matching the demand of market operators with the availability of notified bodies.[56] The Commission has already indicated that the current measures set out in MDCG 2022-14[57] are not enough.[58]

Notifying Member States policy for monitoring notified bodies on whether they refuse access to certification services on non-discriminatory or non-arbitrary grounds is not harmonised. The Member States that do monitor do not publish the result of this monitoring and the consequences for their policy. There is no effective formal pathway to complain to a notifying Member State about a notified body refusing service.

Especially SMEs and first-time applicants are often unable to find notified bodies willing to onboard them, which is an indication that the market access system for medical devices is not functioning well because its access mechanism discriminates

[54] Annex VII, 4.3 MDR / IVDR
[55] Commission Information note to the Council 6484/23 of 8 March 2023, p. 6
[56] Annex 2 EU4Health work programme 2022, Commission Implementing Decision C(2022) 5436 final of 25.7.2022, action HS-g-22-19. p. 76
[57] MDCG 2022-14, under 12 -13
[58] Commission Information note to the Council 6484/23 of 8 March 2023, p. 7

between applicants based on their size and incumbency in the system. This is contrary to the principle of good administration.

4.4.3 Solutions for discussion and opportunities

The principles of good administration enshrined in article 41 of the EU Charter of Human Rights should be implemented for the medical device market access system, one of which is that persons relying on the approval system are treated equally and must be able to appeal a decision of a notified body, just as would be possible when market access decisions are taken by government body.

Several options can be considered:

- Annex VII is amended to add a prohibition against discrimination and non-arbitrary onboarding of customers in the QMS of notified bodies, subject to surveillance in the notifying member state;
- Onboarding procedures of notified bodies must provide explicitly how the notified body will ensure non-discriminatory access to service, taking the interests of notified bodies into account. This policy and its application should be audited and monitored by the notifying Member State. The MDCG, the European level structure or an oversight body could develop harmonized elements for the procedure as this would be in scope of explicitly attributed competence under articles 105 (b)[59], (g)[60] and (h)[61] MDR / 99 (b), (g) and (h) IVDR;
- Possibility to file a complaint at the notifying Member State or the European level structure directly for refusal of service if no appeal is possible against notified body decisions to refuse service. The Member State or the European level structure will handle the complaint and a responsible authority (for example the European level structure) will publish periodically which notified bodies have refused service on what grounds;
- Refusal of service by a notified body should constitute an administrative decision subject to appeal in the notifying Member State. Good administrative practice dictates that a decision of Member State to indirectly refuse to take a decision on market access of a medical device must be subject to appeal and scrutiny by a court by analogy to decisions by government agencies that refuse an application;

[59] "to advise the Commission, at its request, in matters concerning the coordination group of notified bodies as established pursuant to Article [49 MDR/ 45 IVDR]"
[60] "to provide advice, either on its own initiative or at request of the Commission, in the assessment of any issue related to the implementation of this Regulation;"
[61] "to contribute to harmonised administrative practice with regard to devices in the Member States"

- A central load balancing mechanism administrated via the European level structure, or requirement for Member States to balance between their notified bodies, could be contemplated. Notified bodies from all Union Member States could be obliged to continuously indicate capacity to take on new customers, which could be consolidated on Union level, leading to a Union scoreboard showing what notified bodies have capacity. A call for a mechanism like this has already been made under the EU4Health work programme 2022.[62]

4.5 Transparency of notified body procedure and surveillance

4.5.1 Issue

There is no effective control over or transparency with regard to the functioning of notified bodies, neither on a national level nor on an EU level. Annex VII MDR / IVDR requires that notified bodies should have internal procedures for customer facing activities[63] but does not require that these are transparent to the stakeholders. It is not transparent what directives notified bodies receive from their notifying competent authorities or the Joint Assessment Teams that can lead to national divergences in notified body practice, such as with respect to possibilities for remote audit. Notified bodies are not allowed to have a discussion with their customer regarding their procedures as this is deemed prohibited consultancy. Notified bodies are not EU administration as such, nor are they seen by Member States as part of their administrative organs. As such, the notified bodies escape the level of transparency and accountability that would normally be expected from government agencies that exercise state decision making authority.

4.5.2 Background

Historically Member States (re-)designate their own notified bodies according to rather loosely defined criteria in the notified body designation handbook. Under the MDR and IVDR this has become more of a cooperative exercise involving other Member States and the Commission in the Joint Assessment Team (JAT).[64] The MDCG Notified Body Oversight Group (NBO) oversees issues relating to notified bodies and the application of conformity assessment procedures with the aim of a consistent application of requirements and procedures. However, this subgroup is closed to

[62] Annex 2 EU4Health work programme 2022, Commission Implementing Decision C(2022) 5436 final of 25.7.2022, action HS-g-22-19.03, p. 76.
[63] See e.g. Annex VII, 4.8 which states that notified bodies should have procedures for the issuance, suspension and withdrawal of certificates without imposing any degree of transparency with respect to the exercise of these delegated government powers.
[64] Article 39 (3) MDR / 35 (3) IVDR

stakeholders, while all of the other MDCG Working Groups except PMS are open to stakeholder participation.

Transparency is further hampered because notified bodies are prohibited from offering procedural assistance to market actors, which severely limits transparency, predictability and efficiency of the conformity assessment process. Current measures of the MDCG and the Commission are only oriented to increasing notified body capacity but not to increasing notified body quality and customer-friendliness. MDCG 2022-14 only refers to the MDCG wish expressed that "notified bodies should **rationalise and streamline internal administrative procedures**, and ensure that proper conformity assessments are carried out in a timely and efficient manner in accordance with the Regulations."[65] The MDCG encourages notified bodies in the same guidance document "to organise **structured dialogues** before and during the conformity assessment process aimed at regulatory procedures where this is useful to enhance the efficiency and predictability of the conformity assessment process, while respecting the independence and impartiality of the notified body".[66] Structured dialogues will greatly improve the quality of applications for conformity assessment, as manufacturers will have a better picture of what the notified body would like to see in an application. Pre-submission meetings for precisely this purpose are a normal procedural phenomenon for medicines marketing authorisation applications, intended to discuss details regarding the procedure with the persons responsible at the government body. However, the MDCG does not provide any transparent detail on what a structured dialogue would look like for (in vitro diagnostic) medical devices and refer the further implementation to the MDCG and its subgroup the NBO (one of the two MDCG subgroups that does not admit stakeholders). Transparency about work processes and internal procedures at notified bodies is an important step for procedural accountability of notified bodies if these procedures concern establishing or affecting the rights of citizens, such as issuing, restricting, suspending or revoking certificates. Precisely for this reason government agencies are required to be transparent about their work processes, so they may be held accountable for their correct application of these processes. Article 41 of the Charter requires that as a function of good administration the principle of consistency and legitimate expectations public administration shall be consistent in its own behaviour and shall follow its normal administrative practice, which shall be made public. This is precisely where accountability of notified bodies is lacking because there is no requirement to make their administrative practices public. Even

[65] MDCG 2022-14, point 6
[66] MDCG 2022-14, point 15

the MDCG does not stimulate this in MDCG 2022-14, point 6, where it merely promotes harmonisation of internal administrative procedures of notified bodies.

4.5.3 Solutions for discussion and opportunities

As a first step, mandatory publication of and transparency about internal administrative practices of notified bodies as required by EU guaranteed fundamental rights of citizens (good administration under article 41 of the Charter) would serve to establish baseline procedural accountability for notified bodies. This way it becomes possible for stakeholders to verify if notified bodies adhere to their own internal procedures that they are legally obliged to have. This is also required for the structural dialogue process to lead to reliable enhancement of efficiency and predictability of the conformity assessment process. A flanking measure for harmonisation of notified body procedure would be introduction of a harmonised conformity assessment application submission framework like the eCTD (electronic common technical document) for medicinal products.[67] A good substantive basis for this has been laid by Team-NB notified bodies with the Best Practice Guidance for the Submission of Technical Documentation under Annex II and III of the MDR[68] and the IVDR[69]. An electronic Common Technical Documentation for Medical Devices (eCTDMD) could be developed as a harmonised technical solution to implementing Annex II and III electronically. This could comprise the submission of PDF documents, stored in the eCTDMD directory structure, accessed through the XML backbone and with the files integrity guaranteed by a checksum. Such dossiers should be able to be submitted and managed by means of machine-to-machine (M2M) communication.

The MDCG subgroup NBO, in cooperation with notified bodies, could develop a Code of Notified Body procedure in addition to the requirements in Annex VII to 'have a procedure'. This Code should be developed in cooperation with all stakeholders and should include details on the structured dialogues mentioned in MDCG 2022-14.

Alternatively, Annex VII could be amended to provide procedural detail for procedures that may lead to any individual measure which would affect no rights or obligations of a manufacturer adversely to be taken, including details on the structured dialogues mentioned in MDCG 2022-14. This requires that the NBO working group at the MDCG is opened up to stakeholder participation. Stakeholder participation will also enable the Member State members of the MDCG and the Commission to be better informed about performance of notified body guidance

[67] https://esubmission.ema.europa.eu/ectd/index.html
[68] https://www.team-nb.org/wp-content/uploads/2022/10/Team-NB-PositionPaper-BPG-TechnicalDocEU-MDR-2017-745-V1-20221005.pdf
[69] While no public version of this document has been published by Team-NB a draft for stakeholder consultation has been circulated and a final version is expected to be published soon.

issued by the MDCG. Also, stakeholder participation allows for a better process of developing of guidance by means of impact assessment involving stakeholders. The Commission itself states that impact assessments are to be carried out on initiatives expected to have significant economic, social or environmental impacts.[70] Impact assessments form a key part of the Commission's Better Regulation agenda, which seeks to design and evaluate EU policies and laws so that they achieve their objectives in the most efficient and effective way.[71] Given the impact of MDCG guidance documents for the EU regulatory system as function of EU policy to be followed such impact assessments should be performed for MDCG guidance in the field of notified bodies and even more generally.

There should be a clear contact point in the notifying Member State where complaints about the notified body can be lodged by economic operators that Member States must follow-up on and provide the economic operator with feedback about their handling of the complaint, in keeping with article 41 of the Charter (good administration). At present the MDR / IVDR only allows for challenge of the competence of the notified body as such.[72] Alternatively stakeholders should have access to the European Ombudsman.

The Member State's audit of notified body performance in accordance with article 45 (1) MDR / 41 (1) IVDR should also include a review of how the notified body has treated customers procedurally and of procedurally defined KPIs, e.g. the amount of appeals lodged against notified body decisions, the grounds for complaints and the statistics on the notified body's decisions on these complaints. These KPIs can be published on the Commission website in a KPI dashboard overview, so customers can compare notified bodies, and they can serve as a basis for audit by designated Member States. For example, a notified body that has relatively high complaint rejection rate compared to others on certain specific appeal grounds may be acting arbitrarily or not be impartial.

There should be further going harmonisation and transparency of national and EU level controls on notified bodies performance. Harmonisation currently only covers the designation criteria with no transparency on MDCG and Member States' controls over notified bodies.

[70] https://commission.europa.eu/law/law-making-process/planning-and-proposing-law/impact-assessmentsen
[71] https://commission.europa.eu/law/law-making-process/planning-and-proposing-law/better-regulationen
[72] Article 47 MDR / 42 IVDR

4.6 Substantial Change

4.6.1 Issue

The current mechanism of approval of each substantial change before it can be implemented leads to an undue regulatory burden, unnecessary costs and to delays in changes (which may include innovations or smaller iterations to improve the safety or performance of a device). There is a need for a recalibration with regard to changes that the manufacturer can perform himself within the qualify system and changes that need notified body assessment. Also, there is a need for a reliable and predictable procedure for evaluation of changes that must be approved by the notified body.

4.6.2 Background

Each individual substantial change to a device must be approved by the notified body before the change can be implemented, and the manufacturer must notify each change for the notified body to determine if it is substantial or not. However, there is no duration for the change approval procedure and there is no defined concept of substantial change in the MDR or IVDR. There is an old NBOG guidance document[73] that defines substantial changes, but this is not appropriate anymore for the MDR or IVDR. Reportable changes are not described logically and consistently in the MDR and IVDR.

The 'old' substantial change thinking under the Directives is Annex X thinking, see Annex X 5.1 and 5.2 MDR / IVDR, which does not return in Annex IX, see Annex IX 2.4 MDR and IVDR. Which is focused on evaluation of every change to a device type. Under Annex IX the manufacturer should be able to do a lot more himself in terms of changes, because this is the rationale of a full QMS assessment: that the manufacturer has been certified to be able to manufacture the devices in scope of the product certificate coupled to the QMS certificate. The intention behind Annex IX is to give the manufacturer considerable room within the guardrails of the scope of the technical documentation and QMS evaluated.[74]

4.6.3 Solutions for discussion and opportunities

A much clearer definition of substantial change is required. A definition could be included in article 2 of the MDR / IVDR, which could be elaborated in Annex IX and/or (further) elaborated in an MDCG guidance document. This will also allow solving of the continuing confusion between the concepts of substantial change and significant

[73] NBOG 2014-3 Guidance for manufacturers and Notified Bodies on reporting of Design Changes and Changes of the Quality System

[74] See also Module D as set out in Blue Guide p. 143 (Annex 4) and Decision 768/2008.

change in the meaning of article 120 (3c) MDR and 110 (3) IVDR regarding legacy devices now that MDR legacy devices will have certificates with validity of up to 31 December 2028 and IVDR legacy devices up to 26 May 2027.

It should be possible to group notifications of potential substantial changes and transmit them to the notified body on a periodical basis. Grouping of variations for medicines is for example possible; the Variation Regulation contains a specific regime for variation grouping that allows grouping the same variations concerning for example several products of the same marketing authorisation holder or several variations affecting the same medicinal product.[75]

There should be a procedure with time limits for the notified body to review submitted changes. This procedure should contain a mechanism that may or may not be only applicable to certain categories of changes) that allows the manufacturer to proceed with the change as non-substantial if the notified body does not indicate that further review is needed within a fixed period (e.g. two weeks) of notification.

Review of changes should be subject to a standard fixed procedure fee by analogy to variations under the medicinal products framework.[76]

4.7 System-inherent possibility to complain

4.7.1 Appeal at notified bodies and other parties involved in the application of the regulatory system

The MDR and IVDR do not provide for a standardised pathway for complaints at parties involved in application of the regulatory system under the MDR / IVDR that meets the basic requirements of good administration as out in article 41 Charter.

4.7.2 Background

Various actors are involved in the application of the MDR and IVDR: notified bodies, expert panels, Member State authorities attributed with competence in the field of clinical investigation application assessments and competent authorities. In the case of Member States authorities appeal against first instance decisions is provided for under national law. In the case of expert panels or consultation of medicines authorities a scientific opinion is delivered that the notified body must give due consideration to, but the expert panel or medicines authority does not take a

[75] https://www.ema.europa.eu/en/human-regulatory/post-authorisation/variations/grouping-variations-questions-answers

[76] Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products, OJ 2008 L334/7

decision itself.[77] This means that as of the actors involved in application of the MDR and IVDR only notified bodies take decisions with legal effect as regards the rights of citizens, but without requirements of good administration applying to them. The principles of good administration in relation to the application of the MDR and IVDR only apply to competent authorities.[78]

Annex VII MDR / IVDR obliges notified bodies to have a procedure for complaints in their quality system, but this procedure is not standardised or described in any transparent detail.[79] The procedural guarantees of good administrative practice are not set out for this procedure. It is not possible for manufacturers to file a complaint in a standardised way against a decision of the notified body that comes down to exercise of delegated Member State competence (issuing, suspending, restricting or revoking CE certificates).

However, good administrative practice enshrined in article 41 of the Charter provides that decisions taken by public bodies exercising Member State authority should be subject to a number of harmonised principles of good administration[80]:

- Principle of non-discrimination and equal treatment (currently not addressed in Annex VII MDR / IVDR);
- Principle of proportionality (currently not addressed in Annex VII MDR / IVDR);
- Principle of impartiality (currently addressed in Annex VII MDR / IVDR to a limited extent);
- Principle of consistency and legitimate expectations (currently not addressed in Annex VII MDR / IVDR); and
- Principle of transparency (currently not addressed in Annex VII MDR / IVDR).

Notified body internal procedure to arrive at binding decisions regarding conformity assessment and regarding the restriction, revocation and suspension of certificates should be built on these principles. Internal appeals procedures should moreover be in line with article 47 Charter (right to a fair trial) which dictates procedural requirements for internal appeals procedures.

It is a legal hiatus that notified body decisions based on exercise of delegated state authority (grant, suspension, restriction and revocation of certificates) are not subject to legal review, as is for example the case with medicinal products marketing authorisations (see below under 4.8 regarding legal review), and moreover contrary

[77] Annex IX, 5.1 (g) MDR / Annex IX, 5.2 (e) IVDR
[78] Article 99 MDR / 94 IVDR
[79] There is only the ISO 17021 standard by way of standardisation, which gives very high level direction but no concrete procedures implementing good administrative practices.
[80] https://fra.europa.eu/en/eu-charter/article/41-right-good-administration#eu-law

to article 47 of the Charter and article 6 (1) of the European Convention on Human Rights (right to a fair trial).

4.7.3 Solutions for discussion and opportunities

Annex VII of the MDR and IVDR could be amended to define a precisely prescribed pathway for a complaint procedure against a decision that is modelled on the principles of good administration as set out in European Parliament resolution of 15 January 2013 with recommendations to the Commission on a Law of Administrative Procedure of the European Union (2012/2024(INL))[81], which defines a complete internal appeal pathway for a conformity assessment body (CAB)/notified body that conforms to the principles of good administration laid down in article 41 Charter, such as setting of procedural timelines.

Article 53 MDR / 49 IVDR could be amended with a reference to an internal appeals procedure detailed in Annex VII and a legal review pathway in a Member State court in conformity with Article 47 Charter, see below under 4.8 for more details.

For the purposes of transparency and non-discrimination EU level procedural templates should be developed, which could form part of Annex VII.

4.8 Legal review of decisions

4.8.1 Issue

In practice it is impossible for manufacturers to challenge a decision by a notified body regarding the certification status of their devices in an independent court or to engage a notifying Member State in case of disagreement between notified body and manufacturer other than in classification disputes (for which the MDR provides a specific escalation procedure in article 51 (2) MDR and 48 (2) IVDR). There is no viable pathway for a challenge other than a claim in contract in civil court based on non-performance under the certification agreement. Any legal recourse taken by the manufacturer generally leads to the notified body ceasing conformity assessment activity for the manufacturer. Accordingly, there is no effective mechanism of administrative accountability for the notified body's decisions that affect the rights and obligations of citizens.

4.8.2 Background

Notified bodies take decisions with delegated state authority where they decide about rights and obligations of citizens by means of grant, restriction, suspension or

[81] https://fra.europa.eu/en/eu-charter/article/41-right-good-administration#eu-law

withdrawal of CE certificates. Yet, the relationship between a notified body and the manufacturer is based on a civil law contract that does not provide for any viable ways to challenge a decision regarding certification status, as this would need to be cast legally as non-performance under the certification agreement.

Where a government body would need to follow principles of good administration, notified bodies are merely required to have a procedure[82] and to operate on a basis of impartiality[83], without effective controls or appeal possibilities. The only remedy that manufacturer have is to take contract or tort law legal action based on the certification agreement, which does not provide for effective legal recourse. Where a notified body exercises state authority, EU law and the European Treaty for Human Rights (ECHR) requires that an effective procedure for legal recourse is available.[84] Where government authority is exercised this must take place based on the principles of good administration, which are currently not a requirement for exercise of government authority by notified bodies. This is a requirement for competent authorities under the MDR and IVDR [85] but inexplicably this is not the case for notified bodies, even if they also exercise state authority that is delegated to them.

In case of a legal challenge based on the certification agreement or in tort notified bodies have QMS procedures that cause them to put a hold on any other activity for the manufacturer, which makes it impossible for the manufacturer at the moment to have notified body activity reviewed by a court. Any legal action triggers a complete halt of activities for manufacturer products under evaluation, which effectively prevents manufacturer access to a fair trial regarding the exercise of government authority, which is therefore contrary to article 47 Charter and Article 6 (1) ECHR. An entity attributed with state authority cannot refuse service as a deterrent to being held accountable by means of legal review, and this does not happen with market access procedures administrated by government agencies, with medicines as a case in point.

4.8.3 Solutions for discussion and opportunities

The problems with lack of good administration and access to a fair trial can be remedied by either moving (part of) notified body exercise of state authority to a government body that takes the market access decision (option 2) or subjecting notified body exercise of state authority to legal review procedures in Member States

[82] See for example Annex VII, 4.8 in relation to notified body decision relating to issuance, restriction, suspension or revocation of the CE certificate.
[83] Annex VII, section 1.2.2 and 1.2.3
[84] Article 6 (1) ECHR and article 47 of the EU Charter on Human Rights; ECHR Van Benthem case (23 October 1985, case 1/1984/73/111 (https://nl.wikipedia.org/wiki/ArrestBenthem))
[85] See article 99 MDR / 94 IVDR on good administrative practice

or at the General Court in Luxembourg that would apply to similar decisions, e.g. like marketing authorisation decisions for medicines (option 1).

Option 1

Notified bodies can be made subject to the requirements of good administrative procedure by including notified bodies in the scope of article 99 MDR / 94 IVDR for notified body decisions with effect on the scope or validity of the certificate (restriction of scope, suspension and revocation). By analogy to article 54 (2) MDR / 47 (2) IVDR regarding classification disputes between the manufacturer and a notified body a general right to appeal a notified body decision to a competent authority in a Member State or a court in a Member State could be provided for, thus ensuring implementation of the fundamental principles of good administration and a fair trial as enshrined in the Charter and the ECHR. This would require significantly more in terms of central oversight to ensure uniform application of legal review of notified body decisions and makes stakeholder participation extra important as an instrument to spot national differences and calibrate the overall system.

Option 2

To have the final market access decision taken by a government structure for market access to the whole internal market the model of the EMA and Commission can be copied from Regulation 726/2004 under which the EMA provides an advice and the Commission takes the decision.[86] By analogy the notified body could provide a certification advice to either the notifying Member State or a central EU structure or the Commission like it currently provides to its internal certification board, based on which the government structure issues a decision subject to legal review in the Member State (in case of Member State competent authority) or at the General Court (in case of an EU level government structure /Commission). This should apply to all notified body decisions with effect on the scope or validity of the certificate. This option would allow for the most harmonisation of notified body decisions through the consolidation of all currently existing certification bodies while keeping the system of conformity assessment by notified bodies intact. This option has been contemplated as policy option 1G in the Impact Assessment for the MDR and IVDR.[87] For this option to not delay approval the period between submission of certification advice and certification decision should be as short as possible and the procedure

[86] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ 2004, L136/1

[87] Impact Assessment, Part I (SWD(2012) 274 final), p. 30

should be limited to specific categories of high risk devices.[88] This way an proportionate balance can be struck between a longer procedure but more harmonisation and legal certainty.

4.9 Overlapping EU legislation and national legislation

4.9.1 Issue

Overlapping EU regulations require manufacturers to obtain CE marking or approval under multiple different regulations, leading to unnecessary costs, regulatory burden and time to approval.

The slow implementation of MDR and IVDR lead Member States to impose national controls to compensate for lacking EU implementation, notably with respect to registration of economic operators and devices. This has caused additional formalities and overlapping registration requirements where the MDR and IVDR were supposed to eliminate these.

4.9.2 Background

Devices in scope of the MDR and IVDR can also be in scope of many other regulations, such as the Radio Equipment Directive, the AI Regulation and various EU legal instruments in scope of the EU Green Deal. This overlap leads to multiple product regulations applying to a single product. These multiple regulations use different definitions for often the same concepts, which makes them impossible to apply to a single product.[89]

There is not a single methodology for dealing with these overlaps. As can be seen in article 1 MDR / IVDR, there are a large number of overlaps with other legislation that are dealt with in a number of different ways:

1. MDR / IVDR is *lex specialis* – other regulation does not apply (EMC Directive[90]);
2. MDR / IVDR is *lex specialis* and risks not sufficiently addressed under MDR / IVDR but addressed in other regulation are taken into account for MDR / IVDR conformity assessment (Machinery Directive[91]); and

[88] Impact Assessment, Part I (SWD(2012) 274 final), p. 44
[89] An example is the AI Act, which defines concepts defined in the MDR and IVDR differently than under the MDR and IVDR yet requires that in case of overlap the manufacturer uses overlapping technical documentation.
[90] See article 1 (11) MDR / 1 (5) IVDR
[91] See article 1 (12) MDR / 1 (6) IVDR

3. Overlap is not managed at all (for example: Radio Equipment Directive[92], draft AI regulation[93], EcoDesign Directive[94], REACH Regulation[95], CLP Regulation[96], Packaging and Waste Directive[97], Batteries Directive[98] and POP Regulation[99]).

This makes it complex and costly for manufacturers to comply with regulation. Especially the third group of regulation often dovetails with the MDR / IVDR in very unproductive ways. A case in point is the draft AI Regulation that requires CE marking under both the MDR/IVDR and the AI Regulation by notified bodies that must be designated under the AI Regulation or under the MDR/IVDR (or both), doubling the certification burden for a device with AI. It furthermore contemplates the use of overlapping technical documentation for MDR / IVDR and AI Regulation compliance but uses different definitions for the same basic CE marking related concepts, making such overlapping technical documentation technically impossible.[100]

The slow implementation of aspects of the MDR and IVDR, notably as regards Eudamed, has led Member States to fill in the gaps with their own national legislation, even if the Commission has requested Member States specifically not to do so. As a result some Member States have introduced new national databases, mandatory use of Eudamed or other requirements, leading to additional costs and time needed for manufacturers to comply.

[92] Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC, OJ 2014 L153/62

[93] Proposal for a Regulation of the European Parliament and of the Council Laying Down Harmonised Rules on Artificial Intelligence (Artificial Intelligence Act) And Amending Certain Union Legislative Acts, COM(2021) 206 final

[94] Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products (recast) (Text with EEA relevance) OJ 2009 L285/10

[95] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ 2006 L396/1

[96] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, OJ 2008 L353/1

[97] Directive 94/62/EC of 20 December 1994 on packaging and packaging waste, OJ 1994 OJ L365/10

[98] Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC , OJ 2006 L 266/1

[99] Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants**,** OJ 2019 L169/45

[100] https://www.government.nl/documents/publications/2022/05/25/legal-analysis-european-legislative-proposal-draft-ai-act-and-mdr-ivdr

4.9.3 Solutions for discussion and opportunities

The MDR and IVDR would benefit from one clear overlap rule that applies for all overlapping regulation and leads to the least administrative burden for the manufacturer, while at the same time ensuring that all relevant risks are managed. This would be the *lex specialis* principle in indent 1 in the list above in section 4.9.2 (Background), which would cause the MDR / IVDR to be the only regulation to apply for design, safety and performance requirements of medical devices. The MDR / IVDR GSPRs are flexible enough to accommodate all known safety and performance requirements and the MDR should, as most specific legislation applicable for medical devices and based on its public health goals have precedence as *lex specialis*. Where the MDR / IVDR GSPRs are lacking or address certain specific risks they can easily be amended by means of an implementing act.[101] Where standardization is lacking for a specific GSPR this can be provided by means of Common Specifications.[102]

Where the opinion in indent 1 in the list above is not feasible from a policy perspective indent 2 is a reasonable alternative and a proven solution for managing overlap in the MDR / IVDR.

The MDR and IVDR should be amended to limit national 'solutions' by Member States during roll-out of legislation and the Commission should actively engage with Member States when they introduce such new measures, even if these are intended to be temporary. Where MDR and IVDR roll-out requires Commission resources (such as Eudamed) these project should be appropriately resourced and managed to account for their strategic importance.

5 Reform of certification cycle

5.1 Reform of (re-)certification process of MDR and IVDR devices

5.1.1 Issue

The CE certificates issued by notified bodies for devices are currently limited in duration to five years, which necessitates re-assessment for a renewed certificate every five years. When a notified body – as happens more and more – is unable to finish recertification before expiry of the certificate the manufacturer is forced to cease placing devices on the market until the notified body has completed the certification procedure.

[101] Article 5 (6) MDR / IVDR provides a legal basis for this
[102] Article 9 MDR / IVDR

Under the IVDR an enormous amount of devices has been made subject to notified body certification compared to the IVDD, creating instant critical congestion in the conformity assessment system.

5.1.2 Background

An MDR or IVDR device certificate has a maximum duration of five years, after which the conformity assessment must be repeated for certification extension.[103] However, this five years duration is justified nowhere in the MDR or IVDR, nor was it subject of discussion when the MDR and IVDR were adopted.[104]

During the current five years duration the certificate is subject to annual surveillance audits, possible unannounced audits and the manufacturer has to periodically provide PSURs to the notified body.[105] In addition, a significant and substantial change to the product must be specifically indicated, checked and approved in a separate procedure. The QMS must ensure that the clinical / performance evaluation remains aligned with the state of art over time.[106] Based on article 61 (12) and 83 MDR and articles 56 (2) 78 IVDR the technical documentation and underlying clinical / performance evaluation must be continuously updated with data sourced from a large number of relevant sources to ensure that the device is continuously compared to the state of the art in clinical practice and competitor devices. All these processes provide for input about whether the device remains state of art over time as is required under Annex I, 1 MDR and IVDR (a positive risk/benefit balance must remain positive over time). As a result, a periodic re-assessment and re-issuing of the certificate duplicates notified body activities, because it requires among other things[107]:

- Re-assessment of all changes to the originally approved device, including changes not notified (in other words: changes that have already been evaluated when reported by the manufacturer are evaluated again, and changes that did not need to be evaluated before implementation are evaluated nonetheless); and

[103] Article 56 (2) MDR / 51 (2) IVDR
[104] The duration is not discussed as an option anywhere in the Impact Assessment (SWD(2012) 274 final)
[105] Article 86 MDR and 81 IVDR; in addition manufacturers of class I devices / class A and B IVD devices must prepare (but not submit) post-market surveillance reports that are kept available to the competent authorities pursuant to article 85 MDR / 80 IVDR
[106] Annex IX, 2.1 last indent and Annex XIV (1) (a) 6th indent MDR / Annex XIII (1.1) 10th indent IVDR
[107] Annex VII, 4.11 MDR and IVDR

- Assessment of experience from PMS, PMCF/PMPF and risk management (in other words, re-assessment of information already provided to the notified body in PSURs[108])

There is no requirement for medicines to have the marketing authorisation re-issued periodically. Once issued the validity of the marketing authorisation is indefinite, provided that the marketing authorisation holder applies the agreed pharmacovigilance plan and variations are notified and assessed by the authorities. There is no periodic duplication of assessment of pharmacovigilance data or variations in an overall marketing authorisation re-assessment.

Also, medical devices market approvals in other markets like the US do not need to be periodically re-issued based on a review of the device against the then current state of the art as is required for EU CE certificates for devices.

For the IVDR the policy choice was made to enormously increase the devices under the requirement for notified body conformity assessment where these devices were subject to self-assessment under the IVDD: 736%.[109] This policy decision has not been motivated by safety or performance issues with IVDs under the IVDR and does not serve a purpose of increasing patient safety or test performance. As a result, the conformity assessment system under the IVDR is congested with a large amount of low risk (class B) devices that used to be subject to self-assessment[110] but for which notified body capacity under the IVDR is scarce and of which the added value of notified body conformity assessment is questionable. This creates an enormous extra cost to the healthcare system that is not justified by any benefits in terms of increased performance or safety of tests. The Impact Assessment for the IVDR stated that adoption of the GHTF classification structure for IVDs would necessarily mean conformity assessment for class B devices by a notified body.[111] This does however not follow as a necessary option from GHTF recommendations for IVD conformity assessment, as these also allow for competent authority ex-post supervision on this point as an alternative to notified body assessment.[112] Accordingly, this has been an EU policy choice, which may be revisited. There is all the more reason to revisit this

[108] See article 86 MDR / 81 IVDR

[109] MedTech Europe Survey Report analysing the availability of In vitro Diagnostic Medical Devices (IVDs) in May 2022 when the new EU IVD Regulation applies, 8 September 2021, p. 2 (https://www.medtecheurope.org/wp-content/uploads/2021/09/medtech-europe-survey-report-analysing-the-availability-of-in-vitro-diagnostic-medical-devices-ivds-in-may-2022-when-the-new-eu-ivd-regulation-applies-8-september-2021.pdf)

[110] Class B IVDs were estimated to comprise about 50% of the IVDs on the European market at the time of the Impact Assessment for the IVDR in 2012, see Impact Assessment SWD(2012) 273 final, PART III - Annex 2, p. 16

[111] Impact Assessment SWD(2012) 273 final, PART III - Annex 2, p. 15-16

[112] GHTF/SG1/N046:2008 Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices, p. 8

choice and calibrate its consequences, because the expected benefits of the implementation of the GHTF risk classes have not led to the benefits justifying this policy choice that were expected in the Impact Assessment. The Impact Assessment predicted a significant increase in costs for manufacturers (which indeed took place) but justified these based on "enhanced robustness of the classification system, as well as international harmonisation".[113] So far the advantages that underly this policy choice have not materialized and BVMed and VDGH do not expect them to materialise without recalibration of the IVDR's certification process.

5.1.3 Solutions for discussion and opportunities

Extension of standard certificate duration or automatic renewal

Since there is no objective justification for a five-year certification duration in the case of devices and the MDR and IVDR have significantly increased PMS (including PMCF-PMPF activities) to ensure continued compliance of the device throughout its life cycle, certificates should have unlimited duration (subject to PMS and PMCF/PMPF) or at least substantially extended and duplication of activities in re-assessment should be avoided.

A certificate, once granted, should be subject to the many PMS controls under the MDR and IVDR only and should not be subject to periodic renewal. Where a device performs as intended and the manufacturer demonstrates this on a continuous basis with PMS and PMCF/PMPF data, there is no reason to periodically revisit the certification decision and the certificate can continue to be valid subject to appropriate surveillance by the notified body.

Continued certificate validity should rather be risk and data based, based on PMS and PMCF/PMPF performance by the manufacturer as monitored by the notified body. If the manufacturer's PMS and PMCF/PMPF real-world data show that the device performs as intended after CE marking and to the state of art as is required under MDR or IVDR PMS and PMCF/PMPF requirements, there is no objective reason to repeat the certification and the notified body can earmark a certificate as in good standing without need to be re-issued. Manufacturers and notified should be granted access to secondary data available for example in national registries clinical performance databases kept by health institutions for reimbursement purposes and other relevant sources of data to better meet Article 83 (3) MDR / 78 (3) IVDR PMS objectives, such as contributing to the PMS of other devices, trend detection and reporting and identification of options to improve aspects of the device. Access to a broader scope of real-world quality data that is already available would benefit all

[113] Impact Assessment SWD(2012) 273 final, PART III - Annex 2, p. 22

parties with an interest in PMS for devices: the patient, the authorities and the manufacturers. This is discussed in detail below in section 5.2 (PMS).

Non-duplicative certificate renewal

In cases where an extended (e.g. 10-year) certificate duration would be opted for, the re-assessment for extension should not duplicate activities and should be risk based and leverage existing evidence to the maximum extent as is also foreseen for MDR and IVDR conformity assessment applications in MDCG 2022-14. In the cases where the device has continuously performed to the state of art for the device as this evolved over time it should not be needed for the CE certificate to be reissued based on conformity assessment against the then current state of art. Rather, the large amount of PMS and PMCF/PMPF information that manufacturers have to collect and share with a notified body should used as a basis to determine if there is reason to believe that the device is not state of art anymore or has started to pose a threat to health and safety over time.[114]

Repeating of the conformity assessment for certificate renewal should become a 'for-cause' process where conformity of the state of art is not supported sufficiently. Causes that would warrant recertification could be open non-conformities or pending vigilance reports, basically causes that would warrant scope reduction or suspension of the certificate.

No expiry of certificates during recertification process

There are known cases where the notified body moved audit dates repeatedly as a result of its own internal planning and then forced the manufacturer to purchase an expedited review because there was not sufficient time left to complete recertification before expiry of the certificate. This left the manufacturer with only that option to avoid not being able to place devices on the market for an unknown period of time. To avoid scenarios like this the MDR and IVDR should be amended with a rule that a certificate for which a notified body has started the recertification process cannot expire until the recertification procedure is finished. The notified body can then be audited on its ability to recertify before expiry of the certificate, but this should not be made the manufacturer's problem, as this causes damage to the manufacturer and undermines trust in the system.

Variation process for M&A

Re-issuing of the certificate is currently needed in case of mergers and acquisitions (M&A) activity that involve a change of the identity legal manufacturer (such as

[114] By analogy to the condition in article 120 (3c) MDR for continued validity of extended legacy device certificates under the MDR.

typically in an asset purchase), which leads to unnecessary formalities as these changes are currently seen as a significant change under the MDCG 2020-3 Rev 1 (MDR) and MDCG 2022-6 (IVDR). There should be a simplified process for transfer of certificates within a single quality system or for transfer of the certificate as part of an asset transaction as to support corporate housekeeping and M&A by means of asset transactions, analogous to the variation process for medicines. Alternatively it should be possible for the acquiring manufacturer to submit an application for a substitute device by analogy to article 120 (3) MDR as amended, both under the MDR and IVDR.

Summary of Safety and Performance

Article 29 IVDR requires preparation and publication of a Summary of Safety and Performance for all class C and D IVDs with the goal of informing the user and patient. This presents an enormous administrative burden for manufacturers and notified bodies, who need to prepare, compose, evaluate and validate these reports. In practice only lay user tests (self-tests) would have a need for lay user presentation of information about safety and performance. Patients are not concerned with the performance of tests ordered for their samples by healthcare professionals for which the patient receives quantitative or qualitative results. These tests are interchangeable to the professional user and therefore not subject to a discussion with the patient. Any information on the test results, without healthcare professional interpretation, raises additional risk of misinterpretation. In that sense there is a marked difference between an IVD with which a patient sample is tested and a permanent implant of a patient to restore mobility. In the latter case the patient has a much more direct interest in a lay version of the Summary of Safety and Clinical Performance to know what to expect from the device's performance. Furthermore, professional IVD users rely on the information in the IFU for the test, which is subject to Post-Market Surveillance and must be adapted if there are any changes to safety or performance relevant for the user of the test. Following this rationale an SSP it is very unlikely to be used by a patient and user. The administrative burden can be significantly reduced by not requiring such a document.

Self-assessment for class B devices

Removing class B devices from the requirement of notified body conformity assessment pursuant to article 48 (9) IVDR would create much needed relief of congestion in the conformity assessment process and unnecessary costly formalities for class B devices. This was also originally foreseen in the IVDR proposal in article 40 (4).[115] The requirement of sampling of technical documentation in article 48 (9) IVDR

[115] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0541:FIN:EN:PDF; see also p. 6 of the Explanatory Memorandum in the proposal.

was added later. Removing the sampling requirement would free up the resources to allow both manufacturers and the few available notified bodies to concentrate on conformity assessment of more complex and/or higher risk devices for which where notified body conformity assessment has added value from a performance and safety perspective: the class C and D devices.

5.2 Post market surveillance

5.2.1 Issue

Manufacturers must collect vast amounts of PMS and PMCF/PMPF data under the MDR and IVDR, most of which pursuant to rigid one-size-fits all procedures applicable to a device regardless of its stage in the lifecycle, leading to high costs of compliance and production of data that is not leveraged optimally in practice. As was discussed above in section 5.1.3, an additional complication is that high-quality data that is collected and available in the healthcare system cannot be used as secondary data for PMS purposes.

5.2.2 Background

At the moment the MDR and IVDR impose a significant increase in requirements for PMS compared to the (AI)MDD and IVDD that requires a significant additional investment from the manufacturer in RA/QA capacity to complete all the additional tasks and reports required under the MDR and IVDR, such as SSCP/SSP, PSUR, PMCF/PMPF information collection and the long (not even closed) list of objectives of the PMS programme set out in article 83 (3) MDR / 78 (3) IVDR. While there is a degree of differentiation in requirements by risk class, the system is mostly a one-size fits one-way all information gathering exercise that is very labour intensive without a clearly thought-out strategy about the use of all data generated.

Yet, the main objectives of PMS under the MDR and IVDR remain for the manufacturer to actively gather PMS data to update the technical documentation and make vigilance notifications in case of serious incidents.[116]

5.2.3 Solutions for discussion and opportunities

The PMS process should be capable of being automated and statistics driven to ensure that costs for compliance are kept at reasonable levels and processes are appropriate for the devices concerned. PMS and PMCF/PMPF should not be about producing data and putting this in reports but rather about detecting signals relevant to PMS and PMCF/PMPF. As discussed above in section 5.1.3 clinical performance

[116] Recital (74) MDR / (75) IVDR

and real-world data that is already available from various sources in the market should be leveraged more effectively. For example, PMS processes under the MDR and IVDR could benefit greatly from manufacturer access to device performance data collected in European Health Data Space frameworks (such as PROMs, PREMs and RWD[117]) for secondary use for PMS and PMCF/PMPF purposes.

Manufacturer access to such data for these purposes would allow patient outcomes related to devices to be improved in accordance with the existing MedTech Europe position on the European Health Data Space.[118] Confidentiality of data and secondary use of personal data can be managed for this purpose within the legal framework provided by articles 109 and 110 MDR / 102 and 103 IVDR, which require that parties keep personal data obtained for carrying out their tasks under the MDR and IVDR confidentially and process any personal data in accordance with GDPR[119] requirements.

Key Risk Indicators (KRIs), baselines and stratification criteria[120] could be defined for groups of devices by the MDCG or by the notified bodies in cooperation with stakeholders. KRIs could also be defined for types of input, such as patient and user reports, which would allow better trending of potential misuse.

The MDCG could further refine its PSUR related grouping guidance in MDCG 2022-21 and provide additional guidance on the definition of 'significant increase' in article 88 (1) MDR / 83 (1) IVDR. This would allow for better calibration of methods required under Part B, point 6.1 of Annex XIV MDR / Part B, point 5.2 of Annex XIII IVDR.

This would not only lead to a vast increase of comparability of data between manufacturers within a specific device group but it would also ensure that only relevant data is captured and analysed. PSURs could have a standard XML format that can be populated as to provide input for a periodic rolling dashboard of information. The XML format will allow comparison of devices and overall trending in Eudamed, once the vigilance and PMS module is active.

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[117] Patient-reported outcomes measures (PROMs), patient-reported experience measures (PREMs), surgical audios/videos, and real-world data (RWD), which all comprise data that manufacturers are instructed to collect under the MDR for PMS and PMCF / PMPF purposes.

[118] https://www.medtecheurope.org/wp-content/uploads/2023/02/230222-ehds-position-paper-final.pdf

[119] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ 2016 L119/1

[120] Stratification is a data collection and analysis technique that separates the data so that patterns can be seen and the root cause of the excursion of the trended metric can be discovered because the different strata of data are analysed separately. Stratification helps in resolving the signal into its source components so the manufacturer can check the sources in terms of their contribution to the signal.

The PMS plan could then focus on justification of the methodology, KRIs and baseline for the device concerned, leading to more relevant and comparable PMS and PMCF/PMPF results. This improved PMS plan could be the basis for supporting continued validity or for automatic certificate renewal as discussed above in section 5.1.3.

6 International cooperation and reliance

6.1 EU participation in the MDSAP

6.1.1 Issue

The EU does not recognize MDSAP reports, as a result of which a full QMS audit under MDR and IVDR standards always remains necessary even if a manufacturer has been audited under the MSDAP program (although MDSAP reports can be taken into account only to an extent and not for initial MDR / IVDR or unannounced audits[121]), leading to duplication of auditing and reporting efforts and associated costs.

6.1.2 Background

MDSAP allows for a single audit of a medical device manufacturer's QMS, which satisfies the requirements of the participating regulatory jurisdictions. At the moment several large jurisdictions are MDSAP members and recognize MDSAP reports (US, Australia, Canada, Brazil and Japan), but not the EU. Conversely, a QMS audit report under the MDR or IVDR is not recognized in MDSAP jurisdictions. While the EU states in the MDR and IVDR that it wants to promote international convergence of medical devices regulations, including conformity assessment procedures[122], the EU is not a member of MDSAP. Several Union notified bodies are already recognized Auditing Organizations (AO) to audit under MDSAP requirements. So far the EU has been observer in the MDSAP (pilot) because of concerns it would be difficult to obtain agreement among all Member States. It is uncertain if and when the EU will join MDSAP.

MDCG 2020-14 provides guidance to notified bodies with guidance on how to take MDSAP reports into account for MDR and IVDR QMS reviews. Since notified bodies designated under the MDR or IVDR fulfil both the AO as the Regulating Authority (RA) role, the roles performed by notified bodies and MDSAP AOs differ. The use of MDSAP audit reports within the EU legislative framework is possible only where the

[121] MDCG 2020-14 Guidance for notified bodies on the use of MDSAP audit reports in the context of surveillance audits carried out under the Medical Devices Regulation (MDR)/In Vitro Diagnostic medical devices Regulation (IVDR), p. 3 and 4
[122] Recital (5) MDR / IVDR

MDSAP audit covers similar or equivalent MDR or IVDR requirements. At the moment the audit model used for MDSAP does not incorporate all requirement from the MDR and IVDR.

Notified bodies must work on their normal surveillance audit cycle but may take MDSAP report results into consideration after which they can make an assessment of the gap with MDR or IVDR requirements not or partially covered in the MDSAP report.

6.1.3 Solutions for discussion and opportunities

The MDCG seems to make an artificial distinction between the nature of notified bodies and AOs under the MDSAP. Not only is it theoretically possible to combine a QMS certificate of one notified body with a conformity assessment of another notified body under the MDR or IVDR, notified bodies also typically issue a separate QMS system and product conformity certificate under the MDR or IVDR.

The intention behind the MDSAP model is to allow an AO to conduct a single regulatory audit of a medical device manufacturer that satisfies the relevant requirements of the regulatory authorities participating in the program.[123] While some of the MDSAP members accept MDSAP audit as fully meeting the regulatory requirements, others accept MDSAP reports as meeting part of the regulatory requirements. Given the rationale in MDCG 2020-14 that notified bodies can already take MDSAP reports into account (but just not rely on them as such) and the fact that some notified bodies are AOs for MDSAP purposes as well, there is no objective reason why the EU could not close the gap to accept MDSAP reports as a standard element of QMS requirements. Rather than leaving definition of a gap between the MDSAP report and an MDR or IVDR QMS audit to each notified body the EU could define standard gap between MDSAP audit scope and full QMS audit scope under the MDR and IVDR. This would allow the EU to become a full participant in MDSAP as well as to participate more fully in the IMDRF MDSAP activities that are aimed to arrive at a single IMDRF audit program as promoting global convergence of medical devices regulations through the IMDRF is a specific EU goal under the MDR and IVDR.[124] It would allow the EU to export MDR and IVDR QMS audits under the MDSAP program, making the MDR and IVDR more relevant internationally.

[123] https://www.fda.gov/medical-devices/cdrh-international-programs/medical-device-single-audit-program-mdsap

[124] Recital (5) MDR / IVDR

6.2 International reliance

6.2.1 Issue

While medical devices are generally of the exact same design everywhere in the world, manufacturers must obtain separate market access approval in each jurisdiction under different local rules with different regulatory logic. This leads to an enormous administrative burden and delays in market access, depriving patients of medical technology that is available but cannot be provided because of formalities. As a result of increased formalities and bottlenecks within the implementation of the regulations the Union is at risk of losing its position as market of first launch for (innovative) medical devices and IVDs.

6.2.2 Background

The CE mark has been very successful as a regulatory export product and many countries have attached importance to the CE mark as a benchmark for local approval and registration purposes. The Union was also the jurisdiction of choice for the first launch of new medical technology because of the efficiency of the approval system and the high standards that underpinned the CE mark as a basis for third country approval. However, as a result of the issues with the MDR and IVDR transitional regime and scarcity of notified body capacity the CE mark is increasingly losing international importance and the Union market is losing its attractiveness as medical devices manufacturers that seek to obtain regulatory approval in Europe first are confronted with an inefficient, costly, unreliable and congested approval system. Approximately 50% of respondents to MedTech Europe's April 2022 survey are deprioritising the EU market (or will do so) as the geography of choice for first regulatory approval of their new devices under the MDR.[125] Under the IVDR MedTech Europe's data shows a 28% drop in manufacturers who would prioritise the EU for first product launches.[126]

In addition, countries currently recognising CE mark are more and more considering relying on and/or recognising approval from other jurisdictions, notably the US with FDA approval.[127]

Since most devices are not designed and produced for the Union market alone there is a potential for enormous efficiencies if the EU and other jurisdictions with a mature regulatory system for devices such as the US increase reliance on each other's approval systems for medical devices. Mutual recognition of conformity assessment

[125] MedTech Europe Survey Report analysing the availability of Medical Devices in 2022 in connection to the Medical Device Regulation (MDR) implementation, 14 July 2022, p. 3
[126] Transition to the IVD Regulation, MedTech Europe Survey Results for October 2022, February 2023, p. 3
[127] Notably Switzerland and Australia

could be an important reliance endpoint for enhancing market access between the EU and the US. More broadly the development of a Medical Device Single Review Program in the IMDRF would be an important driver for regulatory reliance in a global context.

Finally, there is development towards fragmentation in Europe with the UK and Switzerland having opted out of mutual recognition for devices, which makes Europe more and more fragmented as regards regulatory approval of devices with the UK working on its own UKCA mark based on the CE mark regulatory template and Switzerland unilaterally recognising the CE mark but taking steps towards FDA approval recognition.

6.2.3 Solutions for discussion and opportunities

BVMed and VDGH see many opportunities for the EU to further recognition- and reliance practices internationally and to promote international convergence of regulation both under existing structures and under new structures.

In dealings with other jurisdictions with a mature regulatory system for devices, the EU should facilitate the use of reliance and recognition mechanisms, as appropriate. Recognition according to the World Health Organization is the acceptance of the regulatory decision of another regulator or trusted institution.[128] Reliance is the act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision.[129]

International reliance can be promoted by exchange of PMS reporting, vigilance and market surveillance information.

Solving the current issues with the MDR and IVDR system

For the CE mark to regain its international reputation that has served the Union so well in the past, the issues created by the MDR and IVDR that have eroded the strategy of ‘Europe first’ for new medical technology need to be remedied. BVMed and VDGH have made recommendations and have raised points for discussion in this paper that will make an important contribution to restoring the efficiency of the

[128] WHO Expert Committee on Specifications for Pharmaceutical Preparation, 55th report, 2021, page 243 (https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations)
[129] WHO Expert Committee on Specifications for Pharmaceutical Preparation, 55th report, 2021, page 243 (https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations)

approval system without compromising on patient safety and performance of devices.

Continuing work on regulatory convergence at IMDRF level and beyond

Secondly, although the IMDRF and other collaboration platforms on regulatory convergence do not have as their goal to arrive at a situation of mutual recognition between their members, international harmonisation within the could lead to convergence of regulation that may facilitate opportunities for reliance and/or recognition. The EU could play a more active role in the IMDRF and other fora by strengthening the international reputation of the CE mark as a regulatory benchmark.

Reviving the existing EU-US MRA

Thirdly, an opportunity for reliance between the EU and the US and improvement of efficiency of patient access to medical devices is the Mutual Recognition Agreement (MRA) that is in place between the EU and the US, which dates back to 1999, which includes medical devices in its scope and applies in parallel to existing regulatory approval processes.[130] Specifically, it provides a structure for the EU and the US to accept the results of quality system-related evaluations and inspections and premarket evaluations of the other Party with regard to medical devices as conducted by listed conformity assessment bodies (CABs) and to provide for other related cooperative activities.[131] In this regard the MRA closes the gap identified as regards MDSAP scope in MDCG 2020-14 as this MRA concerns full scope regulatory approval recognition and not only acceptance of QMS audit result.

The MRA recognises that carrying out its goals will further public health protection, will be an important means of facilitating commerce in medical devices and will lead to reduced costs for regulators and manufacturers of both Parties[132], which it today still as relevant as it was in 1999. The MRA specifies the conditions by which the EU and US will accept or recognise results of conformity assessment procedures, produced by the other's designated conformity assessment bodies or authorities, in assessing conformity to the importing Party's requirements, as specified for medical devices on a medical device sector-specific basis, and to provide for other related cooperative activities.[133] The EU-US MRA already has been fitted officially into their cooperation with regards to harmonisation activities in the IMDRF[134] and establishes

[130] Agreement on mutual recognition between the European Community and the United States of America, OJ 1999 L31/3
[131] Article 1 MRA Sectoral Annex on Medical Devices
[132] Preamble of the MRA Sectoral Annex on Medical Devices
[133] Article 2 MRA
[134] Article 18 MRA Sectoral Annex on Medical Devices

a bilateral regulatory cooperation mechanism.[135] While there has been no significant activity under this MRA for medical devices so far, there has been a lot of activity with in the field of the sectoral annex on electromagnetic compatibility (EMC). The EU could endeavour to restart the process of confidence building activities under the devices sectoral annex of the MRA, leading up to the MRA entering its operation period and providing for actual mutual recognition of approval between the EU and the US.

The Commission should actively pursue MRAs with UK and Switzerland

Fourthly, the Commission should actively seek to prevent regulatory fragmentation at the EU frontiers and seek to maintain the Union geographic scope in which the CE mark applies for medical devices. This would mean active efforts to conclude or reinstate mutual recognition and reliance with the UK and Switzerland insofar as politically feasible.

A legal basis for international convergence and reliance

When implemented responsibly, international convergence and reliance is an efficient strategy for utilizing resources among mature regulators, while building regulatory expertise and capacity, and elevating speedy access to safe and effective, quality-assured medical devices. In the long term, the EU legislation needs a sufficient legal basis for such practices that apply across the total product lifecycle.

International exchange of vigilance and market surveillance data

Finally, the EU-US MRA provides for a comprehensive mechanism for exchange of PMS and vigilance data as well as an alert system for public health threats[136], as well as a wider framework for the exchange of confidential information between market surveillance authorities. Article 102 MDR and 97 IVDR on (international) cooperation could be amended with a specific mandate for the Commission to pursue such networks with third countries and other relevant international cooperation by analogy to the active international cooperation mandate granted by the Commission under article 50 GDPR. By analogy to article 50 GDPR such active pursuit of international cooperation should include appropriate stakeholder involvement.

[135] Article 19 MRA Sectoral Annex on Medical Devices

[136] Articles 3 sub 3 and 20 Sectoral Annex on Medical Devices: “Post-market vigilance reports will be exchanged with regard to all products regulated under both US and EC law as medical devices.” and “An alert system will be set up during the transition period and maintained thereafter by which the Parties will notify each other when there is an immediate danger to public health.”

7 Centralisation of responsibility

7.1 Structuring of certification procedures and self-certification

7.1.1 Issue

As a result of inefficiencies in the functioning of the current regulated market-based market access mechanism relying on decentralised notified bodies that are notified and supervised by single member states patients are deprived of medical technology that can improve their outcomes and manufacturers are deprived of predictable conformity assessment options. The joint assessment process under article 39 MDR and article 35 IVDR has failed and continues to fail to deliver the intended outcome of harmonisation.

7.1.2 Background

The option of centralisation of market access decisions was explicitly one of the policy options when the MDR and IVDR were conceived: “A central marketing authorisation (at EU level) would require building a new EU public body with a sufficiently skilled staff to assess devices, similar to the US FDA. It would have significant impact on the EU budget, on manufacturers in terms of costs and administrative burden and on innovation in terms of time to market.” [137]

There was a modest support for this policy option at the time from mainly the public sector and healthcare insurance funds, but especially industry stakeholders were opposed to that option.[138] Also, the Commission was not convinced that a central agency would have prevented the PIP scandal.[139] Therefore the Commission concluded at the time that “such a radical shift in the regulatory system would be inappropriate.”.[140]

BVMed and VDGH believe that given the MDR’s and IVDR’s performance so far, there is reason to revisit the philosophy of decentralisation under the "New Approach" as this approach has not turned out optimal under the MDR and IVDR. [141] The same is true for the assumption at the time that a pre-market authorization procedure by regulatory authorities with longer deadlines and higher fees (EMA was given as an

[137] Impact Assessment, Executive Summary (SWD(2012) 274 final), p. 7
[138] Impact Assessment, Part I (SWD(2012) 274 final), p. 28; see also Impact Assessment, Part IV (SWD(2012) 274 final), p. 3: “The rejection of a larger role for EMEA by the vast majority of respondents was mainly based on the fear that the involvement of EMEA would represent a move towards the adoption of a pharmaceuticals-like regulation for medical devices. Such an approach could lead to undue delays and higher costs for placing new devices on the market which, according to the majority of contributions, would have an adverse effect on SMEs, which make up around 80% of the sector.:
[139] Impact Assessment, Executive Summary (SWD(2012) 274 final), p. 7
[140] Impact Assessment, Executive Summary (SWD(2012) 274 final), p. 7
[141] Impact Assessment, Part IV (SWD(2012) 274 final), p. 5

example) would not increase public health, but would be detrimental to the competitiveness and innovativeness of the industry, and thus ultimately be against patients' interests.[142] Also this assumption has not been proven necessarily true for the MDR and IVDR. Rather, the system would benefit from centralisation of responsibility and policy in a central European governance structure.

The regulated market-based system of outsourcing market approval decisions to notified bodies has allowed the Member States' competent authorities to limit themselves to a role of (post) market surveillance that requires relatively little resources from them (compared to for example medicinal products authorisation surveillance). This has led to historic under-resourcing of medical devices competent authorities by Member States and of the medical devices policy function at the European Commission, creating a situation in which the existing medical devices structures are not adequately resourced for the work that society expects of them. This has become painfully clear with the amount of work required for implementation and administration of the MDR and IVDR where the system clearly has underdelivered. Currently the system does not produce the desired outcome for any of the stakeholders involved: not for patients, not for Member States, not for competent authorities, not for the Commission, not for notified bodies, not for industry and importantly not for the patients. The system does not meet its public health and internal market goals anymore and the structure set up under the MDR and IVDR has proven unable to remedy this so far as a result of its decentralised nature. For example, even welcome and widely agreed policy initiatives like set out in the MDCG 2022-14 position paper take far too long to first mature and then to be implemented and executed.

The (re-)designation process for notified bodies under the MDR and IVDR has performed absolutely below standards. A large part of the problem is the slow process relying on a combination of the JAT and the notifying Member State, which is very inefficient, time consuming and does not concentrate the relevant experience.[143] Notified bodies have had to embark on a massive recruitment exercise

[142] Impact Assessment, Part IV (SWD(2012) 274 final), p. 5

[143] See Commission Information note for EPSCO meeting, 8 March 2023, 6484/23, p. 4: "The Commission is offering its assistance to national designating authorities to gain efficiency in the process. The Commission has also offered additional supports to national designating authorities and applicant conformity assessment bodies in relation to the corrective and preventive action phase of the joint assessment procedure (the most lengthy phase of the process). At the same time, the Commission notes that for 6 applications, designating authorities have not yet submitted their preliminary assessment reports, which are needed to launch the joint assessment phase. The Commission therefore calls upon all designating authorities to submit outstanding preliminary assessment reports without undue delay. According to the relevant MDCG best practice guide, the estimated time to complete such a preliminary assessment is three months but current waiting times for submission vary from a few weeks to 18 months, in some cases up to 24 months. The Commission also commits to shorten its reaction time wherever possible."

to increase FTEs for processing all conformity assessment applications for devices that were already approved under the Directives[144], massively adding to their costs of operations and, consequently, fees for manufacturers. Also, although there may be a small degree of harmonisation brought about by the process as currently set up, in practice more harmonisation can be achieved by concentrating expertise and experience in one place at a central accountable managing structure.

Attributing a central accountable managing structure with competence to take market access decisions for medical devices has the problem that the accountable managing structure will likely not have the capacity and technical competence to deal with assessment activities for all devices in scope of the MDR and IVDR in all risk classes or for all types of procedures. As a result it would not be possible to make the accountable managing structure responsible for all possible categories of devices and the notified bodies would need to continue to play the important role that they current play with respect to conformity assessment of devices. This allows the system to be able to deal with the larger volume of devices that pose no particular problems because the technology is well-understood and there is sufficient clinical evidence.

7.1.3 Solution

Establishing a central accountable managing structure for medical devices would have important advantages over the current system. It would lead to a scenario where good administration is applied to decisions concerning certificate grant and certification status, just like with medicinal products and as is actually required under the EU Charter of Human Rights and the European Convention on Human Rights (ECHR). An accountable managing structure would have a transparent and fair single rate structure that can compensate for SMEs or special devices such as nice or orphan devices like the EMA fee structure. A single fair and transparent rate structure combined with predictable deadlines for procedures subject to principles of good administration would the serve public interest better for the devices in scope of the accountable managing structure.

BVMed and VDGH do not have a preference as to the organisation of the accountable managing structure. If this is would be set up as a singular entity BVMed and VDGH believe that it should be set up as a standalone EU agency (and not as a branch of the EMA) for oversight the Union medical devices policy and approval of certain devices based on the EU template for a 'decentralised agency'.[145] Although the EMA currently

[144] See Team NB survey 2022, slide 27 (https://www.team-nb.org/wp-content/uploads/members/M2023/Survey-2022-20230411.pdf)
[145] https://european-union.europa.eu/system/files/2022-06/joint_statement_on_decentralised_agencies_en.pdf

has limited involvement in the application of parts of the MDR and IVDR and administrates certain processes, the EMA is and remains a medicines agency. The medical devices policy elements already administrated by EMA should be transferred to the accountable managing structure.

The same structure could be used as is currently used for EMA medicines marketing authorisation procedure: the EMA issues an advice and the European Commission takes the formal decision, allowing for appeal to the General Court.

Because the accountable managing structure will not have the capacity to deal with market access for all risk classes and types of devices it would be opportune to restrict the competence of the accountable managing structure for certification to certain specific minority of devices and/or specific roles in the approval process. The remainder would be subject to certification decisions by notified bodies. There was support for such a blended model in 2012 when the MDR and IVDR were conceived.[146]

The accountable managing structure could for example provide certification decisions for devices currently in scope of the clinical evaluation consultation procedure under article 54 MDR and the scrutiny procedure under article 50 IVDR.

The accountable managing structure would have a framework for engagement with patients and consumers that can be modelled on the EMA patient engagement framework to ensure that the patient voice is included in the different regulatory activities of a device‘s lifecycle. This will improve the quality of and trust in the regulatory decisions and in new devices placed onto the EU market.[147] In addition, the accountable managing structure would need to allow for engagement with other stakeholders, notably manufacturers and notified bodies.

The accountable managing structure, as discussed in this White Paper, can consolidate responsibility for a number of indispensable roles and responsibilities for the functioning of the Union medical devices regulatory system, such as:

- an SME office by analogy to the EMA SME office;
- monitoring notified body fees and providing harmonisation of fees structures for notified bodies;
- an administrative appeal instance for appeal against notified body decisions regarding (non)grant, suspension, restriction of revocation of CE certificates;

[146] Impact Assessment, Part IV (SWD(2012) 274 final), p. 9-10
[147] https://www.ema.europa.eu/en/documents/other/engagement-framework-european-medicines-agency-patients-consumers-their-organisations_en.pdf

- taking over tasks from the MDCG and the Commission such as guidance development, harmonisation of notified body auditing, notified body oversight, integration of processes and development of EUDAMED; and
- overseeing designation, quality control and renewal of designation of notified bodies as well as coordination and harmonisation of notified body policy, consolidating responsibility for this process and notified body policy harmonisation in a single place. This would relieve pressure of under-resourced processes of the JAT, which have consistently posed a major, if not the biggest, bottleneck in the notified body designation process under the MDR and IVDR.

Another policy option in the Impact Assessment was the "Systematic ex ante control of conformity assessment reports for specific device types" (policy option 1F).[148] This option would oblige Notified Bodies to systematically submit their preliminary conformity assessment reports for certain devices or technologies to an expert panel (e.g. under supervision of the accountable managing structure) for scrutiny before a certificate could be issued.

On the basis of a number of criteria, the Commission could specify in a delegated or implementing act which device types would be submitted to a systematic prior scrutiny. The criteria to define those device types could be the following:

- new technology, i.e. a breakthrough technology which may have a significant clinical impact;
- "high risk" due to components or source material (e.g. tissues) or due to the impact in case of failure;
- increased rate of incidents;
- existence of significant discrepancies in the conformity assessment carried out by different Notified Bodies;
- existence of public health concerns regarding a specific device type or technology.

Within a predefined standstill period (e.g. three months), the accountable managing structure could raise concerns which would have to be taken into account by the Notified Bodies. This policy option would lead to harmonization of various aspects related to the underlying clinical data for the devices in scope, such as the level of clinical data required.

BVMed and VDGH believe that concentrating expertise at the accountable managing structure would be a preferable option because of the limited resources and FTEs

[148] Impact Assessment, Part I (SWD(2012) 274 final), section 4.4.3.2

available to DG SANTE and to Member State authorities for devices policy. The accountable managing structure could and should be adequately resourced from the start to be able to play a central role in the much needed procedural harmonisation of EU medical devices policy and conformity assessment and, to that end, consolidate the responsibilities necessary for this to succeed in one place.

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Positionspapier
KMUs in der Medizintechnik – Unverzichtbarer Bestandteil einer zuverlässigen Patientenversorgung

Juni 2025

Vorbemerkung

Die Stärkung von kleinst-, kleinen und mittleren Unternehmen („KMUs“) in Europa ist essenziell für eine wettbewerbsfähigere EU. Die Medizintechnikbranche spiegelt diese Notwendigkeit deutlich wider:
Die Medizintechnik-Industrie in Deutschland und Europa besteht zum allergrößten Teil aus KMUs, die einerseits in der breiten Öffentlichkeit oft nicht bekannt sind, andererseits in ihrem Tätigkeitsfeld jedoch oftmals Weltmarktführer und Innovationstreiber sind. Medizinprodukte-Hersteller beschäftigen in Deutschland rund 161.000 Mitarbeiter in 1.480 Betrieben mit mehr als 20 Beschäftigten. Hinzu kommen rund 12.000 Kleinstunternehmen mit weiteren knapp 104.000 Beschäftigten[1]. Der Anteil an KMUs liegt bei ca. 93%[1]. Diese Unternehmen leisten somit sowohl einen wichtigen Beitrag im Bereich der Gesundheitsversorgung als auch als Jobmotor.
Vor diesem Hintergrund begrüßen der BVMed und der VDGH ausdrücklich die Ankündigung der EU-Kommission, gezielte Maßnahmen zu ergreifen, um die Wettbewerbsfähigkeit der europäischen Industrie zu stärken und dabei einen speziellen Fokus auf KMUs zu legen.
Die Medizintechnik-Branche steht nicht erst mit Inkrafttreten der Medical Device Regulation (Verordnung (EU) 2017/745 „MDR“) und der In vitro Diagnostic Medical Device Regulation (Verordnung (EU) 2017/746 „IVDR“) vor der Herausforderung, für den Marktzugang in Europa hohe Anforderungen erfüllen zu müssen. Sie hat jedoch zu sehr langen und kostenintensiven, sich immer wieder – teilweise sogar während laufender Verfahren – ändernden Zertifizierungsprozessen geführt.
Darüber hinaus belasten Anforderungen und Pflichten aus horizontalen EU-Regelwerken im Bereich der Digitalisierung, der Chemikaliengesetzgebung sowie der Nachhaltigkeitsberichterstattung KMUs erheblich und bedrohen dadurch deren ökonomische Zukunftsfähigkeit.

Der BVMed und der VDGH fordern den europäischen Gesetzgeber auf, zur Stärkung der Wettbewerbsfähigkeit von KMUs in der Medizintechnik und zur Sicherstellung der Gesundheitsversorgung in Deutschland und Europa die folgenden Maßnahmen zu ergreifen:

1. Aktualisierung der KMU-Definition und Schaffung der „mid-cap“-Kategorie
2. Repräsentanz von KMUs in Europa stärken
3. KMU-Belange in Gesetzgebungsverfahren stärker berücksichtigen
4. Fördermaßnahmen für KMUs bei MDR- und IVDR-Zertifizierungskosten
5. Faire Chancen für KMUs bei öffentlichen Ausschreibungen

[1] Zahlen gemäß BVMed Branchenbericht Stand 11/2024 (https://www.bvmed.de/branche/zahlen-und-fakten)

1.
Aktualisierung der KMU-Definition und Schaffung der „mid-cap“-Kategorie

1.1
Aktualisierung der KMU-Definition

Die Empfehlung der EU-Kommission (2003/361/EG) beschreibt Kriterien, nach denen Unternehmen unter eine der drei KMU-Kategorien „Kleinstunternehmen“, „Kleinunternehmen“ oder „mittlere Unternehmen“ fallen. Maßgeblich ist dabei die Anzahl an Mitarbeitern und der Jahresumsatz bzw. die Jahresbilanz des Unternehmens (siehe nachfolgende Tabelle).

Tabelle 1: Aktuelle KMU-Schwellenwerte gemäß Empfehlung der EU-Kommission (2003/361/EG)

Unternehmenskategorie	**Schwellenwert Mitarbeitende**	**Schwellenwert Jahresumsatz/ -bilanzsumme**
Kleinstunternehmen	Weniger als 10	Bis zu 2 mio. Euro
Kleinunternehmen	Weniger als 50	Bis zu 10 mio. Euro
Mittlere Unternehmen	Weniger als 250	Bis zu 50 mio. Euro Jahresumsatz oder bis zu 43 mio. Euro Jahresbilanzsumme

Mit Veröffentlichung der Empfehlung der EU-Kommission im Jahr 2003 wurde eine Vorgängerempfehlung aus dem Jahr 1996 abgelöst. Mit der Ablösung im Jahr 2003 wurden die Schwellenwerte für den Jahresumsatz bzw. die Jahresbilanz an die Preisentwicklungen in Europa (Inflation) angepasst. Auch die Empfehlung von 2003 erwähnt, dass entsprechende Anpassungen notwendigerweise durchgeführt werden können. Die Schwellenwerte für Jahresumsatz und Jahresbilanz wurden jedoch seit 2003 nicht an die Inflation angepasst, was aktuell nicht mehr die wirtschaftliche Realität widerspiegelt und somit eine zusätzliche Hürde für KMU im Hinblick auf das Unternehmenswachstum darstellt.
Basierend auf dem harmonisierten Verbraucherpreisindex (HICP) betrug die durchschnittliche jährliche Inflation in der Eurozone laut Daten von Eurostat im Zeitraum zwischen 2003 und 2024 2,1%[2]. Unter Berücksichtigung der Inflation für diesen Zeitraum (2003 bis 2024) wäre eine Aktualisierung und Anhebung der Schwellenwerte für Jahresumsatz und Jahresbilanz um 57% gerechtfertigt.

1.2
Schaffung der „mid-cap“-Kategorie

Wir schlagen die Einführung von zwei weiteren Unternehmenskategorien mit entsprechenden Schwellenwerten vor, die größer als KMU, aber kleiner als Großunternehmen sind. Diese Unternehmen würden in der EU - ebenso wie KMUs - von maßgeschneiderten Vereinfachungen in den Rechtsvorschriften profitieren.
Wie bereits im Zuge des Wettbewerbskompasses der EU[3] angedacht und im „Omnibus 1 Paket“[4], sowie im „Omnibus 4 Paket“ [5] konkreter spezifiziert, sollte eine Unternehmenskategorie „small mid-cap“ mit bis zu 750 Mitarbeitenden eingeführt werden. Darüber hinaus sollte eine weitere Kategorie „mid-cap“ geschaffen werden, mit bis zu 3.000 Mitarbeitenden. Der Schwellenwert entspricht dem angesetzten Wert der Unternehmensgröße für die gestaffelten Anwendungsfristen gemäß „Stop the clock“ Richtlinie[6].

[2] https://ec.europa.eu/eurostat/en/
[3] https://ec.europa.eu/commission/presscorner/detail/de/ip_25_339
[4] https://ec.europa.eu/commission/presscorner/detail/en/qanda_25_615 , Stand 26.02.2025
[5] https://single-market-economy.ec.europa.eu/publications/omnibus-iv_en, Stand 21.05.2025
[6] Vom Europäischen Parlament angenommener Vorschlag COM(2025) 80 final 2025/0044 (COD) vom 26.02.2025

Aktualisierung der Schwellenwerte für KMUs:

Eine regelmäßige Überprüfung und Anpassung der Schwellenwerte für den Jahresumsatz bzw. die Jahresbilanz unter Berücksichtigung der Inflation würde sicherstellen, dass mehr Unternehmen von den Vorteilen und Förderprogrammen für KMUs profitieren und somit ihre Innovationskraft und Wettbewerbsfähigkeit stärken können.
Die Schwellenwerte sollten unter Berücksichtigung der Inflation im Zeitraum 2003-2024 wie folgt angepasst werden:

- Kleinstunternehmen: bis zu ~~2~~ 3 mio. Euro Jahresumsatz / Jahresbilanz
- Kleinunternehmen: mehr als ~~2~~ 3 und bis zu ~~10~~ 15 mio. Euro Jahresumsatz / Jahresbilanz
- Mittlere Unternehmen: mehr als ~~10~~ 15 und bis zu ~~50~~ 75 mio. Euro Jahresumsatz oder bis zu ~~43~~ 67 mio. Euro Jahresbilanz

Darüber hinaus sollte eine Überprüfung der Schwellenwerte sowie eine Aktualisierung mindestens alle fünf Jahre durchgeführt werden.

Schaffung der Unternehmenskategorie „mid-cap“:

Mit der Schaffung von zwei neuen Unternehmenskategorie, die größer als KMU, aber kleiner als Großunternehmen sind, würden Tausende von Unternehmen in der EU von einer maßgeschneiderten Vereinfachung der Rechtsvorschriften profitieren.
Schwellenwerte:

- „Small Mid-cap“ Unternehmen: bis zu 750 Mitarbeitende
- „Mid-cap“ Unternehmen: bis zu 3.000 Mitarbeitende

2.
Repräsentanz von KMUs in Europa stärken

2.1
Europa braucht einen KMU-Beauftragten

EU-Kommissionspräsidentin Ursula von der Leyen hatte 2019 angekündigt, einen KMU-Beauftragten direkt in ihrem Umfeld zu besetzen und betonte zu Beginn der jetzigen Legislatur erneut, wie wichtig die Rolle der KMUs in Europa ist. Die Medizintechnikbranche bewertet daher sehr kritisch, dass Kommissionspräsidentin von der Leyen von ihrer Zusage abgerückt ist, einen hochrangigen Sonderbeauftragten als Vertreter der Interessen der Mittelständler zu installieren. Diese Funktion könnte sicherstellen, dass mittelständische Perspektiven frühzeitig in europäische Gesetzgebungsvorhaben einfließen und berücksichtigt werden. Sie sollte direkt bei der Kommissionspräsidentin angesiedelt sein und mit einem klaren Mandat sowie der nötigen Handlungskompetenz, insbesondere im Hinblick auf Bürokratieabbau, ausgestattet werden.

2.2
Stärkung der KMU-Stimme bei der Einbindung von Stakeholdern

Um die Innovationskraft und Wettbewerbsfähigkeit der europäischen Medizintechnik nachhaltig zu stärken, sollten die Interessen von KMUs in der Arbeit der Koordinierungsgruppe Medizinprodukte (Medical Devices Coordination Group, MDCG[7]) künftig deutlich gezielter einbezogen werden. Eine dauerhafte Einbindung von KMU – etwa durch eine ständige Vertretung oder institutionalisierte Beteiligung an Stakeholder-Konsultationen – würde deren Perspektiven und spezifische Herausforderungen frühzeitig sichtbar machen und zur praxisnäheren Ausgestaltung regulatorischer Maßnahmen beitragen. Dies wäre ein wichtiger Schritt hin zu einem ausgewogeneren und gleichzeitig leistungsfähigen europäischen Regulierungssystem für Medizinprodukte.

[7] Gemäß Artikel 103 MDR

3.
KMU-Belange in Gesetzgebungsverfahren stärker berücksichtigen

3.1
Folgenabschätzung in EU-Gesetzgebungen für KMUs

KMUs unterliegen in der Regel denselben strengen Regularien wie große Unternehmen. Die Anpassung an neue Regularien und deren Einhaltung erfordert oft erhebliche finanzielle, zeitliche und personelle Investitionen, die KMUs deutlich schwerer aufbringen können. Innovationsprojekte müssen häufig zugunsten von regulatorischen Vorgaben zurückgestellt werden.
In der Praxis ergibt sich dadurch im Hinblick auf die Zukunftsfestigkeit für KMUs sogar im Verhältnis eine höhere Gesamtbelastung in der Umsetzung von regulatorischen Anforderungen, als dies bei großen Unternehmen der Fall ist. Dies zeigt beispielhaft eine Analyse im „Draghi-Bericht[8]“ anhand der neuen EU-Gesetzgebungen GDPR[9], PPWR[10] und CSRD[11] sowie CSDDD[12], welche derzeit auch für Medizinprodukteunternehmen anzuwenden sind.

3.2
Ausnahmen in EU-Gesetzgebungen für KMUs

Ein positiver Entwicklungsschritt ist, dass das Ende Februar 2025 von der EU-Kommission vorgeschlagene „Omnibus 1 Paket[13]“ zur Nachhaltigkeit vorsieht, Unternehmen mit maximal 1.000 Beschäftigen und 50 mio. Euro Umsatz, vom Anwendungsbereich der CSRD auszuschließen[14].
Ebenfalls positiv zu bewerten ist, dass die EU-Kommission im vorgeschlagenen „Omnibus 1 Paket“ dem sogenannten „Trickle-Down-Effekt“ entgegenwirken will. Dieser Effekt beschreibt indirekte Berichtsaufwände, mit denen sich speziell KMUs konfrontiert sehen, wenn größere berichtspflichtige Unternehmen Nachhaltigkeitsinformationen bei Zulieferern oder Partnern innerhalb ihrer Lieferkette anfragen.

3.3
Reduktion von Berichtspflichten für KMUs

Die EU-Kommission will bis zum Ende der aktuellen Legislatur (2029) die Berichtspflichten von Unternehmen um mindestens 25% und von KMUs um mindestens 35% reduzieren. Aus Sicht des BVMed und des VDGH sollten daher bei jedem Gesetzesvorhaben eine detaillierte und systematische Folgenabschätzung, gezielte Ausnahmemöglichkeiten für KMUs sowie Bürokratieentlastung in Form einer Anpassung bzw. Abschaffung von Berichtspflichten gemeinsam Anwendung finden, um das übergeordnete Ziel der Stärkung der Wettbewerbsfähigkeit zu erreichen.

[8] https://commission.europa.eu/topics/eu-competitiveness/draghi-report_en Stand 09.09.2024
[9] General data protection regulation
[10] Packaging and packaging waste regulation
[11] Corporate sustainability reporting directive
[12] Corporate sustainability due diligence directive
[13] https://commission.europa.eu/publications/omnibus-i_en?prefLang=de
[14] https://ec.europa.eu/commission/presscorner/detail/de/qanda_25_615 Stand 26.02.2025

- Konkrete KMU-Folgenabschätzung in EU-Gesetzgebungsprozesse integrieren: Bewertung, ob die Anforderungen durch KMUs zumutbar erfüllt werden können;
- Benachteiligung von KMUs vermeiden: Bewertung ob KMUs durch Anforderungen in EU-Gesetzgebungen gegenüber größeren Unternehmen benachteiligt werden;
- Gezielte Ausnahmeregelung vorsehen, speziell für KMUs, sodass diese aus dem Anwendungsbereich von EU-Gesetzgebungen ausgenommen werden, sollten die Anforderungen für KMUs nicht mit zumutbarem Aufwand zu erfüllen sein, bzw. KMUs gegenüber größeren Unternehmen benachteiligt werden;
- Gezielte Anpassung bzw. Abschaffung von Berichtspflichten, wenn die Anforderungen durch KMUs nicht mit zumutbarem Aufwand zu erfüllen sind, bzw. KMUs gegenüber größeren Unternehmen benachteiligt werden;

Diese Systematik sollte grundlegend zur Anwendung kommen und entsprechend den Bewertungsergebnissen zu einem Ausschluss von KMUs aus dem Geltungsbereich von EU-Regularien, mindestens aber zu spezifischen Ausnahmen und zur Verschlankung von Berichtspflichten führen.

4. Fördermaßnahmen für KMUs bei MDR-Zertifizierungs-kosten

Die US-amerikanische Behörde FDA bietet im Rahmen der „Medical Device User Fee Amendments“ (MDUFA) reduzierte Gebühren[15] für kleine Unternehmen an. Ein "kleines Unternehmen" wird definiert als ein Unternehmen, einschließlich seiner verbundenen Unternehmen, mit einem Bruttojahresumsatz von weniger als 100 mio. US-Dollar im letzten Steuerjahr.[16] Die Gebühren für den Zulassungsprozess von Medizinprodukten werden für solche Unternehmen um 50 bis 75% reduziert.
Zusätzlich können Unternehmen mit einem Bruttojahresumsatz von weniger als 30 mio. US-Dollar einen kompletten Gebührenerlass für ihre erste PMA[17]-Zulassung erhalten. Die jährliche Registrierungsgebühr hingegen ist für alle Unternehmensgrößen gleich.
Von den deutlich reduzierten Zulassungskosten profitieren somit Unternehmen mit einem Umsatzschwellenwert (100 mio. US-Dollar oder weniger) der doppelt so hoch liegt, wie jener gemäß Empfehlung der EU-Kommission für eine Einstufung als „mittleres Unternehmen“ (50 mio. Euro Jahresumsatz oder weniger).
Während die FDA in den USA als Regierungsbehörde entsprechende Gebührenreduktionen zentral steuern kann, existiert in der EU für die Zertifizierung von Medizinprodukten nach MDR bzw. IVDR eine dezentrale Struktur über privatwirtschaftlich agierende Benannte Stellen. Daher müsste eine Reduktion von Zertifizierungsgebühren für KMUs in der EU anders geregelt werden.
Eine Möglichkeit wäre die im „Draghi-Bericht“ vorgeschlagene Stärkung des European Investment Fund (EIF), welcher zentrale Finanzierungsmöglichkeiten für KMUs bereit-stellen könnte. Dabei muss zwingend berücksichtigt werden, dass die Gesamtdauer des Zertifizierungsprozesses nicht durch einen seriell vorgeschalteten Genehmigungsprozess einer EU-Förderung zu Verzögerungen führt.
Darüber hinaus muss sichergestellt sein, dass Förderprogramme möglichst bürokratiearm aufgesetzt werden. Sowohl der Nachweis eines Unternehmens, dass es in eine der KMU-Kategorien gemäß Mitarbeiterzahl und Jahresumsatz /-bilanz fällt als auch der Nachweis der förderfähigen Kosten im Zuge der Zertifizierung müssen schlank und effizient aufgesetzt werden, sodass der Anreiz und der Nutzen für KMUs möglichst hoch ist.

[15] https://www.fda.gov/industry/fda-user-fee-programs/medical-device-user-fee-amendments-mdufa?utm
[16] https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/reduced-medical-device-user-fees-small-business-determination-sbd-program?utm
[17] Pre-market approval application

Gezielte Förderungen der MDR/IVDR-Zertifizierungskosten für KMUs:

- Es sollte die Möglichkeit geschaffen werden, dass sich Unternehmen bei einer zentralen EU-Instanz als KMU registrieren lassen können. Durch eine entsprechende Einstufung als KMU, wären damit die Voraussetzungen erfüllt, dass MDR/IVDR-Zertifizierungskosten durch unbürokratische EU-Fördermaßnahmen in Form von Zuschüssen anteilig erstattet werden. Dieser Prozess muss möglichst schlank gestaltet werden und sollte auf den Nachweis von Mitarbeiteranzahl und Jahresumsatz /-bilanz reduziert sein.
- Das Unternehmen durchläuft regulär den MDR/IVDR-Zertifizierungsprozess bei seiner Benannten Stellen.
- Das Unternehmen kann für den Zertifizierungsprozess angefallene Kosten durch eine EU-Förderung bei einer zentralen EU-Instanz einreichen und erhält eine (noch festzulegende) anteilige Erstattung. Dieser Prozess muss möglichst schlank und bürokratiearm gestaltet werden, sodass der Anreiz und Nutzen für KMUs möglichst hoch ist.

5.
Faire Chancen für KMU bei öffentlichen Ausschreibungen

Um die Wettbewerbsfähigkeit kleiner und mittlerer Unternehmen in Europa zu stärken, braucht es gezielte Verbesserungen im öffentlichen Vergabewesen. Ausschreibungen sollten so gestaltet sein, dass sie Innovationen fördern, Qualitätsaspekte statt reiner
Kosten priorisieren und unnötige Bürokratie vermeiden. Ausschreibungskriterien sollten auf Anforderungen an Produkteigenschaften und -qualität sowie gesetzliche Vorschriften beschränkt sein und es muss speziell in Bezug auf Nachhaltigkeitsberichtspflichten der in 3.2 beschriebene „Trickle-Down-Effekt“ verhindert werden.
Ebenfalls relevant sind vereinfachte und standardisierte Dokumentationsanforderungen, Mechanismen, die es ermöglichen, dass auch KMUs an Ausschreibungen mit großen Austragsvolumina teilhaben können, sowie transparente und innovationsfreundliche Bewertungsverfahren. Zur Förderung der Harmonisierung und Reduktion der administrativen Aufwände, sollte eine EU-weite digitale Vergabeplattform geschaffen werden.

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Hier Text eingeben

Position paper
SMEs in medical technology – an essential part of ensuring reliable patient care

June 2025

Preliminary remark

Strengthening of micro, small and medium-sized enterprises ("SMEs") in Europe is essential for the competitiveness of the EU. The medical technology sector clearly reflects this need:
The backbone of the medical technology industry in Germany and Europe are SMEs, which are often not well known to the general public but are regularly world market leaders and drivers of innovation in their business area. Medical device manufacturers in Germany employ around 161,000 people in 1,480 companies with more than 20 employees. In addition, there are approximately 12,000 micro-enterprises employing another 104,000 people[1]. SMEs account for around 93%[1]. These companies therefore contribute significantly to public health and act as a driving force for employment.

Given this, BVMed and VDGH strongly welcome the EU Commission's announcement to take specific steps to strengthen the competitiveness of European industry, with a special focus on SMEs.

The medical technology industry has been facing the challenge of complying with high requirements for market access in Europe, even before the implementation of the Medical Device Regulation (Regulation (EU) 2017/745, 'MDR') and the In Vitro Diagnostic Medical Device Regulation (Regulation (EU) 2017/746, 'IVDR'). However, these regulations have resulted in very long and cost-intensive certification processes, which are constantly changing - sometimes even during ongoing procedures.

Moreover, requirements and obligations imposed by horizontal EU regulations in the fields of digitalisation, chemicals legislation and sustainability reporting place a considerable burden on SMEs and jeopardize their economic viability.

BVMed and VDGH call on the European legislator to take the following actions to strengthen the competitiveness of SMEs in medical technology and to ensure healthcare in Germany and Europe:

1. Updating the SME definition and establishing a "mid-cap" category
2. Strengthening the representation of SMEs in Europe
3. Better considering SME interests in legislative procedures
4. Supporting measures for SMEs regarding MDR and IVDR certification costs
5. Ensuring fair opportunities for SMEs in public tenders

[1] Figures according to BVMed industry report as of 11/2024 (https://www.bvmed.de/branche/zahlen-und-fakten)

1.
Updating the SME definition and establishing a "mid-cap" category

1.1
Updating the SME definition

The EU Commission Recommendation (2003/361/EC) describes criteria under which companies fall into one of the three SME categories "micro-enterprises", "small enterprises" or "medium-sized enterprises", based on number of employees and either the company's annual turnover or annual balance sheet total (see table below).

Table1 : Current SME thresholds according to the EU Commission Recommendation (2003/361/EC)

Company category	Employee threshold	Annual turnover/balance sheet total threshold
Micro-enterprise	fewer than 10	Not exceeding EUR 2 million
Small enterprise	fewer than 50	Not exceeding EUR 10 million
Medium-sized enterprise	fewer than 250	Not exceeding EUR 50 million annual turnover or EUR 43 million annual balance sheet total

With the replacement of the 1996 version of the recommendation in 2003 the annual turnover and annual balance thresholds have been adjusted to reflect price developments in Europe (inflation). This option for adjustment is also noted in the 2003 recommendation. However, the thresholds for annual turnover and annual balance sheet have not been adjusted for inflation since 2003. This does not longer reflect economic reality and therefore represents an additional hurdle for SMEs in terms of company growth.
Based on the harmonized index of consumer prices (HICP), the average annual inflation in the eurozone was 2.1% between 2003 and 2024, according to Eurostat data[2].
Taking this into account, an update and increase by 57% of the thresholds for annual turnover and annual balance sheet is justified.

1.2
Establishing a "mid-cap" category

We propose the introduction of two new enterprise categories with corresponding thresholds larger than SMEs but smaller than large enterprises. These companies - like SMEs - would benefit from tailored simplifications in legislation in the EU.
As envisioned in the EU's competition compass[3] and specified in more detail in the "Omnibus 1 Package"[4] and "Omnibus 4 Package"[5], a "small mid-cap" category with up to 750 employees should be introduced. In addition, a "mid-cap" category should be created, with up to 3,000 employees. The thresholds correspond to the company size used for the staggered application deadlines in accordance with the "Stop the clock" directive[6].

[2] https://ec.europa.eu/eurostat/en/
[3] https://ec.europa.eu/commission/presscorner/detail/de/ip_25_339
[4] https://ec.europa.eu/commission/presscorner/detail/en/qanda_25_615 , as at 26.02.2025
[5] https://single-market-economy.ec.europa.eu/publications/omnibus-iv_en, as at 21.05.2025
[6] Proposal adopted by the European Parliament COM(2025) 80 final 2025/0044 (COD) of 26.02.2025

Updating the SME definition:

Regularly review and adjustment of the thresholds for annual turnover and annual balance sheet, taking inflation into account, to allow more companies to benefit from the advantages and support programs for SMEs and to strengthen their innovative power and competitiveness.

Adjusted thresholds, taking inflation in the period 2003-2024 into account:

- Micro-enterprises: not exceeding EUR ~~2~~ 3 annual turnover / annual balance sheet
- Small enterprises: not exceeding EUR ~~10~~ 15 annual turnover / annual balance sheet
- Medium-sized enterprises: not exceeding EUR ~~50~~ 75 million annual turnover or EUR ~~43~~ 67 million annual balance sheet

Reviews of the thresholds should be conducted every five years.

Establish a "mid-cap" category:

Two new categories of enterprises that are larger than SMEs but smaller than large companies, to allow thousands of businesses in the EU to benefit from tailored simplification of legislation:

- "Small mid-cap" companies: up to 750 employees
- "Mid-cap" companies: up to 3,000 employees

2.
Strengthening the representation of SMEs in Europe

2.1
Europe needs an SME Envoy

European Commission President Ursula von der Leyen announced in 2019 that she would appoint an SME Envoy within her immediate circle. At the outset of the current legislative term, she once again emphasized the vital role that small and medium-sized enterprises (SMEs) play in Europe. The medical technology sector is therefore very critical of the fact that Commission President von der Leyen has backed down from her promise to appoint a high-ranking special SME representative. This function could ensure that SME perspectives are incorporated and taken into account at an early stage in European legislative projects. It should be based directly with the Commission President and be given a clear mandate and the necessary authority to act, particularly with regards to reducing bureaucracy.

2.2
Strengthening the voice of SMEs in stakeholder engagement

To sustainably enhance the innovative power and competitiveness of European medical technology, the interests of SMEs should be included in the work of the Medical Devices Coordination Group (MDCG[7]) in a much more targeted manner in the future. Permanent involvement of SMEs - for example through permanent representation or institutionalized participation in stakeholder consultations - would make their perspectives and specific challenges visible at an early stage and contribute to a more practical approach. This would be an important step towards a more balanced and at the same time efficient European regulatory system for medical devices.

[7] In accordance with Article 103 MDR

3.
Better considering SME interests in legislative procedures

3.1
Impact assessment in EU legislation for SMEs

SMEs are generally subject to the same regulations as large companies. Adapting to new regulations and being compliant often requires considerable financial, time and personnel investment, which SMEs find much more difficult to raise. As a result, innovation projects are often postponed. In practice, implementing regulatory requirements places a comparatively greater strain on SMEs, affecting their ability to remain competitive and future-proof. This is exemplified by an analysis in the "Draghi Report[8]" based on the new EU legislation GDPR[9] , PPWR[10] and CSRD[11] as well as CSDD[12], which are currently also applicable to medical device companies.

3.2
Exemptions in EU legislation for SMEs

A positive development is that the "Omnibus 1 package[13]" on sustainability proposed by the EU Commission at the end of February 2025 provides for companies with a maximum of 1,000 employees and a turnover of EUR 50 million to be excluded from the scope of the CSRD[14] . Another positive aspect is that the EU Commission wants to mitigate the so-called "trickle-down effect" in the proposed "Omnibus 1 Package". This effect describes indirect reporting efforts that SMEs in particular are confronted with when larger companies subject to reporting requirements request sustainability information from suppliers or partners within their supply chain.

3.3
Reduction of reporting obligations for SMEs

The EU Commission aims to reduce reporting obligations by at least 25% overall and by at least 35% for SMEs by the end of the current legislative term (2029). In the view of BVMed and VDGH, a detailed and systematic impact assessment, targeted exemptions for SMEs and a reduction in bureaucracy in the form of an adjustment or abolishment of reporting obligations should therefore be jointly applied to every legislative proposal in order to achieve the overarching goal of strengthening competitiveness.

- Incorporate concrete SME impact assessments in all EU legislative processes:
  Assessment of whether the requirements can be reasonably met by SMEs;
- Avoid disadvantages for SMEs:
  Assessment of whether SMEs are disadvantaged by requirements in EU legislation compared to larger companies;
- Provide for targeted exemptions from the scope of EU legislation or simplified reporting obligations for SMEs, if the requirements cannot be met with reasonable effort, or if SMEs are disadvantaged compared to larger companies;

This systematic approach should lead to SME exclusions or at least tailored exemptions in EU legislation.

[8] https://commission.europa.eu/topics/eu-competitiveness/draghi-report_en Status 09.09.2024
[9] General data protection regulation
[10] Packaging and packaging waste regulation
[11] Corporate sustainability reporting directive
[12] Corporate sustainability due diligence directive
[13] https://commission.europa.eu/publications/omnibus-i_en?prefLang=de
[14] https://ec.europa.eu/commission/presscorner/detail/de/qanda_25_615 As at 26.02.2025

4.
Supporting measures for SMEs regarding MDR/IVDR certification costs

As part of the Medical Device User Fee Amendments (MDUFA), the US FDA offers reduced fees[15] for small businesses. A "small business" is defined as a company, including its affiliates, with gross annual sales of less than USD 100 million in the last fiscal year.[16] Such businesses receive a 50 to 75% fee reduction for the approval process of medical devices.
In addition, companies with a gross annual turnover of less than USD 30 million can receive a full fee waiver for their first PMA[17] registration. The annual registration fee, on the other hand, is the same for all company sizes.
The threshold for companies that benefit from significantly reduces approval costs in the US is twice as high (USD 100 million or less) than the threshold for “medium-sized enterprises” according to the recommendation by the EU Commission, which is another aspect that demonstrates the need for updating the existing SME thresholds to strengthen the competitiveness of the Union market for SMEs.
While the FDA centrally manages approval fees, the EU has a decentralized certification system for medical devices via notified bodies. Therefore, support in the EU must be structured differently. One possible solution, as proposed in the “Draghi Report”, could be the strengthening of the European Investment Fund (EIF), which could provide financial support for SMEs. It is essential to avoid a delay in certification timelines by decoupling the certification stream from funding application and approval activities. By being classified as a SME, the company meets the necessary requirements to benefit from EU-funding of certification costs.

Funding programs must be set up efficient, lean and transparent to maximize the incentive and benefit for companies to participate in such programs. Therefore, documentation and evidence needed to demonstrate that a company falls into one of the SME categories must be limited to the number of employees and annual turnover/balance sheet. Also, the submission and approval of a refund must be limited to the information strictly necessary.

Targeted subsidies of MDR/IVDR certification costs for SMEs:

- Create a central EU entity where companies register as SME, by providing the number of employees and the annual turnover / annual balance sheet,
- Provide grants for MDR/IVDR for certification costs for SMEs e.g. via the European Investment Fund (EIF),
- Provide efficient, lean and transparent processes for companies to submit MDR/IVDR certification costs and for the approval of refunds;

5.
Fair opportunities for SMEs in public tenders

In order to strengthen the competitiveness of small and medium-sized enterprises in Europe, targeted improvements are needed in the public procurement system. Tenders should be designed in such a way that they promote innovation, prioritize quality aspects rather than pure costs and avoid unnecessary bureaucracy. Tender criteria should be limited to requirements related to product characteristics and quality as well as legal regulations. Additionally, the "trickle-down effect" described in 3.2 must be prevented, especially regarding sustainability reporting obligations.

[15] https://www.fda.gov/industry/fda-user-fee-programs/medical-device-user-fee-amendments-mdufa?utm
[16] https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/reduced-medical-device-user-fees-small-business-determination-sbd-program?utm
[17] Pre-market approval application

Also relevant are simplified and standardized documentation requirements, mechanisms that make it possible for SMEs to participate in tenders with large tender volumes, as well as transparent and innovation-friendly evaluation procedures. An EU-wide digital procurement platform should be created to promote harmonization and reduce administrative costs.

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Joint Opinion of German industry associations: Urgent need for legal measures to facilitate MDR/IVDR implementation.

27.10.2024

The signing German industry associations greatly welcome the opportunity to propose several legal measures that would facilitate MDR/IVDR implementation and make the system more functional. Our proposals result from the experiences made since the MDR/IVDR entered into force in 2017. The solutions proposed aim to resolve some of the main issues for which there is common understanding and that have been identified in multiple surveys. The results of the data gathered from different sources repeatedly point out that the original objectives of MDR and IVDR are not met due to deficiencies in the system.

We observe the following:

> Devices and companies are disappearing from the market.

> Overall costs and time to market are unpredictable and have both increased considerably.

> Interpretations of the regulations and the application of guidance documents which vary greatly which contradicts the aim to harmonize.

> Products and especially innovations are being shifted to other markets.

> Small and medium sized enterprises (SMEs) are disproportionately affected.

All of this is leading to deterioration of patient care.

The proposal aims to provide solutions not only in relation to the targeted evaluation of the MDR/IVDR by the European Commission (COM) in accordance with Art.121 MDR and Art.111 IVDR, but also concerning the current MDD/MDR and IVDD/IVDR transfer activities of the manufacturers and Notified Bodies (NBs) and the “reduction of bureaucratic burden” package of the president of the European Commission.

Manufacturers and NBs require legal certainty for conformity assessment procedures (CAPs) and a common understanding and harmonized implementation of the legal requirements.

Whereas legally non-binding guidance documents are well meant to support implementation, experience shows, that where there is no common approach and understanding of its content as well as acceptance by all stakeholders, guidances fail to achieve their goal. A prominent example is MDCG 2022-14 which already recognized significant and urgent challenges and proposed a mix of solutions to improve the situation. However, more than two years later, there is little improvement as important actions have not been implemented.

Therefore, we propose legal measures that include amendments to the MDR/IVDR legal text, implementing acts (e.g., through Art. 36 (3) MDR and Art. 32 (3) IVDR, Art. 81 g) MDR and Art. 77 g) IVDR) and delegated acts as well as common specifications (CS).

While an ordinary legislative procedure to amendment the MDR/IVDR legal texts takes time, implementing and delegated acts as well as CS provide a suitable legal basis for short-term measures.

In summary, the following topics have the highest relevance to facilitate MDR/IVDR implementation. More detailed information is provided in the respective sections of Annex 1.

1.
Better planning of the certification processes to ensure predictability (see Annex 1, section 1)

MDCG-Guidance 2022-14 already includes several aspects, which could improve the predictability and planning of the certification processes (e.g., leveraging evidence, structured dialogue, streamline administrative procedures, etc.) They should be incorporated into implementing acts.

The harmonization of the application and the CAPs can be achieved by the following measures:

> Introduction and publication of fixed timelines for the CAP or parts of it (e.g. acknowledgement of receipt of application, completeness check, issuance of certificate after concluded review);

> Publication of notified bodies' average time needed for services provided in relation to their hourly fees, to allow economic operators to compare notified bodies fees and estimate the overall costs ;

> Template for the contract between the manufacturer and the NB to ensure contracts do not go beyond requirements in the MDR and to ensure level playing field for SMEs;

> Introduction of an accelerated pathway for innovations and orphan devices / IVDs

> Acceleration of the publication of harmonised standards used to demonstrate conformity of devices / IVDs with the GSPRs

> Implementation of a harmonised methodology for technical documentations including digitisation;

> Clarification in terms of the required activities for (substantial) changes and modifications;

> Clarification in terms of „structured dialogue";

> Clarification on leveraging evidence for legacy devices transitioning from MDD/IVDD to MDR/IVDR, as well as for successor devices.

> Implementation of a governance structure that ensure better harmonisation of notified body practices.

2
Proportionate assessment of the clinical evidence/performance (see Annex 1, section 2)

Legacy devices usually have a long-lasting history, and it is difficult and challenging to retrospectively establish all new requirements of the MDR/IVDR in regard to clinical evidence/performance. The strict application of the new clinical requirements, does not necessarily result in new information about the safety and efficacy of the affected legacy device under the MDR and IVDR.

In contrast, both the long-lasting surveillance by NBs and the post market surveillance (PMS) activities of the manufacturers usually provide a clear picture of the safety and efficacy profile of such medical devices/IVDs.

In order to avoid unnecessary time and cost intensive effort for the compilation of new data without an additional benefit the following short-term measures are proposed:

> Definition and extended use of the concept of „well established technologies“ (WET);
> Reassessment of the application of Art.61 (10) MDR and Art. 56 (4) IVDR;
> Revision of the principle of equivalence;
> Simplified requirements in regard to clinical evaluation for low-risk medical devices and IVDs without affecting patient safety.

3
Recertification / reassessment of certificate validity (see Annex 1, section 3)

The current re-certification procedures appear to be obsolete taking into account the life cycle approach with annual surveillance audits and activities by the NBs, as well as the post market surveillance (PMS) activities and the respective documentation (e.g. management review, trend report, summary of safety and clinical performance, clinical evaluation report, risk management, change management, reporting of severe incidents etc.). The quality management system as well as technical documentation of class III medical devices and class D IVDs are annually reviewed by the NBs.

Hence, instead of a formal and bureaucratic re-certification process the NBs may reassess the validity of the certificates and hereby reinforce the life cycle approach introduced by MDR/IVDR. Certificates should have unlimited validity provided that the surveillance activities of the NBs do not identify unsolved (major) non-conformities.

Furthermore, the sampling of class IIa and class IIb medical devices and class C IVDs should be streamlined; i.e. a complete review of the technical documentation every year, if a manufacturer just possesses one or less than 5 devices / IVDs is not appropriate as it does not result in an improved safety of efficacy profile of the affected product and is a competitive disadvantage for manufacturers with small product portfolios (typically SMEs) compared to those with a large variety of products. Products of class B IVDR should not undergo an

assessment of the technical documentation as described in Art. 49 (9) IVDR. The retention of this category should be reconsidered.

4
Adapt procedures for and content of some MDCG guidance documents (see Annex 1, section 4)

MDCG guidance documents are meant as interpretative aids that should facilitate a harmonized interpretation for the European Union, even though they are legally non-binding. However, MDCG guidance documents today, have a relevant impact on CAPs as they are usually considered not only by Competent Authorities and NB but also by civil and administrative courts (see 1)).

The release of new MDCG guidance documents during ongoing CAPs must not result in the rejection of an ongoing application solely due to non-compliance with any new MDCG guidance.

Furthermore, current MDCG guidances are limited by two factors:

1) Procedure: The endorsement of a MDCG guidance is problematic where a minority of votes in favour can lead to an adoption of the guidance[1]. It is highly questionable to regard such guidance documents as harmonised interpretation. There is also no harmonized and clear procedure for stakeholder consultation, and generally voting processes lack transparency.

2) Acceptance: Stakeholder participation varies greatly, and in some instances, affected stakeholders are not consulted at all. Stakeholders are also not entitled to vote.

In order to achieve a greater acceptance and a more harmonized implementation of MDCG guidance documents the following measures should be implemented for new and existing MDCG guidance documents, which should be revised according to the new principles:

> The objective and scope of a guidance document should be clearly communicated at the start of its compilation and all stakeholders should be able to provide input from the start;

> Clear procedures should be established and made transparent;

> The delegates of the Member States should be obliged to justify their voting (even in the case of abstention) in writing;

> Submitted comments of all stakeholders should be duly assessed and documented;

> A MDCG guidance document should only be endorsed in accordance with a revised voting procedure;

> The compliance with a newly endorsed MDCG guidance document must not be decisive for ongoing CAPs.

[1] MDCG 2022-5 has been endorsed based on 9 affirmative votes, whereas 2 MS voted against the endorsement and 16 MS abstained from voting, i.e. a majority of 18/27 MS did not support the proposed MDCG guidance text and MDCG 2022-5 is not a harmonized interpretation of the MDR

5
Further measures to facilitate the MDR/IVDR implementation (see Annex 1, section 5)

Apart from proposals (1) – (4) further measures would have a positive impact on the MDR/IVDR implementation. Without claim of completeness such measures include:

> Digitalisation of processes and documents / Broach application of electronic instruction for use (eIFU) (Art. 2 (14), Annex I, Impl. regulation 2021/2226);

> Reassessment of some classification rules (e.g. 6, 8, 11, 19) via implementing acts (Art. 51 (2) (3) (4) MDR, Annex VIII) / Publication of classification decisions;

> Others

The German industry associations highly welcome the European Parliament resolution of 23 October 2024 on the urgent need to revise the Medical Devices Regulation (2024/2849(RSP)) and support the proposed measures outlined therein.

We acknowledge the significant efforts already made to establish a reliable and suitable legal framework for medical devices and IVDs. We confirm our full commitment to provide further practical information and proposals to facilitate the MDR/IVDR implementation.

To ensure continuous and safe patient care, as well as innovations, it is important to act swiftly on the proposed actions. By doing so, the original objectives of the MDR /IVDR can be achieved for the benefit of patients, the national health economy, the industry and the EU as a key business location and innovation hub.

Please do not hesitate to contact us for any question.

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November 25, 2024

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Urgent need for action: Legal short-term measures to facilitate MDR/IVDR implementation in Q1 2025

Dear Flora,

Recital (1) of Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR) states that the objective is "to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation". Furthermore, according to recital (2), the MDR and IVDR aim to ensure the smooth functioning of the internal market for medical devices, with a high level of health protection for patients and users, taking into account the small- and medium-sized enterprises active in the sector.

However, after more than six years of implementing these regulations, the availability of both long-standing and new modern medical devices in Europe has declined, negatively impacting patient care. The unpredictability, complexity and lack of harmonization, as well as the administrative burden of the regulations have led to high and unproportionate costs, product discontinuations and migration of innovation.

While the undersigned associations welcome a targeted evaluation in 2025 to further explore root causes and simplification, urgent legal measures are required now, to restore trust in the system and among all stakeholders, to protect patient care with both proven and modern medical devices, and to maintain the EU as a competitive center of innovation.

In line with the European Parliament's resolution of 23 October 2024 on the urgent need to revise the Medical Device Regulations (2024/2849(RSP)), we support a prioritized approach, beginning with short-term solutions that can be implemented through implementing acts. These measures also support EU Commission President von der Leyen's agenda to reduce bureaucracy.

Specifically, we propose the following deliverables for Q1 2025:

1. **Implementing Act regarding Annex VII**

Article 36 (3) MDR/ article 32 (3) IVDR allows the Commission to establish implementing acts in regard to the application of Annex VII. *„In order to ensure the uniform application of the requirements set out in Annex VII, the Commission may adopt an implementing act, to the extent necessary to resolve issues of divergent interpretation and of practical application."* Topics of major importance that could be addressed here are related but not limited to e.g. establishing a common understanding of the steps and timelines for conformity assessment in order to enhance predictability, efficient change notification and management, structured dialog, content of a written agreement ensuring a level playing field, templates for certificates, Notified Body contract, and technical documentation structure and format. More details regarding possible measures within this legal act are highlighted in yellow in the attached list.

2. **Implementing Act regarding clinical evidence**

To *"ensure the uniform application of Annex XIV, the Commission may, having due regard to technical and scientific progress, adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application"* (see article 61 (13) MDR/ article 56 (7) IVDR). Also, in order to achieve a *"uniform application of the requirements regarding the clinical evidence or data needed to demonstrate compliance with the general safety and performance requirements set out in Annex I"* the Commission may establish implementing acts (see article 81 (g) MDR/ article 77 (g) IVDR). Other specific provisions also allow for implementing and delegated acts (e.g. article 32 (3), article 52 (5) MDR/ article 29 (3), article 48 (13) IVDR). Questions in regard to the summary of safety and clinical performance (SSCP), the concept of well-established technologies and to making use of the possibility outlined in article 61 (10) MDR can thus be addressed. Possible measures are marked in green.

3. **Adapt certification to follow a life cycle approach**

Today, recertification for medical technologies is required every 5 years, which represents a high bureaucratic effort and re-investment burden without resulting in additional safety benefits. This is because the Notified Bodies are already required to continually assess devices and quality systems after their certification on an annual and ongoing basis. Therefore, there is an immediate need for aligning certification with the life-cycle approach introduced by the regulations in order to avoid unnecessary bureaucracy, costs and potential bottlenecks. Proposals to do so are outlined in blue.

4. **Implementing Act in regard to the digitalization of processes and documents/eIFU**

Results of multiple surveys show that the current framework for the very limited use of electronic instructions for use is outdated. A broad application of electronic instructions for use will help reduce

bureaucracy and protect the environment. Improvements in regard to e-labelling and digitization of processes are also needed. Proposed solutions are highlighted in purple.

5. **Implementing act regarding Classification rules as well as pathways for orphan devices and breakthrough innovations**

Article 51 MDR/ article 47 IVDR allows for the Commission to decide by means of implementing acts on issues that refer to the application of Annex VIII, that is classification and/or reclassification of a given device or category or group of devices. There are a number of proposals in this regard that are outlined in red.

In summary, the compilation of these solutions would immediately reduce administrative and financial burden for manufacturers and Notified Bodies, without compromising the safety or performance of medical devices or patient well-being. Swift implementation would also enhance the EU's innovative strength and global competitiveness.

Following this, a supplementary amendment to the regulations should be enacted within 2025. Additional proposals that should be considered for this amendment as well as ongoing short term specific measures to improve the implementation of the regulations are also provided (without colour) in the following table.

For the benefit of patients, the national healthcare economy, industry, and the EU as a vital business and innovation hub, the original objectives of the MDR/IVDR can only be achieved by addressing all steps mentioned above.

We would be pleased to provide a more detailed explanation of the points outlined. Please don´t hesitate to contact us in case of questions.

Best regards,

Corinna Mutter on behalf of the above listed associations
Attorney at law / In-house Council
Director Regulatory and EU-Affairs SPECTARIS

Joint Opinion of D-A-CH region industry associations: Urgent need for legal measures to facilitate MDR/IVDR implementation

Annex I | D-A-CH region industry associations proposals for urgent measures to decrease bureaucracy and facilitate MDR/IVDR implementation

15.11.2024

Content

1. Better planning of the certification processes to ensure predictability

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
1.	Establishment of binding deadlines for the conformity assessment procedures	Diverging NB practices Lack of clear and binding timelines in the MDR / Annexes	Currently, there are significant delays in procedures, making it nearly impossible for manufacturers to plan the review of technical documentation and the overall completion of the conformity assessment and certification. Additionally, timelines for conformity assessment differ greatly between Notified Bodies.	To define a binding overall timeframe for the conformity assessment and certification procedure is the only way to give manufacturers the essential planning certainty they need in order to market products. This planning certainty is existential and urgently needed to secure the EU and Member State markets as a business location. First, it is essential that there is a common understanding of the necessary steps in the process and when and how these can move forward. Where possible, steps in the process should be able to run in parallel. Fixed timelines should be predetermined and implemented at least for some	Establish a common understanding of necessary steps in the conformity assessment process, introduce predetermined timelines for at least some of the steps, and predefine a binding overall timeframe for the whole process. Integrate a clock stop mechanism.	Implementing act according to Article 36 (3) MDR/32(3) IVDR to adapt Annex VII by • establishing a common understanding of necessary steps in the conformity assessment process • introducing predetermined timelines for at least some of the steps • predefining a binding overall timeframe for the whole process. integrating a clock stop mechanism.	Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
				steps (e.g. application received, processed and assessed for completeness xx days; conclusion of a contract xx days, final issuance of the certificate after successful conformity assessment procedure xx days) Further timelines should be specified and predetermined in regards to specific conformity assessment activities. Any deviations (e.g. for necessary processing of non-conformities) from the schedule can be made after consultation with and approval by the manufacturer. The evaluation of a medical device is officially stopped with a clock stop for the amount of time the applicant needs to respond to questions. The clock resumes when the applicant has sent its responses.	Amendment of Annex VII Section 4.5.1 MDR: "The notified body and its personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical and scientific competence in the specific fields. The notified body shall confirm completeness or reject an application for conformity assessment within 10 days as of the date of application. If the notified body decides that the application is complete this is deemed to constitute an offer of a contract that may be accepted by the manufacturer. The notified body shall ensure that the procedure for conformity assessment is completed within a maximum of 180 days after the submission of a valid application, excluding consultation with competent authorities as part of the conformity assessment procedure. A clock stop is foreseen."		Mid term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
2.	Technical documentation structure | Master Document	Divergent notified body practice	Notified body reviewers do not accept modular TD but rather expect parts of TD that they review to contain all information for the relevant part of the review. This includes also the fact that every document has to include every information, no references are allowed. A standardized TD should also be compatible with international documentation standards to reduce the overall bureaucratic burden.	As a result of diverging interpretations of the structure of TD between notified bodies, manufacturers cannot use a single 'organised, readily searchable and unambiguous' TD. The Team-NB BPG on technical documentation does not provide for harmonisation of interpretation on this point.	Option 1: Article 9 (1) MDR/IVDR: Commission to adopt CS regarding Annexes II and III by means of implementing act.	CS adopted by the Commission would provide a standard template for the TD structure that cannot be subject to divergent practice by notified bodies anymore. Use one master document and allow references in documents of the technical documentation to „other" documents or „parts" of documents in the same technical documentation; reduce any redundant texts/figures. If this takes more time for the notified bodies in reviews, the review fees should be fixed (!). And if partial documents (PEP/PER)	Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
						are reviewed by other experts, then these experts need to get access to any referenced documents to have complete information. An implementing act adopted by the Commission could resolve multiple issues regarding the application of Annex VII, including aspects related to conformity assessment activities. Thus, a standard template for the TD structure that cannot be subject to divergent practice by notified bodies anymore, could be implemented and combined with further measures, for example in regard to timelines.	Short term
3.	Technical documentation format	MDR/IVDR requirement Divergent notified body practice	The MDR should contain a uniform electronic structure for the technical documentation. In practice each notified body can determine how precisely the manufacturer should organise the	Making the TD specific to a specific notified body's requirements makes switching between notified bodies and market surveillance much more difficult. A standard format	Option 1: Article 9 (1) MDR/IVDR: Commission to adopt CS regarding Annexes II and III by means of implementing act.	CS adopted by the Commission would provide a standard electronic format for	Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
			technical documentation. There are examples of notified bodies that require manufacturers to re-format and in some cases disassemble their technical documentation only to make it fit to the specific notified body's system.	would make this much easier and less costly. Also, standard technical documentation improves market surveillance, as it will lead to increased transparency to technical documentation.	Option 2: Article 36 (3)/32 (3) IVDR In order to ensure the uniform application of the requirements set out in Annex VII, the Commission may adopt implementing acts, to the extent necessary to resolve issues of divergent interpretation and of practical application.	the TD much like the eCTD for medicines.[1] An implementing act adopted by the Commission could resolve multiple issues in regard to the application of Annex VII, including aspects related to conformity assessment activities. Thus, a standard format for the TD that cannot be subject to divergent practice by notified bodies anymore, could be implemented and combined with further measures, for example in regard to timelines.	Short term
4.	Structured dialogue | Clinical Evidence	Notified Body practice / Team NB code of conduct Competent Authority practice	Article 61 (1) MDR requires that conformity of the device shall be based on clinical data providing sufficient clinical evidence". In practice it is often not possible for the manufacturer to determine what will be sufficient clinical evidence for the device. This is exacerbated by the fact that also the latest version of the Team NB	Currently, it is still not possible to discuss a clinical development strategy in a structured dialogue and rolling review. Such a discussion is, however, necessary and should allow the notified body to, when the level of evidence is not deemed acceptable,	• Commission to adopt implementing act based on article 36 (3) to add to section 4.5.1 of Annex VII a specific obligation for the notified body to have a procedure for structured dialogue that includes - among other things - discussion of and feedback		Short term

[1] See White Paper BVMed and VDGH, section 4.5.3

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
			Code of Conduct does not allow for the notified body to "Review clinical development strategy". Pre-submission meetings for precisely this purpose are a normal procedural phenomenon for medicines marketing authorisation applications, intended to discuss details regarding the procedure with the persons responsible at the government body. However, the MDCG does not provide any transparent detail on what a structured dialogue would look like. Moreover, MDCG refers the further implementation its subgroup the NBO (one of the two MDCG subgroups that **does not** admit stakeholders). This is counterproductive as input from what is needed in practice is essential in this regard.	indicate what is not acceptable and why.	on sufficiency of clinical evidence. • Member states to instruct notified bodies that structured dialogue may include discussion of clinical development strategy, including indication of what evidence is not deemed acceptable. This does not constitute prohibited consultancy and should be explained accordingly with reference to ISO 17021-1:2015, which addresses consultancy explicitly and provides a number of examples that do not constitute consultancy such as clarifying requirements (sections 3.3 and note to section 5.2.5[2]).		

[2] "The certification body and any part of the same legal entity and any entity under the organizational control of the certification body […] shall not offer or provide management system consultancy. […] NOTE This does not preclude the possibility of exchange of information (e.g. explanation of findings or clarification of requirements) between the certification body and its clients."

2. Proportionate assessment of the clinical evidence/performance

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
5.	SSCP | Exemption for Well Established Technology (WET)	MDR requirement Lack of optimisation	WET implants are subject to SSCP obligation (article 32 (1) MDR), while they are exempted from other document requirements under the MDR, such as implant card (article 18 (3) MDR) and assessment of the technical documentation (Art. 52(4) 2nd section). This forces the manufacturer to produce and validate an SSCP for a device that does not (or no longer) change in any material sense, because the technology is well-established. SSCP obligations are not suitable for WET, because periodic updates to the SSCP will not reveal new	The very fact that the technology is well-established means that yearly updates of the SSCP in accordance with article 61 (11) MDR are redundant exercises. The initial SSCP for initial conformity assessment is sourced completely from the TD, so will not contain any new information compared to the IFU. HCPs and patients have no use for SSCP for WET precisely because it is well-established and will therefore not differ materially from the IFU. For this reason, WET implants are exempted from having an	[**option 1**] Implementing act based on article 32 (3) MDR	Implementing act to clarify that "implantable devices" for the application of article 32 exclude the following" "sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and any other implants exempted from the obligations in article 18"	Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
			developments relevant to health care professionals (HCPs) and patients.	implant card (article 18 (3) MDR).	[**option 2**] Amendment of article 32 (1) MDR to exclude the same WET devices as excluded under article 18 (3) MDR	Add in article 32 (1) MDR behind "other than custom-made or investigational devices" the following "sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and any other implants exempted from the obligations in article 18".	Mid term
					[**option 3**] Amend article 61 (11) to exempt WET from yearly SSCP publication	Change of article 61 (11) MDR to provide after "and, if indicated, the summary of safety and clinical performance referred to in Article 32" in article 61 (11) 2nd paragraph "expect for sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and any other implants exempted from the obligations in article 18."	

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
6.	Definition of Well-Established Technologies (WET) subject to exemptions under articles 52 (4) and (5) MDR	MDR requirement	The use of the general terms "sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors" for WET in article 54 (4) and (5) and other places in the MDR beg the question for a more precise and at the same time more flexible definition of WET to reflect the intention of the EU legislator.	Clearly, the EU legislator sought to create a category of devices within the same risk class of implants that would be subject to lighter conformity assessment because the technology is well-established. The concept of WET could be established better by adding more general types of devices to the group listed in article 52 (4) MDR, which the Commission is entitled to do by delegated act based on article 52 (5) MDR. This would allow updating the list on the basis of experience gained with the application of the MDR and it would reduce the administrative burden for manufacturers of the devices concerned considerably because these devices can be approved on a sampling basis rather than dossier examination (see article 52 (4) MDR.	Delegated act by the Commission pursuant to article 52 (5) to amend the article 52 (4) list with more general types of implantable devices.		Short term
7.	SSCP frequency (yearly update)	MDR requirement Lack of optimisation (considering the state of the art)	The PMS process should be capable of being automated and statistics driven to ensure that costs for compliance are kept at reasonable levels and processes are appropriate for the devices concerned. PMS and PMCF should not be about producing data	Yearly publication and validation of an SSCP is an extremely time consuming and costly process, which needs to be conducted also if there are no relevant changes to report. This can be implemented by means of a small amendment	[**option 1**] Implementing act under article 61 (13) MDR for setting out KRIs (Key Risk Indicators) that would trigger an SSCP update;		Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
			periodically and putting this in reports to be evaluated by a third but rather about detecting signals relevant to PMS and PMCF and informing HCPs and patients on a targeted basis. Targeted information will perform better than periodic similar reports in which it is not clear what has changed.	to Article 61 (11) MDR or could be done by means of an implementing act based on article 61 (13) MDR, supported by MDCG guidance. In addition, the scope of devices for which an SSCP is considered relevant by the MDCG in MDCG 2019-9 is overly broad as there is no evidence that an SSCP actually benefits or even reaches patients. If there are issues with the devices concerned that patients must know about this can be better achieved through other channels than Eudamed. The notified body is needed for any interaction with Eudamed for SSCPs but this creates administrative costs and delays – the manufacturer should be able to upload documents himself that are validated in Eudamed by the notified body if needed.	[**option 2**] Adopt CS based on article 9 (1) to amend PMCF in Annex XIV to define KRIs for PMCF that would trigger need for SSCP update.		Short term
					[**option 3**] Amendment to article 61 (11) 2nd paragraph MDR	Article 61 (11) 2nd paragraph is amended as follows: "For class III devices and implantable devices, the PMCF evaluation report ~~and, if indicated, the summary of safety and clinical performance referred to in Article 32~~ shall be updated at least annually with such data. <u>The summary of safety and clinical performance referred to in Article 32 shall be updated with data if needed to ensure that any clinical and/or safety information in the SSCP remains correct and complete.</u>"	Mid term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
					Amend MDCG 2019-9 on SSCP to clarify that the patient part of SSCP is only needed in cases where this is relevant and not in all cases of class III and implantable devices for which patients receive an implant card and that the manufacturer can upload non-validated documents and translations of SSCP without the intervention of the notified body.		Short term
8.	SSP only for products used directly by laypersons ("selftests").	IVDR requirement	SSP is not seen by the patient. In addition, professional users have already access to the instructions for use, containing already a lot of information also being part of the SSP and they are often in contact with the manufacturer's experts. Consequently, professional users don't need any SSP as well.	SSPs are made for patients to get an insight into the performance of the test. professional tests are "not seen" by the patient, so the SSP is not needed. SSP is a high bureaucracy burden (check, upload, validation, translation). Additionally, there is a high overlap with the IFU.	Amendment to article 29 (1) IVDR as follows: 1. For class C and D **lay use device**s, except for devices for performance studies, the manufacturer shall draw up a summary of safety and performance.		Mid term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
9.	CECP application requirement	MDR requirement	Pursuant to Article 54 (1) MDR and subject to limited derogations under Article 54 (2) MDR the CECP must always be followed. Yet, the expert panel (EP) rarely issues an opinion after an application by the Commission's data (12% of the cases in the period of July 2022-July 2023).[3] However, this percentage only concerned screened applications. When calculated over all applications made (353) in that period the percentage turns out to be 1%. This leads to a vast amount of unnecessary applications to the expert panels and unnecessary	Use of CECP must be adapted given the fact that 99 % of the applications are unnecessary as they do not lead to an expert panel opinion. Under the current requirements an application must always be made. If the MDR could specify criteria or provide for the option to define them, the number of unnecessary applications could be reduced radically. Even more important, the decision whether the device deserves an opinion of the EP	• **Option 1:** On the basis of Article 54 (5) MDR the European Commission may make proposals for amendments to the regulation. Amend Section 5.1 (a) Annex IX and 6 Annex X criteria or procedure for certain devices ("For class III implantable devices, and for class IIb active devices intended to administer and/or remove a medicinal product as referred to in Section 6.4. of Annex VIII (Rule 12)")		Mid term

[3] The Commission's most recent report states that this happens in 12% (SWD (2024) 76 final, p. 7 (Annual overview of devices subject to the clinical evaluation consultation procedure pursuant to Article 54(4) of Regulation (EU) 2017/745 on medical devices (July 2022- June 2023)

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
			work by the notified bodies to prepare them and shows that the application criteria should be adapted. Even if NBs use exemptions per Art. 54(2) or if the EPs do not provide opinions based on provisions per Annex IX, 5.1 c., the NB needs to prepare and submit a wealth of documents to numerous authorities which remain predominantly unread. Moreover, the CECP process is utilized at a time the review process for the device is completed and therefore the CECP occurs on the "time-critical path" of the conformity assessment project.	should be decided early in the conformity assessment project off the time-critical path.	• **Option 2** Adopt CS for devices' clinical evaluation that excludes them from the CECP		Short term
10.	CECP procedure	MDR requirement Lack of optimisation (considering the state of the art)	CECP procedure is inefficient and designed to be completely linear with institutions waiting for each other to complete processes where processes could be completed in parallel.	The processes at EP and NB must run in parallel in order to save time, resources and effort without jeopardising the safety or quality of the product or concealing a product from the experts. This also includes a collection obligation of the screening panel, if necessary.	Amendment of Annex IX 5.1	Amendment of Annex IX 5.1 on the following points: • NB requests slot for panel review at EP secretariat upon receipt of conformity assessment application for device(s) concerned. Secretariat gives notified body date for delivery of CER to EP secretariat.	Mid term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
						EP secretariat delivers CER to Commission if needed for Commission involvement in EP decision under (c) and (d). • Presentation of NB conclusions takes place within the 60 days period under 5.1 (c). • 60 days starts on delivery of CER to EP secretariat. • EP decides within 14 days about whether or not to give opinion. • Same as under (d) EP decides within 14 days about whether or not to give opinion. • [no change] • Remove sentence "Where the expert panel [...] as appropriate." The notified body shall set out in the CAR how it has taken the EP advice into	

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
						account. This is not published publicly although the EP opinion may be after anonymisation pursuant to article 109 MDR. The Commission shall evaluate EP opinions and periodically and based on this evaluation update guidance for expert panels for consistent interpretation of the criteria in point (c)	
11.	Scope of article 61 (10)	Notified Body practice Competent Authority practice	Article 61 (10) MDR allows for the manufacturer to adequately demonstrate and justify conformity with the general safety and performance requirements (GSPR) based on the results of non-clinical testing methods alone.	It is important that this option, that is already outlined in the legal text, is applied and made functional. With the current advances in technology, medical device testing environment are expanding. Considering this,	• Article 61 (13) MDR allows the Commission to adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application of Annex XIV MDR.	Implementing act according to Art. 61 (13) MDR regarding the use of non-clinical data to demonstrate conformity with the applicable GSPRs as well as examples of devices in scope.	Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
			In practice, however, this option is not applied and/or accepted by NB. For example[4]: Notified bodies require clinical data for devices that are not intended to be used on humans (e.g. devices for cleaning, disinfection and sterilisation). Article 61 (10) MDR is creating uncertainty on its interpretation and correct application, especially for medical devices falling into the low to moderate risk class (Class IIa) and in the moderate to high (class IIb) risk class, where the requirement to perform a clinical investigation for the demonstration of conformity with the GSPRs is not imposed by the legislation.	digital twinning, curative databases, computer modelling, use of physical or digital phantoms, generation of artificial (patients) data or use of retrospective patient data may provide controlled and scientifically valid concept to be utilized as non-clinical data within the device's clinical evaluation. The focus on the assessment within the clinical evaluation should be on scientific validity of the testing methodology, test case design and the output, whether the data can be extrapolated to the expected clinical use of the device and in the intended clinical use environment, and whether the non-clinical data solely is sufficient to cover all clinically relevant characteristics and claims made on the device by the manufacturer, and thus demonstrate the conformity of the device with the applicable GSPRs.	• In the meantime, Member States and Commission to raise awareness and instruct notified bodies to allow and make use of Article 61 (10) MDR.		Short term
					• MDCG guidance about type of devices in scope of article 61 (10) and regarding the use of non-clinical data to demonstrate conformity with the applicable GSPRs.		Short term

[4] For more examples see also: 20220525_COCIR_White_Paper_MDR_Article_61__10_.pdf

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
12.	Need of PMCF studies | required by notified bodies if MDR does not specifically call out the need	Notified Body practice Competent Authority practice	PMCF under the MDR and under the previous MDD/AIMDD differs. Under the MDR it is a life cycle PMS process, whereas under the MDD/AIMDD it referred to conditions that a notified body would impose to be fulfilled by the manufacturer as a condition for continued validity of the CE certificate.[5] Notified bodies occasionally require PMCF studies under the MDR as a condition for continued validity of the CE certificate like under the MDD/AIMDD.	Annex XIV Part B 6.2 (b) MDR provides that the PMCF plan shall include at least "the specific methods and procedures of PMCF to be applied, such as evaluation of suitable registers or PMCF studies". PMCF studies are therefore not a requirement but specifics of the PMCF plan. Only where the PMCF plan itself states that PMCF study is indicated should there be a need to do PMCF studies. Otherwise, the NB could only find that the clinical data supporting that the device is not up to the state of the art (PMS goal in article 83 (3) (c) MDR[6]) and suggest to the manufacturer to collect additional state of the art data, leaving it to the manufacturer to determine the right instrument for this purpose.	No specific instrument required. Notifying authorities of Member States to clarify PMCF under MDR to notified body.		Short term
13.	Qualification of PMCF studies without additional invasive or burdensome procedures	MDR requirement	Article 74(1) MDR explicitly regulates only notifiable PMCF investigations, if the subjects are submitted to invasive or burdensome procedures in	This leads to **confusion, misunderstandings, and divergent practices** among Member states as some classify such PMCF investigations as	**Targeted change to the MDR legal text art 74:** Clarification of the legal classification of post-market clinical investigations of a	Proposal Art 74(3) MDR (new): "The provisions of Articles 62 to 81 shall not apply to PMCF	Mid term

[5] See MEDDEV 2.12/2 Rev. 2

[6] "to update the clinical evaluation;"

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
		Competent Authority practice Guidance or other interpretation of MDR legal text	addition to the normal conditions of use of the device. PMCF investigations without such additional invasive or burdensome procedures are not explicitly regulated in Article 74.	other clinical investigations per Art. 82 MDR. However, this is incorrect, since PMCF investigations are in general conducted for one of the purposes set out in Article 62(1) of the MDR, such as data collection as part of the ongoing conformity review. This explicitly excludes them from the scope of Article 82 (1) MDR.	device **within the scope of its intended purpose**, in which subjects are NOT submitted to additional invasive or burdensome procedures compared to the normal conditions of use of the device ("Non-notifiable PMCF investigations").	investigations in which subjects are not submitted to additional invasive or burdensome procedures compared to the normal conditions of use of the device."	
14.	Clarification on documentation needed for PMCF investigations per Article 74(1) MDR (with additional invasive or burdensome procedures, within the intended purpose)	MDR requirement Competent authority practise Guidance or other interpretation of MDR legal text	These investigations must be notified accordingly and the **complete documentation per Annex XV** MDR is required for the Ethics Committee assessment and for the CA notification. Annex XV does currently not differentiate between documentation requirements for clinical investigations subject to **authorisation** and clinical investigations subject to **notification**.	This is only justified for devices without CE marking, as the conformity assessment procedure has not yet been completed and the authorities must assess safety and performance. However, if a CE-marked device is to be investigated only with additional burdensome or invasive procedures there is no reason to (re)request this technical documentation and summarise it in an investigator's brochure, since the safety and performance have already been demonstrated in the conformity assessment (plus CIP and IFU).	**Targeted changes to the MDR legal text art 74 (and related articles accordingly):** Clarifications of the content of the documents to be submitted for post-market clinical investigations of a device **within the scope of its intended purpose**, in the context of which subjects are submitted to additional invasive or burdensome procedures compared to the normal conditions of use of the device ('Notifiable PMCF investigations').		Mid term
15.	Correction of timelines for submission of the	MDR requirement	In the case of an **early termination,** a lot of preparatory activities are not possible: In these	In the case of **an early termination**, it takes more time to compile the data and write	**Targeted change to the MDR legal text art 77(5):**	Proposal Art 77(5) subparagraph 1 MDR/Art 73(5) IVDR*:*	Mid term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
	final report for clinical investigations according to Art 77 (5) MDR/Art 73 (5) IVDR	Guidance or other interpretation of MDR legal text	cases, the clinical investigation is still ongoing and some non-monitored data are available at the study sites, queries are open, SAE status is not conclusively known, and in blinded study arms, the assignment is not yet known. In case of a **temporary halt**, priority must be given to whether and under what changed conditions this clinical investigation can be resumed, and a substantial amendment must usually also be submitted with appropriate measures to ensure the safety of the investigation subjects. Root cause analysis, determination of corrective actions and adaptation of documents, and submission pending approval of a significant change are the essential steps in this situation.	the final report than for a regular termination. The period of 3 months is not achievable in practice. In case of a **temporary halt**, a final report is not expedient and stands in the way of continuing the study, since the analysis and disclosure of the data obtained up to that point makes the continuation of the study subject to a considerable bias, especially in the case of well-designed clinical investigations (with randomization, blinding, ...).	It is proposed that the deadline for prematurely terminated clinical investigations should also be set at 12 months and that no final report should be required for temporarily halted clinical investigations, as these clinical investigations have not yet been terminated by definition.	"(5) Irrespective of the outcome of the clinical investigation, within one year of the end of the clinical investigation or ~~within three months~~ of the early termination ~~or temporary halt~~, the sponsor shall submit to the Member States in which a clinical investigation was conducted a clinical investigation report as referred to in Section 2.8 of Chapter I and Section 7 of Chapter III of Annex XV.(MDR)/ Section 2.3.3. of Part A of Annex XIII (IVDR)"	
16.	Correction of application for extension of the deadline of the final report according to Art 77 (5) subparagraph 3 MDR/ Art. 73 (5) IVDR	MDR/IVDR requirement Guidance or other interpretation of MDR legal text	The requirement stated in subparagraph 3 of Article 77 (5) MDR/ Art. 73 (5) IVDR is hardly feasible, because it requires that the scientific justification for exceeding the deadline of one year after completion should already be stated **in the clinical investigation plan**.	Experience of sponsors or their contract data processors shows that the scientific reasons why the final report cannot be completed on time only emerge during the evaluation and reporting phase.	**Targeted change to the MDR legal text art 77(5) subparagraph 3**/ Art. 73 (5) IVDR**:** A possibility should be provided to grant the sponsor an extension of the deadline upon request.	Proposal Art 77 (5) subparagraph 3 MDR/ Art. 73 (5) IVDR*:* "Where, for scientific reasons, it is not possible to submit the clinical investigation report within one year of the end of the investigation, it shall be	Mid term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
						submitted as soon as it is available. In such case, ~~the clinical investigation plan referred to in Section 3 of Chapter II of Annex XV~~ the sponsor submits an application for an extension of the deadline to the Member States no later than 3 months before the due date of the final report. This application shall specify when the results of the clinical investigation are going to be available, together with a justification."	
17.	Annex XIII.2.3.2 IVDR: Requirement of Clinical Performance Study Plan / Report.	IVDR requirement	Both documents have no real benefit. The existing Clinical Performance Protocol (that has already been established under IVDD) and the Clinical Performance part of the PER already contain most of the information. CPSP contains the same information as other documents (e.g. Intended Purpose / metrological traceability from PEP). Triggers extra work.		Update Annex XIII and delete the 2 documents.		Mid term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
18.	Clarification of the timeline of Article 70(7) MDR	MDR requirement Very different application by Member States	The timeline mentioned in Article 70(7) MDR is interpreted very differently by the Member States. In some Member States the sponsor has to wait much more longer to be notified of the final authorisation. Also, it should be clearer that the extension of the period by the Member State is possible for a maximum of 20 days. In practice, some Member States interpret this possibility differently.		Targeted change to the MDR legal text Art. 70(7) MDR: A clarification of the timeline of Art. 70(7) MDR is needed.	Amendment to Art. 70(7) MDR: "(b) in the case of investigational devices, other than those referred to in point (a), as soon as the Member State concerned has notified the sponsor of its authorisation, and provided that a negative opinion which is valid for the entire Member State, under national law, has not been issued by an ethics committee in the Member State concerned in respect of the clinical investigation. The Member State shall notify the sponsor of the <u>final</u> authorisation within 45 days of the validation date referred to in paragraph 5. <u>During the validation, the period of time is officially stopped while the applicant prepares responses to questions from the Member</u>	Mid term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
						State («clock stop»). The Member State may extend this period by a maximum of further 20 days for the purpose of consulting with experts.”	

3. Recertification / reassessment of certificate validity

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
19.	Validity of certificates / Optimisation of the certification process / PMS controlled regulatory certification (process)	MDR/IVDR requirement	**Reassess provisions on the validity of certificates and optimize the certification process, taking into account the life cycle approach.** There is no objective justification for a five-year certification duration in the case of devices and the MDR and IVDR have significantly increased PMS (including PMCF-PMPF activities) to ensure continued compliance of the device throughout its life cycle, certificates should have unlimited duration (subject to PMS and PMCF/PMPF) or at least substantially extended and duplication of activities in re-assessment should be avoided. A certificate, once granted, should be subject to the many PMS controls under the MDR and IVDR only and should not be subject to periodic renewal. **PMS controlled market access**		It could be contemplated to interpret the duration of the certificate as an Annex XII element (see Annex VII 4.11), in which case the Commission could amend the MDR by delegated act pursuant to article 56 (6) MDR/article 51 (6) IVDR	"The certificates issued by the notified bodies in accordance with Annexes IX, X and XI for devices shall be valid for the lifetime of the device, subject to the manufacturer's post-market surveillance system supporting the quality, safety and performance over the lifetime of the device in accordance with Chapter VII, Section 1 and Part B of Annex XIV. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid."	Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
			Where a device performs as intended and the manufacturer demonstrates this on a continuous basis with PMS and PMCF/PMPF data, there is no reason to periodically revisit the certification decision, and the certificate can continue to be valid subject to appropriate surveillance by the notified body. Continued certificate validity should rather be risk and data based, based on PMS and PMCF/PMPF performance by the manufacturer as monitored by the notified body. If the manufacturer's PMS and PMCF/PMPF real-world data show that the device performs as intended after CE marking and to the state of art as is required under MDR or IVDR PMS and PMCF/PMPF requirements, there is no objective reason to repeat the certification, and the notified body can earmark a certificate as in good standing without need to be re-issued.		Amendment of article 56 (2) MDR/Article 52 (2) IVDR and corresponding provisions in the Annexes (e.g. Annex VII 4.11) by legislative change to MDR		Mid term
20.	Elimination of an annual certificate usage /maintenance fee.	MDCG guidance 2023-2 NB practice	MDCG 2023-2 includes a list of standard fees for "**conformity assessment activities**". It is not justifiable why notified bodies are able to charge an (internal) annual "maintenance fee" that is not part of conformity assessment activities	MDCG 2023-2 in regard an annual maintenance fee goes beyond MDR and needs to be eliminated.	Change of existing MDCG guidance	Adapt MDCG 2023-2. Eliminate "Annual certificate maintenance fee" as it is not justified.	Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
			rendered to a manufacturer. It is completely unclear and not explained (contrary to what it says in the guidance) what particular "activity" would justify another annual fee for "maintenance". As part of the surveillance obligations, notified bodies conduct audits on at least an annual basis. These activities are already subject to fees charged, as well as any other service in relation to the conformity assessment activities (e.g. changes, issuance of certificate etc.) It is not plausible at all that a company should pay continuously for the *use* of a certificate when the one-off service– i.e. the issuing of the certificate – has long since taken place and has already been paid for.				
21.	Harmonized content of a certificate across the EU	Diverging NB practices	Currently, no standard templates for certificates exist. The current different interpretations of the notified bodies are causing confusion among authorities outside the EU.	It would be beneficial to specify the content and design of the certificates in order to harmonize this across the EU and make communication with authorities outside EU easier.	Standard template for certificates		Short term

4. Adapt procedures for and content of some MDCG guidance documents

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
22.	MDCG rules of procedure / guidance development	Various stakeholder e.g. MDCG / NBCG med / CAMD Guidance or other interpretation of MDR legal text	The MDCG functions as a de facto rule maker without formal attribution of competence and without transparent procedural rules for stakeholder participation and decision making / voting. Many of the MDCG guidance documents contain new implementing rules rather than guidance for existing rules. Member States require notified bodies to apply MDCG guidance as if it were mandatory requirements. Also, the MDCG guidance documents regularly contain legal mistakes or are inconsistent / incoherent with EU requirements in mandatory law. Finally, MDCG guidance is applied inconsistently between Member States, such as MDCG 2022-5.	The MDCG should <u>contribute</u> to guidance development as foreseen in article 105 (c) MDR and not be finally responsible for the development of guidance. It is problematic that its procedural rules are not transparent and insufficient. Interpretation of the law is Commission prerogative, which means that the Commission should own the drafting process of guidance and provide quality control regarding consistency and coherence of (draft) guidance with EU law, e.g. via its Legal Service. This means that the Commission is owner of the drafting process and uses its legal service for ensuring	• Correct application of Article 105 (c) MDR – no specific change of legislation needed.	Adapt MDCG Rules of Procedure. Correct Point 1 (3) to reflect actual responsibility of DG Health. Include rules regarding the development of Guidance documents and clarify that in accordance with Article 105 (c) MDR the MDCG and its working groups contribute to the development of guidance by the Commission. To this end the MDCG may provide proposals to the Commission for guidance proposed to	Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
			Furthermore, existing rules of procedure are outdated. Point 1 (3) of the MDCG's Rules of Procedure still provides that "The MDCG shall be chaired by a representative of DG Internal Market, Industry, Entrepreneurship and SMEs."	guidance quality, consistency and coherence. The Commission is responsible for stakeholder feedback as per Better Regulation requirements.	• Amendment of MDCG rules of procedure to reflect the actual responsibility of DG Health and to include an article on guidance development	be adopted by the Commission, which the services of the Commission may evaluate with respect to quality and consistency with other Regulation (EU) 2017/745, Regulation (EU) 2017/746 or EU requirements, amend and subsequently adopt or not. Additionally, reform the procedure in regard to consistent stakeholder consultations and voting.	Short term

5. Further measures to facilitate the MDR / IVDR implementation

a. Digitisation/Digitalization

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
23.	Implant card | Provision digitally	Guidance or other interpretation of MDR legal text Lack of optimisation (considering the state of the art)	Digital provision of the implant card would allow meeting the requirements in article 18 (1) and (2) MDR better. • This ensures that the implant card data in article 18 (1) are always available to the patient "by any means that allow rapid access to that information" and possibly others (e.g. HCPs) regardless of whether the patient is in possession of the physical implant card. • It makes the link between implant card and implanted devices more direct. Health institutions no longer need to match the device and the implant card information physically. • It also manages the risks related to the filling in of the physical implant card by the HCP (see section 7 of MDCG 2019-8 Rev 2). The HCP can be assisted by electronic means or the digital implant card can automatically	Article 18 MDR states that the implant card must be 'provided' but does not exclude that this happens via electronic means. In fact, article 18 (1) states that it can be provided "by any means that allow rapid access to that information". There is experience with provision of e-Labelling information at EU level with respect to clinical trial medicines, which would be a useful template.[7]	Change MDCG 2019-8 Rev 2 (and possibly MDCG 2021-11) to explicitly clarify that the implant card can be provided by digital means as well. MDCG 2019-8 Rev 2 states that "Ways could be explored by relevant stakeholders to develop common rules on how the necessary information to be placed on the System IC is delivered with the replaceable component and how health professionals could ensure that the System IC is appropriately updated, when necessary." This and other ways to harmonise the technical format of the digital implant card[8] could be addressed in a revised version of the MDCG guidance after stakeholder consultation.		Short term

[7] https://circulardigitalhealth.eu

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
			be populated from the patient's HER, thus eliminating risks. • Electronic implant cards can accommodate for the situations of revisions of (components of) implantable devices (see MDCG 2019-8 Rev 2 section 8) by updating the electronic implant card. • Electronic implant cards are more durable and issues with information wearing (as can be the case with handwritten implant cards) can be avoided. Electronic implant cards can be provided in a format that can reside in or be linked to the patient's EHR.				
24.	e-Labelling	MDR requirement	e-Labelling can take place by means of a data matrix that gives access to a web page with all elements required under Annex I 23.2 MDR. In addition, the following information from Annex 23.2 MDR should appear on the label:	There is experience with provision of e-Labelling information at EU level with respect to clinical trial medicines, which would be a useful template.[9]	**[option 1]** Article 5 (6) MDR: Commission to adopt **implementing acts** regarding Annex I MDR for practical application.		Short term

[9] https://circulardigitalhealth.eu

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
			(a) the name or trade name of the device; (g) the lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an equivalent symbol, as appropriate; (h) the UDI carrier referred to in Article 27(4) and Part C of Annex VII;		**[option 2]** Article 9 (1) MDR: Commission to adopt **CS regarding GSPR**s in Annex I chapter III MDR by implementing act		Short term
25.	eIFU	MDR requirement Lack of optimisation (considering the state of the art)	The risks managed in Implementing Regulation (EU) 2021/2226 are no longer current, and therefore redundant. In addition, the use of eIFUs can lead to significant reduction of the use of paper and reduction in CO2 as a result of weight / size reduction.	Implementing Regulation (EU) 2021/2226 has been caught up by reality as the risks that it purports to manage regarding availability of internet for professional and lay users are no longer state of art. These risks have not been amended since Regulation (EU) 207/2012, while availability of internet and robustness of internet connections have developed	Repeal / adapt Implementing Regulation 2021/2226 and address eIFU aspects in Annex I 23.1 and 22 MDR (as regards lay user specific requirements).	The possibility to provide IFU in electronic form applies to all medical devices and accessories. Users should always have the possibility to obtain those instructions for use in paper form upon request.	Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
				enormously since then. Experiences with other jurisdictions that allow eIFU have confirmed this. The US, for example, allows for eIFU for all medical devices, regardless of professional or lay use. Finally, eIFU would allow for the medical devices to meet obligations under the Accessibility of Products and Services Directive.[10] This directive also has medical devices in scope and imposes, among other requirements, accessibility - requirements that conflict directly with MDR IFU requirements, such as that Information on the use of the product must[11] (i) be made available via more than one sensory channel, while the MDR explicitly limits the availability of the IFU to one sensory channel (writing on paper), (ii) presented to users in ways they can perceive (which is not	[**option 1**] Article 5 (6) MDR: Commission may adopt implementing acts regarding Annex I for practical application		Short term
					[**option 2**] Article 9 (1) MDR: Commission may adopt CS regarding Annex I chapter III by implementing act.		Short term

[10] DIRECTIVE (EU) 2019/882 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 April 2019 on the accessibility requirements for products and services

[11] DIRECTIVE (EU) 2019/882 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 April 2019 on the accessibility requirements for products and services, Annex II section 1 sub 1 (a).

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
				possible under the MDR for users that cannot perceive information in a standard paper IFU, e.g. because they are blind) and (iii) be presented in fonts of adequate size and suitable shape, taking into account foreseeable conditions of use, and using sufficient contrast, as well as adjustable spacing between letters, lines and paragraphs (which is not possible under the MDR because a paper IFU cannot accommodate this requirement).	[**option 3**] Amend MDR text for Annex I sections 22 and 23.1		Mid term
26.	e-Signatures	Notified Body practice Lack of optimisation (considering the state of the art)	Not all notified bodies accept digital signatures as a valid document control measure, with is contrary to the e-IDAS regulation[12] (article 25[13]). Notified bodies may not refuse an electronic signature only because it is electronic. This is also linked to the lack of harmonisation of technical	QMS standards require the control of documents (ISO 13485:2016 sections 4.2.4 and 4.2.5). Electronic signature solutions provide a means to authenticate users and protect documents. A so-called advanced electronic signature in the meaning of article 3 (11)	• Simple application of e-IDAS regulation articles 25 and 26[14] Member States to instruct notified bodies not to refuse electronic signatures contrary to article 25 e-IDAS		Short term

[12] REGULATION (EU) No 910/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC

[13] "An electronic signature shall not be denied legal effect and admissibility as evidence in legal proceedings solely on the grounds that it is in an electronic form or that it does not meet the requirements for qualified electronic signatures."

[14] REGULATION (EU) No 910/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
			documentation format (see further above).	and 26 e-IDAS Regulation meets these criteria as it: (a) it is uniquely linked to the signatory; (b) it is capable of identifying the signatory; (c) it is created using electronic signature creation data that the signatory can, with a high level of confidence, use under his sole control; and (d) it is linked to the data signed therewith in such a way that any subsequent change in the data is detectable.	• Furthermore, option to include e-signature specification in harmonised TD structure (see further above). • Member States to instruct notified bodies not to refuse electronic signatures contrary to article 25 e-IDAS.		

b. Classification

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
27.	Classification of single use surgical instruments and Up-Classification of reusable surgical instruments in class III	MDR requirement Competent Authority practice MDCG guidance	**1. Classification of single use surgical instruments** According to the rule 6 of the MDR, all surgically invasive devices intended for transient use are classified as class IIa unless they are reusable surgical instruments, in which case they are classified as class I. The guidance on classification (MDCG 2021-24) lists examples for surgically invasive devices according to rule 6. While "Single use scalpels" are class IIa, the "scalpels" are class I if they are reusable. As a consequence, a surgical instrument which is supplied sterile and is intended for single use is classified in a higher risk class (IIa) than the same device which is labelled as reusable (class I) and thus must be cleaned, disinfected and sterilized by the user before the first use and each subsequent use. This differentiation is not comprehensible and even	The solution is to classify all surgical instruments for transient use in the same risk class, being class Ir.	• Option 1: Implementing act on the basis of Art. 51 (4) MDR	• Implementing act clarifying that all surgical instruments for transient use are classified as class 1r	Short term
					• Option 2: Revision of rule 6, 2nd indent by means of legislative change to MDR text or by means of corrigendum (given the contradiction between single use and reusable surgical instruments.	• A corrigendum can be used given the contradiction between single use and reusable surgical instruments. Corrigenda have been used before to amend the MDR (translational regime).	Short term
					• Corresponding revision of MDCG 2021-24 regarding rule 6.	• Revision of rule 6, 2nd indent: "All surgically invasive devices intended for transient use are classified as class IIa unless they … are reusable or single-use surgical instruments, in which case they are classified as class I."	Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
			contradictory. The reuse of a device requires further processing by the user and bears a higher risk than a device which is already supplied sterile and for single use only. **2. Classification rule 6 of reusable surgical instruments (Annex VIII, 5.2)** According to the rule 6 of the MDR, all surgically invasive devices intended for transient use are classified as class IIa unless they are - intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class III; - are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class III.”	The solution is to classify all surgical instruments for transient use in the same risk class, being class Ir.	• Amend article 52 (7) MDR to bring single use surgical instruments also under Ir conformity assessment procedure. • Option 1: Implementing act on the basis of Art. 51 (4) and (5) MDR • Amend article 52 (7) MDR to bring reusable surgical instruments also under Ir conformity assessment procedure.	• Amend article 52 (7) MDR: “are reusable or single use surgical instruments”. • Implementing act clarifying that all surgical instruments for transient use are classified as class 1r, or that the indents mentioned in Rule 6 do not apply in principle to reusable surgical instruments	Mid term Short term Mid term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
28.	Relationship between timeframe for transient use and classification of surgical devices	MDR Requirement EN ISO 10093	Surgical Devices (including surgical instruments and independently of reusability or invasiveness) are classified according to Rule 6 (transient use, up to 60 min.) or according to Rule 7 (short term use, up to 30 days) depending on the intended duration of continuous use. This incentivises the manufacturer to set the intended use-time to 59 min. especially for reusable surgical instruments, which may be classified as a class I device under indent 2 in Rule 6. While no such indent exists under Rule 7. For real applications, especially in the case of unforeseen complications and prolonged intervention times in the OR, it is not practical to track the duration of use for e.g. scissors or optics. Furthermore, removing surgical devices during an operation due to the legal threshold of application time could pose a risk to patients. This is further exacerbated by the fact that in connection to Annex VII Chapter II 3.6. the calculation of continuous application time may vastly exceed the actual use-time of the devices.	The narrow time-window for transient use may lead to increased risk for patients due to potentially unforeseen legal requirements, to replace a surgical device during a procedure. In accordance with EN ISO 10093 products subject to rule 6 undergo an evaluation including 24 hours of application ensuring biocompatibility, the major risk factor associated with extended use in this context.	Option 1: Implementing act on the basis of Art. 51 (4) MDR	Option 1: Adaptation of rule 7 for additional integration of second indent of rule 6 (to be seen in combination with proposal No. 27). OR Option 2: Revision of the Definition of transient use (Annex VIII, chapter I, 1.1). Adapting the timeframe from 60 min. to 24 h. This would be in line with EN ISO 10993 *"Limited exposure (A) – medical devices whose cumulative sum of single, multiple or repeated duration of contact is up to 24 h."*	Short Term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
29.	Classification of accessories to active implants in class III (Annex VIII, rule 8)	MDR requirement Competent Authority practice MDCG guidance	Classification of accessories to active implantable devices in class III leads to a severe increase in administrative burden for the devices compared to the situation where the normal classification logic is followed. For example, devices that would normally by in class I (e.g. torque wrench for pacemaker) are in class III without any safety or performance advantage.	The increase in administrative burden for the accessories goes against the classification logic laid down in the implementation rule 3.2 of Annex VIII[15] and is an illogical exception to essential classification that is a regulatory artifact from the fact that the AIMDD did not contain a separate concept of accessory, contrary to its later and more evolved successor for medical devices, the MDD. The up-classification and departure from classification logic for this category of devices is not supported by management of risk or increase of safety, since many of these devices, when classified in their own right, would be class I or IIa devices.	[**option 1**] Change MDCG 2021-24 to clarify that accessories to active implants are subject to the implementing rule 3.2 in Annex VIII and therefore classified in their own right.	A corrigendum can be used to exclude accessories from rule 8. Corrigenda have been used before to amend the MDR (translational regime).	Short term
					[**option 2**] Change text of Annex VIII, rule 8, 6th indent to exclude accessories and change MDCG 2021-24 guidance by means of corrigendum		Mid term
					[**option 3**] by means of implementing act based on Article 51 (4) MDR		Short term
30.	Clarification of classification rule 8 for dental products	MDR requirement MDCG Guidance NB practice	In rule 8 is stated that implantable devices and long term surgically invasive devices are classified as class IIb unless they: - Are intended to be placed in the teeth, in which case they are classified in class IIa		Amendment of the Classification Guidance MDCG 2021-24 to ensure correct classification and harmonisation.		Short term

[15] "Accessories for a medical device shall be classified in their own right ◄ separately from the device with which they are used."

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
			In practice, however, NBs interpret rule 8 in the way that dental products are classified in higher risk classes according to the following intends of rule 8. This is contradicting the risk-based approach and leads to incorrect classification.				
31.	Classification of software (Annex VIII, rule 11)	MDR requirement Notified Body practice Competent Authority practice MDCG guidance	In practice competent authorities and notified bodies assume that all software in scope of the MDR is class IIa or higher and that class I classification in rule 11 is only available to very specific cases of devices (fertility apps). Yet, by the wording of rule 11 it applies only to devices that are "intended to provide information which is used to take decisions with diagnosis or therapeutic purposes" or are "intended to monitor physiological processes". All other software would be class I according to the text of the classification rule.	Notified bodies and competent authorities feel unable to consider nuanced argumentation that supports that a software device can be in scope of the MDR and yet not intended to be used to take decisions with diagnosis or therapeutic purposes. This is the case for accessories (which do not have a medical intended purpose of their own) in the meaning of article 2 (2) MDR and for medical devices in scope of the definition of medical device in Article 2 (1) MDR but with a different intended purpose than to be used to take decisions with diagnosis or therapeutic purposes, e.g. (artificially intelligent) software that controls an exoskeleton for patients with disability. Such software is not intended for diagnostic or therapeutic	• Clarify element in rule 11 "used to take decisions with diagnosis or therapeutic purposes" in MDCG guidance MDCG 2021-24 under heading "General explanation of the rule" in light of the elements of the definition of medical device such as prevention, alleviation, compensation for, an injury or disability and replacement or modification of the anatomy or of a physiological or pathological process or state; which do not concern provision of information for taking decisions with diagnosis or therapeutic purposes		Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
				purposes but rather for alleviation of a disability. This would concern software with intended purposes of prevention, alleviation, compensation for, an injury or disability and replacement or modification of the anatomy or of a physiological or pathological process or state, which will for example comprise (artificially intelligent) software for assisted living and companionship of persons with a degenerative mental disease.	• clarification that all accessories in the meaning of Article 2 (2) MDR are not "intended to provide information which is used to take decisions with diagnosis or therapeutic purpose" or are "intended to monitor physiological processes" in the meaning of rule 11.		
32.	Amendment to classification rule 14	MDR requirement	Many dental filling materials contain such substances and would have to be classified as class III. This would require a disproportionate amount of resources for both manufacturers and notified bodies and is in no way justifiable with regard to relatively low-risk products.	According to Recital (59) of the MDR the objective is to obtain a suitable risk-based classification of devices. This should also be the case for products falling under Rule 14. The classification rule should take into account if the medicinal substance has an impact on the intended purpose of the device. If this is not the case, then it is not justifiable to classify those products under the highest risk class.	**Option 1:** by implementing act via Article 51 (4) MDR **Option 2**: Amendment to Annex VIII Rule 14 MDR "All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as defined in point	Clarify that Rule 14 only applies is the medicinal substance has an impact on the intended purpose of the medical device. If this is not the case, the medical device should not be classified under class III according to Rule 14.	Short term Mid term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
					10 of Article 1 of that Directive, and that has an action ancillary to that of the devices and where such substance has an impact on the intended purpose of the device, are classified as class III		
33.	Amendment to classification rule 19	MDR requirement	The European Parliament had already reduced the up-classification to Class III only when the use of nanomaterials is intentional and part of the intended use of the product (amendments 2 and 304), In its justification, the Parliament stated that "many medical devices contain nanomaterials, but do not pose any danger to the patient."	The risk of the use of nanomaterials shall be taken into account in the risk assessment process. However, too many products with no serious concern for health may fall under this rule. Some of these products have been distributed without incidents for years.	**Option 1**: by implementing act based on article 51 (4) MDR **Option 2**: Amendment to Annex VIII Rule 19 MDR as follows: "Rule 19 All devices incorporating or consisting of nanomaterial are classified as: — class IIb if they present a high or medium potential for internal exposure; — class IIa if they present a low potential for internal exposure; and — class I if they present a negligible potential for internal exposure."		Short term Mid term
34.	Classification rules according annex VIII Article 1.10 IVDR .	IVDR requirement	Each of the classification rules shall apply to first line assays, confirmatory assays and supplemental assays.	The risk for the patient should be reflected in the classification of the device.	Update and define in MDCG guideline 2020-16 lower risk classes for additional / suppl. Assays,		Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
			IVD for a direct/final detection and direct diagnosis have a higher risk. IVDs where additional tests (e.g. several parameters are needed) are necessary for a final diagnosis have lower risk.		should be classified in their own.		
35.	Classification of class B devices IVDR | Self-assessment	IVDR requirement	IVDR: self-certification of low-risk products (class B) to reduce the burden on the system and eliminate bureaucratic reports with no patient benefit	For the IVDR the policy choice was made to enormously increase the devices under the requirement for notified body conformity assessment where these devices were subject to self-assessment under the IVDD: 736%. This policy decision has not been motivated by safety or performance issues with IVDs under the IVDR and does not serve a purpose of increasing patient safety or test performance. As a result, the conformity assessment system under the IVDR is congested with a large amount of low risk (class B) devices that used to be subject to self-assessment, but for which notified body capacity under the IVDR is scarce and of which the added value of notified body conformity assessment is questionable. This creates an enormous extra cost to the healthcare system that is not justified by any benefits in terms of increased	Amendment of Article 48 (9) IVDR as follows: 9. Manufacturers of class B devices, other than devices for performance study, shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, ~~and including an assessment of the technical documentation as specified in Sections 4.4 to 4.8 of that Annex for at least one representative device~~ per category of devices. In addition to the procedures referred to in the first subparagraph, for devices for self-testing ~~and near-patient~~ testing, the manufacturer shall follow the procedure for assessment of the technical documentation set out in Section 5.1 of Annex IX.		Mid term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
				performance or safety of tests. The Impact Assessment for the IVDR stated that adoption of the GHTF classification structure for IVDs would necessarily mean conformity assessment for class B devices by a notified body. This does however not follow as a necessary option from GHTF recommendations for IVD conformity assessment, as these also allow for competent authority ex-post supervision on this point as an alternative to notified body assessment. Accordingly, this has been an EU policy choice, which may be revisited. There is all the more reason to revisit this choice and calibrate its consequences, because the expected benefits of the implementation of the GHTF risk classes have not led to the benefits justifying this policy choice that were expected in the Impact Assessment. The Impact Assessment predicted a significant increase in costs for manufacturers (which indeed took place) but justified these based on "enhanced robustness of the classification system, as well as international	Amendment of Annex IX, Chapter II: Delete class B and Chapter 5 delete class B and near patient test. Removing class B devices from the requirement of notified body conformity assessment pursuant to article 48 (9) IVDR would create much needed relief of congestion in the conformity assessment process and unnecessary costly formalities for class B devices. This was also originally foreseen in the IVDR proposal in article 40 (4). The requirement of sampling of technical documentation in article 48 (9) IVDR was added later. Removing the sampling requirement would free up the resources to allow both manufacturers and the few available notified bodies to concentrate on conformity assessment of more complex and/or higher risk devices for which where notified body conformity assessment has added value from a performance and		

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
				harmonisation". So far the advantages that underly this policy choice have not materialized and industry does not expect them to materialise without recalibration of the IVDR's certification process.	safety perspective: the class C and D devices.		

c. Gold plating and overlapping legislation

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
36.	Change of language requirements concerning devices intended for healthcare professional	MDR requirement	According to Art. 10 (11) MDR, manufacturers shall ensure that the device is accompanied by the information set out in Section 23 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient. This Article does not differentiate between lay persons and healthcare professionals. English is a commonly understood language for health care professional. Therefore, the information set out in Section 23 of Annex I should be provided in English if the device is intended for healthcare professionals.		Amendment to Art. 10 (11) MDR: Manufacturers shall ensure that the device is accompanied by the information set out in Section 23 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient. For devices made available to healthcare professionals, the device is accompanied by the information set out in Section 23 of Annex I in English. The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient.		Mid term
37.	National Databases | Notification of economic operators and devices	National gold-plating	As a result of the delay in Eudamed becoming available on a mandatory basis certain Member States require national notification of devices in diverging local databases. This leads to a significant administrative burden on manufacturers	Eudamed should become applicable as soon as possible for the finished modules. Member States should be made clear that they can no longer require national notification. Eudamed compliance must be made possible to the exclusion of national requirements.	Amend article 123 (3) (e) MDR.A manufacturer that has entered the data in the voluntary modules of Eudamed this excludes national requirements and that this also triggers drag along of the NB and other requirements (SSCP and	Add to article 123 (3) (e) MDR "Member States shall not impose any additional notification or registration obligations for devices for which manufacturers have entered the	Short term in practical implementation by MS

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
					PSUR) under article 123 (3) (ea) – (ec) MDR.	information to be entered in Eudamed in accordance with Article 29 into the relevant Eudamed module(s) available before publication of the notice referred to in Article 34(3)":	mid term by legal changes
38.	National rules and regulations	MDR/IVDR provisions	Review of the opening clauses for the Member States for their necessity and effectiveness	The final sentence of the MDR is "This Regulation shall be binding in its entirety and directly applicable in all Member States." Recital (1) defines the key objectives of the MDR: to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation. However, each Member State has specific national regulations that apply in addition to the MDR. The MDR itself provides for such national opening clauses, allowing national legislators to make independent regulations. However, a relatively large number of opening clauses means that in practice – contrary to a uniform	• All opening clauses of the MDR that allow national supplementary or implementing regulations or delegate them to Member States must be critically evaluated for their necessity and effectiveness. • The possibility of national supplementary regulations must be reduced to an absolute mini-mum and should no longer be permitted in the area of substantive regulations relating to securing the marketability of medical devices on the Union market (including clinical trial legislation). • Where possible, the Medical Device Regulation must constitute an exhaustive regulation for		Short term in practical implementation by MS mid term by legal changes

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
				application of the EU medical device legislation – numerous national peculiarities exist. These national regulations are certainly necessary and useful as far as questions of the jurisdiction of the authorities or penalties pursuant to Article 113 MDR are concerned, which must be adapted to national rules on penalties. However, any additional substantive national regulations that prevent the uniform implementation of the medical device legislation within the Member States must be rejected. Examples include the additional registration of distributors under national law (Article 30(2) MDR), other double registrations in national databases, a sometimes completely different understanding of the term "custom-made devices" or the regulation of other clinical trials, which is largely left to national law (Article 82 MDR) as well as other possibilities for national procedural provisions under the clinical trial legislation. The more national regulatory leeway there is with regard to	medical devices within the EU. • To the extent that national supplementary law is essential (for example, to regulate the responsible authorities in the respective Member States), all national regulations must be made available centrally in order to be binding, at least in an English translation, so that economic operators, users, and other authorities are able to understand these national regulations and, if necessary, implement them. • The contra legem application of special national regulations and administrative practices in the Member States, despite the primacy of EU law, must be monitored and sanctioned much more strictly. To this end, effective mechanisms must be created, for example, at the level of the Medical Devices Coordination Group (MDCG).		

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
				formal and material requirements for medical devices, the greater the resource and cost expenditure for manufacturers and other economic operators to research and implement special national regulations within the EU, provided that these regulations can be determined with any legal certainty in the very different national systems and in view of language barriers. The more national regulations there are, the greater the risk – which has been confirmed time and again in practice in recent years – that national legislators and authorities will issue, interpret, and apply regulations in clear contradiction to the overriding legislation of the MDR. This poses an immediate threat to the smooth functioning of the internal market (Recital (2), Sentence 1 MDR).			
39.	Overlapping <u>substantive</u> requirements with other (horizontal) EU regulation	MDR requirement	MDR lacks a clear hierarchy provision for horizontal legislation. Multiple regulations can apply that impose different, overlapping or contradictory essential requirements. The EU's Blue Guide states that "Two or	A hierarchy clause regarding essential requirements should be included in article 1 MDR, and it should be broad enough to cover all overlaps between MDR and horizontal regulation	Adopt a hierarchy provision based on the model for overlap other legislations e.g. with the Machinery Regulation.	As an example: Amend article 1 (12) MDR: "Devices that are also ~~machinery~~ a regulated product in scope of other Union product	Mid term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
			more Union harmonisation acts can cover the same product, hazard or impact. In such a case, the issue of overlap might be resolved by giving preference to the more specific Union harmonisation act."[16] While there are some provisions for this purpose in the MDR with respect to electric magnetic compatibility (EMC) and Machinery, other product regulations are not addressed, nor does the MDR contain a mechanism for applying the Blue Guide logic that the more specific regulation applies (or to determine which one is the more specific regulation).	that also applies to medical devices.		regulation ~~within the meaning of point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (~~[2]~~)~~ shall, where a hazard relevant under that Regulation or Directive exists, also meet the essential ~~health and safety~~ requirements set out in the relevant Annex I to that Regulation or Directive to the extent to which those requirements are more specific than the general safety and performance requirements set out in this Regulation.	
40.	Overlapping specific requirements with other EU product regulation	MDR/IVDR requirement	MDR/IVDR lacks a clear hierarchy provision for horizontal legislation. The EU's Blue Guide states that "Two or more Union harmonisation acts can cover the same product, hazard or impact.	The Commission should be able to determine by delegated act whether an overlapping regulation is more specific than the MDR and for what specific	Adopt a mechanism for the Commission to establish hierarchy in specific cases.	The following Article 1 (17) (a) is inserted: "The Commission is empowered to adopt delegated acts in	Mid term

[16] Blue Guide 2022, section 2.7

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
			In such a case, the issue of overlap might be resolved by giving preference to the more specific Union harmonisation act."[17] While there are some provisions for this purpose in the MDR/IVDR with respect to electric magnetic compatibility (EMC) and Machinery, other product regulations are not addressed, nor does the MDR contain a mechanism for applying the Blue Guide logic that the more specific regulation applies (or to determine which one is the more specific regulation).	requirements it should apply to a device in scope		accordance with Article 115 in order to amend Article 1 to determine hierarchy of specific requirements pursuant this Regulation in relation overlapping or conflicting requirements in other Union legislation."	
41.	Overlapping requirements between MDR/IVDR and AI Act	MDR/IVDR requirement	MDR/IVDR lacks a clear hierarchy provision for horizontal legislation, also as regards procedural requirements that double requirements under the MDR. For example, Post Market Monitoring (PMM) under AI Act and PMS under the MDR overlap.	As an example: The AI Act and the MDR/IVDR have overlapping PMS systems. The AI Act gives providers of an AI system the "choice of integrating, as appropriate, the necessary elements described in paragraphs 1, 2 and 3 using the template referred in paragraph 3 into systems and plans already existing under that legislation, provided that it achieves an equivalent level of protection". Paragraph 3 provides that the Commission shall adopt an implementing act	AI Office, AI Board, Advisory Forum, Commission, MDCG, and working groups to consult and work together in all aspects related to issues due to overlapping requirements in MDR and AIA. In regard to the example provided: The development of the PMM template in article 72 (3) AI Act must ensure that it is fully consistent with already existing MDR	Set up transparent procedures between AI Office, Commission, AI Board and MDCG (including responsible working groups) that ensure collaboration, coordination and appropriate decision making to achieve coherence.	Short term

[17] Blue Guide 2022, section 2.7

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
				laying down detailed provisions establishing a template for the post-market monitoring plan and the list of elements to be included in the plan by 2 February 2026. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 98(2). Given that PMS objectives and logic are well defined in the MDR but not yet in the AI Act, inconsistencies are likely the result. This template will likely not be consistent with the PMS standards under the MDR and cause problems in the implementation because the AI Act uses defined concepts relating to PMM that are different from defined MDR concepts for PMS, such as the definition of serious incident.	requirements/templates and does not impose any other burden than monitoring the compliance with the requirements in Chapter III section 2 AI Act (articles 8-15)		
42.	Divergent definitions of substantial change under MDR/IVDR (not defined) and definition of 'substantial	MDR requirement	A medical device may also be an AI system and a substantial change to the device may or may not be a substantial modification under the AI Act. Substantial modification is defined in the AI Act. Difference in definitions would lead to the situation that a change to an AI System that is also a medical device or IVD may				Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
	modification' in AI Act (article 3 (23)".[18]		need to be notified under both MDR/IVDR and AI Act or under either and under separate criteria, which makes necessitates two QMS-es for one product.				

[18] "'substantial modification' means a change to an AI system after its placing on the market or putting into service which is not foreseen or planned in the initial conformity assessment carried out by the provider and as a result of which the compliance of the AI system with the requirements set out in Chapter III, Section 2 is affected or results in a modification to the intended purpose for which the AI system has been assessed"

d. Other

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
43.	Substantial changes **to QMS** / Definition / process (Annex VII 4.9, Annex IX, 2.4)	Divergent notified body practice	The MDR/IVDR requires planned **substantial** changes to the quality management system, or the device-range covered to be notified to the notified body so the notified body can evaluate if the proposed substantial change requires additional audits. The issue is that the concept of substantial change is not defined in the MDR, leading notified bodies to require manufacturers to notify them of *any change* (each using their own different change notification process and forms), after which the notified body takes time and fees to evaluate if the change is substantial. causing administrative delays and extra costs for manufacturers. Currently, there are significant delays in assessing substantial changes to the QMS making it nearly impossible for manufacturers to plan. Additionally, timelines for assessment of substantial changes differ greatly between NB.	Notified bodies are unable to come to a clearly delimitated and harmonised scope of the concept of substantial change, in other words what constitutes a substantial change to the quality management system, or the device-range covered and to provide a harmonized notification template. Since this has already been defined once in NBOG BPG 2014-3, the MDCG can update this guidance to current state of art. As regards batch notification there is nothing in the MDR that prevents batch notification. The MDCG has provided in MDCG- 2019-6 Rev. 4 Question IV.9 that "With regard to [substantial changes], the CAB needs to make clear in its communication to the manufacturer (e.g. in the terms and conditions) what it considers as "substantial changes" to the quality management system or the device-range covered. In order to fully comply with all the relevant requirements, the CAB must have documented procedures defining how	Implementing act pursuant to article 36 (3) MDR to address the challenges in regard to change notifications by providing mandatory detail in Annex VII section 4.9, last sentence about what the notified body specifically have in terms of procedures and what these procedures look like.	The implementing act pursuant to article 36 (3) MDR and in regard to change notification should amend Annex VII section 4.9 in the following respects: : • Provide for a definition and common understanding of what constitutes a "substantial change" that needs to be notified by the manufacturer (COM can build on already existing NBOG BPG 2014-3 and should also take into account developments in other applicable legislation such as the AIA that addresses "substantial modifications") • Clarify that manufacturers evaluate changes in accordance with	Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
			Another problem is that there is no process for 'batch' notification.	different changes need to be notified and assessed prior to their implementation and how the assessment will be documented." The root cause of the problem is that although the MDCG has made it clear that notified bodies can be practical on this point they are not in practice. Since notified bodies are not able to harmonise this, an implementing act to address these issues is necessary. It should be possible to use a Predetermined Change Control Process (PCCP) by analogy to the AI Act (Pre-determined change control plan (article 43 (5) AI Act) as well as obtain batch approval for – foreseen changes.		their audited QMS procedures • Clarify that non-substantial changes neither need notification nor approval • Determine a maximum duration for the NB to assess the notified substantial changes as well as further measures. • Incorporate a provision that allows manufacturers procedure to determine if a notified change is substantial, e.g. 30 days plus the right of the manufacturer to implement the change as non-substantial if the notified body does not decide within the given time frame (e.g. 30 days); • Clarify the procedure to evaluate a substantial change;	

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
						• Explicitly include that the NB must have a process to accept both single and batch notifications for substantial changes. • Include a provision for planned changes in surveillance audits and permit a predetermined change control process (PCCP).	
44.	Substantial changes **to devices** / Definition / process (Annex VII 4.9, Annex IX, 4.10)	Divergent notified body practice	Annex IX 4.10 MDR requires that changes to an approved device shall require approval from the notified body which issued the EU technical documentation assessment certificate ***"where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device."*** Only such changes may be considered "substantial". The issue is that substantial changes in this regard are not defined in the MDR, leading notified bodies to require manufacturers to notify them of *any change* (each using their own different change notification process and forms),	Notified bodies do not have a clear understanding of what changes to the device are substantial and require approval. There is no harmonized template and approach which leads to diverging practices. Since NB must have documented procedures defining how different changes need to be notified and assessed prior to their implementation, how the assessment is documented, these decisions have direct impact on manufacturers, and previous calls of the MDCG for "practical implementation" are	**Implementing act pursuant to article 36 (3) MDR to address the challenges in regard to change notifications.**	The implementing act pursuant to article 36 (3) MDR and regarding change notification should contain the following aspects: • Provide for a definition and common understanding of what constitutes a "substantial change" in regard to devices that needs to be notified by the manufacturer (also take into account developments in other applicable legislation such as	Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
			It is essential to understand, that Annex IX 4.10 requires notification **and approval by a NB** of substantial changes (changes that affect safety and performance of the device or the conditions prescribed for use of the device). if the manufacturer plans to introduce such changes. Currently, there are no timelines for NB to assess changes, which, in practice, leads to significant delays of such assessments. This uncertainty and these delays are inacceptable as they make it nearly impossible for manufacturers to plan. Moreover, delays have a direct and very negative impact on manufacturers that have no market access for the impacted product without approval of the NB. Additionally, timelines differ greatly between the NB for the assessment, if the changes require a new conformity assessment or if the changes can be addressed by means of a supplement to the technical documentation assessment certificate.	not resonating, an implementing act to address these issues is necessary.		the AIA that addresses "substantial modifications") • Clarify that manufacturers evaluate changes in accordance with their audited QMS procedures • Clarify that non-substantial changes neither need notification nor approval • Determine a maximum duration for the NB to assess the notified substantial changes and further measures. • Incorporate a provision that allows manufacturers to implement the change if the notified body does not decide within the given time frame (e.g. 30 days); • Clarify the procedure to	

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
			Another problem is that there is no process for 'batch' notification.			evaluate a substantial change; • Explicitly include that the NB must have a process to accept both single and batch notifications for substantial changes. • Include a provision for planned changes in surveillance audits and permit a predetermined change control process (PCCP).	
45.	PSUR and PMS report frequency	MDR/IVDR requirement	Pursuant to article 86 (1) MDR/article 81 (1) IVDR Manufacturers of class IIb and class III/ class C and D devices shall update the PSUR at least annually and class IIa/C devices at least every two years. This applies to both MDR devices and legacy devices and regardless of any developments that would have importance in the manufacturers PMS system.	This requirement should be changed to updates only when there is a relevant change to report (see also under point SSCP frequency (yearly update) Explanation in relation to PMS and PMCF regarding KRIs).	<u>Periodicity</u> • Amendment to Article 86/81 (1) 2nd and 3rd paragraphs to report only in case of significant changes in the conclusions of the benefit-risk determination or in the main findings of the PMCF/PMPF compared to the date of the initial CE certificate for the device concerned or compared to the last PSUR update.	• Amend article 86/81 (1) 2nd paragraph by deleting "at least annually" and replace this by "in case significant changes in the conclusions of the benefit-risk determination or in the main findings of the PMCF compared to the date of the initial CE certificate for the device concerned or compared to the last PSUR update"	Mid term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
					Key Risk Indicators Adopt CS based on article 9 (1) to amend PMCF in Annex XIV to define KRIs for PMCF that would trigger need for PSUR update.	Amend article 86/81 (1) 3rd paragraph by deleting "necessary and at least every two years" and replacing this by "significant changes in the conclusions of the benefit-risk determination or in the main findings of the PMCF compared to the date of the initial CE certificate for the device concerned or compared to the last PSUR update"	short term
46.	Addition of absorbable implants in the list of exemptions from the obligation to have an implant card	MDR requirement MDCG-Guidance 2021-11	The implementation of an implant card is very burdensome. Beside the specifications and material costs, additional production and packaging processes must be installed which impact sterilization and transportation validations. There are many implantable devices which are made of an absorbable material. The absorption time depends on the material and lasts only for a few weeks or months. After the absorption is completed, the implant has gone, and the implant card must be discarded. In fact, the implant		Adoption of a delegated act to amend the list of Art. 18 (3) MDR by adding "absorbable implantable devices". Resulting in Amendment to Art. 18 (3) MDR: "3. The following implants shall be exempted from the obligations laid down in this Article: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, connectors and		Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
			card is useful and beneficial for permanent implants. However, for absorbable products, the suitability and benefits should be reconsidered.		absorbable implantable devices. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend this list by adding other types of implants to it or by removing implants therefrom." Amendment of MDCG 2021-11 by removing Nr. 74 Absorbable haemostats.		 Short term
47.	UDI direct marking	MDR requirement	The UDI direct marking requirement for devices used multiple times on a single individual (single patient, multiple use) is excessive[19].	Clarifications in the MDR are necessary to avoid the UDI direct marking requirement for devices used multiple times on a single individual (single patient, multiple use)	• Annex VI, Part C, Section 4.10, Sentence 1 MDR should be deleted without replacement. • At the same time, a MDCG Guidance should be published to clarify that Section 4.10, Sentence 2 (old version) is only applicable to specific medical devices that are intended to be used on multiple patients and intended to be reprocessed between patient uses, as set out in Article 2(39) MDR. Additionally, the definition according to Article 2(39) MDR must be specified as	Amendment of the MDR	Mid term

[19] For the full version see here pp. 4 ff.: https://www.eurocom-info.de/wp-content/uploads/2024/09/2024-09-19_Position-eurocom_Evaluation-MDR.pdf

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
					follows to assign reprocessing to a procedure to which a used product is subjected under the responsibility of a professional reprocessor, so that it can be safely reused by a user who is not a layperson. This should include procedures for cleaning, disinfection, sterilization, and similar processes, as well as tests and restoration of the technical and functional safety of the used product.		
48.	Definition and differentiation of custom-made / patient-matched	Diverging interpretations by notified bodies Diverging interpretations by Member States / Competent authorities	The terms “custom made devices” and “mass-produced devices” and/or patient-matched are unclear and interpreted differently. There is no harmonised approach according MDCG 2021-3[20] and IMDRF/PMD WG/N49 FINAL:2018[21]	The considerable legal uncertainties arising from the distinction between custom-made devices and patient-matched devices that require CE marking, as well as surrounding the precise regulatory requirements for manufacturers of custom-made devices run counter to the aim of the MDR to ensure the smooth functioning of the internal market[22].	Clear definitions of the terms “custom-made” and “mass-produced devices” in the MDR: Manufacturers must be able to make the essential distinction between a custom-made device and a patient-matched device as clearly as possible. To this end, the definition of custom-made devices must be clarified.		Short term

[20] https://health.ec.europa.eu/document/download/385d7e20-d8b5-49d0-abd7-8daf269bf1b8_en?filename=mdcg_2021-3_en.pdf

[21] https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-181018-pmd-definitions-n49.pdf

[22] For the full version see here pp. 8 ff.: https://www.eurocom-info.de/wp-content/uploads/2024/09/2024-09-19_Position-eurocom_Evaluation-MDR.pdf

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
					The term mass-produced devices, which has not yet been defined, must be additionally defined in the interest of better differentiation, particularly between custom-made devices and patient-matched medical devices. Consistent definitions should be ensured within the language versions of the MDR. The definition of 'custom-made device' should include, according to a written prescription, the specific design characteristics of the product that is adapted to meet the specific requirements of a particular patient and intended for the sole use by that single patient based on their individual condition and needs. This is to be distinguished from mass-produced devices that are adapted or assembled within a pre-validated range specified by the manufacturer to fit the specific anatomical features of an individual patient. The		

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
					definition of 'mass-produced product' should focus on manufacturing and reproducibility in an industrial process. The number of products manufactured should be irrelevant. Requirements for manufacturers of custom-made devices The general obligations of manufacturers under Article 10 MDR in conjunction with the procedure set out in Annex XIII MDR have proven to be inappropriate and overly complex for manufacturers of custom-made devices. As custom-made devices are typically manufactured by small artisanal companies, one of the key objectives of the MDR, namely to ensure the smooth functioning of the internal market taking into account small and medium-sized enterprises, is jeopardised. At the same time, the long-term security of supply of high-quality, individually manufactured medical devices to patients		

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
					is at risk if manufacturers of custom-made devices find themselves forced to cease their activities due to non-transparent and inappropriate regulatory requirements. A solution would be to separate regulation for manufacturers of custom-made devices and to completely exclude them from the general obligations of manufacturers under Article 10 MDR and other manufacturer obligations scattered throughout the MDR. The separate regulation for devices manufactured and used only within health institutions laid down in Article 5(5) MDR, according to which such health institutions are generally exempt from the requirements of the MDR when manufacturing devices within the health institution, provided that all of the conditions under Article 5(5) MDR are met (in particular the general requirements according to		

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
					Annex I), could be used as a model for such a special regulation. This would require a supplementary provision by adding a paragraph to Article 5 MDR or in systematic connection with Article 10 MDR, according to which the requirements of the MDR do not apply to manufacturers of custom-made products, except the requirements set out in Annex XIII MDR, which also refer to Annex I MDR. This would also solve the often excessive requirement of a person responsible for regulatory compliance under Article 15 MDR, which could then not be invoked for manufacturers of custom-made products up to a certain company size. Moreover, within the framework of such a special regulation for manufacturers of custom-made products, the significant problem in practice that the requirements for clinical evaluation are often hard to implement in a sensible way		

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
					could be remedied in a targeted and legally compliant manner through special regulations in Annex XIII MDR.		
49.	Definition Narrow interpretation of the term "surgically invasive" in Art. 58(1a) IVDR, i.e. no inclusion of normal blood samples (harmless quantity for non-vulnerable donors)	In EU there are millions of blood draws every day without tracking patients. These blood draws are even done by medical assistants and not HCP. Under IVDD/MPG (§ 7) this was standard.	Legal uncertainty and, in case of doubt, more approval procedures necessary		Term "surgical invasive" has to be adopted for IVDR or a specific explanation has to be added to ensure that venous blood sampling in adults does not fall under the term 'surgical invasive'. AND This interpretation could, for example, be clarified in the announced MDCG document Q&A on performance studies.		Short term
50.	Double vigilance reporting	Vigilance reports must be made both to the competent authorities and to the notified body while the intention of the MDR is that notified bodies should have automatic access to vigilance data	The intent of the MDR is that notified bodies have automatic access to vigilance information (see Annex VII, section 4.10 last indent), yet notified bodies require separate notification and charge a fee of several hundreds of Euros for just receiving the vigilance notifications. Even if the Eudamed vigilance and PMS module is not available manufacturer should not be subjected to double administrative and costly	Competent authorities can provide the relevant information to notified bodies directly from their databases.	Competent authorities to automatically forward the vigilance reports and follow-up received to the notified body concerned. This can be implemented technically based on the relevant XML fields in the MIR form (notified body, notified body certificate number, device description section in general (2.3 of MIR form).	Amend MDCG 2021-1 Rev.1 Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional with a line at article 87 that member states report vigilance information that notified bodies would otherwise	Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
		(see Annex VII, section 4.10 last indent).	requirements. Charging fees for this is contrary to the fee structure elements set out in MDCG 2023-2.			source from Eudamed based on article 92 to the notified bodies concerned directly.	

Joint Opinion of D-A-CH region industry associations

Strengthening the competitiveness of the MedTech sector through simplification

31th July 2025

Introduction

The Medical Device Regulation (MDR) and the In-Vitro diagnostics Regulation (IVDR) are the result of the need for *a fundamental revision* of the previous *Directives to establish* a robust, trans-parent, predictable and sustainable *regulatory framework for medical devices and IVDs which ensures a high level of safety and health whilst supporting innovation*[1]. It aims to *ensure the* smooth functioning of the internal market *as regards medical, taking as a base a high level of protection of health for patients and users, and taking into account the small- and medium-sized enterprises*[2].

Eight years into implementation, the objectives of the regulations as outlined above have not been successfully attained as several aspects of the regulatory system remain dysfunctional, leading to device shortages, reduced innovation, SME closures, and manufacturers shifting their focus to other markets.
Medical devices and IVDs are essential to saving and improving the lives of millions of people each day. The largely SME driven sector is one of Europe's most innovative industries.
The signing associations are therefore encouraged, by the recent discussions acknowledging the challenges our sector is facing and welcome the many valuable suggestions provided by a variety of stakeholders, including CAMD and the European Parliament, on how to improve the regulatory system. We appreciate the steps already undertaken by the European Commission to gather the necessary evidence to implement legislative changes, as well as for the ongoing efforts to improve the regulatory system, reduce bureaucratic burden and ensure a smooth implementation.

The targeted Evaluation seeks to address some of the deeply rooted structural issues in key areas, such as governance. However, more decisive legal action is required to achieve a streamlined, innovation-friendly regulatory framework. We therefore call on the European Commission to initiate a legal proposal in 2025 to reduce bureaucratic burden within the medical device and IVD frameworks.

Administrative burden must be reduced and regulatory predictability improved, the initial product approval must be faster, more efficient, predictable and less costly.

[1] Recital (1) of Regulation (EU) 2017/745 (MDR)
[2] Recital (2) of Regulation (EU) 2017/745 (MDR)

With a focus on proportionality regulatory processes must be streamlined and reporting obligations must be reconsidered.

In order to achieve and implement these measures, we provide concrete examples of bureaucratic burden and suggest legal avenues for solutions, which are listed in the annex. They are based on the following principles:

1.
Reporting with purpose

Documentation and reporting efforts need to be reasonable and appropriate taking into account a high level of safety and availability of devices.

In addition to reducing individual requirements, such as high reporting frequencies and scope, the abolition of individual reporting obligations and the practice of reporting must be fundamentally reconsidered, in particular redundant reporting requirements and requirements without consequences and follow-up actions must be abolished.

2.
Streamlined regulatory processes

Regulatory processes and workflows need to be optimised to ensure efficiency and predictability especially by reducing redundancies in assessments and audits. They need to be thought through from start to finish.

The principle of good administration must be introduced and implemented to ensure that the CE certification system continues to operate in a fair, transparent and predictable manner under administrative accountability.
Clear timelines for procedural steps or the whole conformity assessment as well as procedures are needed also for breakthrough innovations.
The review of technical documentation must be comprehensive and complete. In further rounds, no completely new questions may be added to address issues and findings already raised.
To streamline time-critical processes, sequential procedures should be replaced by parallel procedures so that patients can access needed products more quickly.
The specific characteristics of well-established technologies must be taken into account to a considerable extend in order to maintain proven and safe products on the market.

3.
Increased focus on proportionality

The documentation effort needs to be appropriate and adequate for demonstrating that the objective pursued is achieved.

To demonstrate safety and performance of a device all obligations under a regulation and the associated effort should follow a least burdensome approach.
The MDR and IVDR contain obligations for Economic Operators, that do not result in any output or direct actions by notified bodies, competent authorities and therefore have no impact on devices or patient safety.

4.
Coherence to horizontal legislation

Where multiple regulatory frameworks apply, the specific requirements of the sectoral medical technology legislation must be taken into account in order to effectively manage overlaps, conflicting provisions and concurrent regulatory obligations.

Due to the principle of the new legislative framework[3] (NLF) multiple EU regulations can apply concurrently to one and the same product. At the same time there is no standard mechanism in NLF managing overlapping, conflicting and concurrent regulatory obligations. This leads to an overcomplexity of legal requirements and difficulties for any manufacturer to determine which requirements apply at which point in time.

5.
Legal Clarity

The legal provisions should be substantively clear, concise, structurally consistent, and linguistically unambiguous - without the need for supplementary interpretive guidance. Requirements containing vague or interpretation-dependent language should be revised, and overly specific provisions that go beyond what is necessary for effective oversight should be removed.

Legal clarity is essential to ensure that compliance with the regulations can take place as intended. It enables all actors to operate based on a shared understanding and helps reduce unnecessary bureaucratic compliance costs. Economic operators seeking to comply with the regulations currently need to be aware of over 150 endorsed MDCG –guidance documents, as well as harmonised standards, court decisions and national laws. This regulatory complexity is caused by non-intuitive, extremely specific or internally inconsistent provisions resulting in the need for guidance and should be amended at the source within the legal text, where possible.

In order to put these basic principles into practice, we have compiled a list of concrete improvement measures, which is attached to this position paper. This list is intended to be seen as a supplement to the administrative burden list of the undersigning provided by the signing associations in November 2024.

[3] https://single-market-economy.ec.europa.eu/single-market/goods/new-legislative-framework_en

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Joint Opinion of D-A-CH region industry associations: Urgent need for legal measures to facilitate MDR/IVDR implementation through simplification.

Supplement to

Annex I | D-A-CH region industry associations proposals for urgent measures to decrease bureaucracy and facilitate MDR/IVDR implementation (15.11.2024***)***

July 2025

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution Proposed instrument / legal basis for resolution	Description	Key principle
1.	Art. 10a	MDR and IVDR requirement Reporting of discontinuation.	The wording of Art. 10a MDR is very broad. Taken literally, it would introduce a massive administrative burden on all manufacturers of medical devices on the EU market, dispro-portionate to the effect the article seeks to achieve.	Appropriate measures are required in response to the respective information. Yet, countermeasures by the compe-tent authorities were not standardised in the course of the introduction of Art. 10a MDR. The competent authorities to which the information is re-ported lack powers to ensure supply, for example in the form of replacement purchases by the Member States. The Commission's Q&A does also not ad-dress any countermeasures.	Delete Art. 10a		1, 2, 3

2.	Article 87(3)	MDR requirement Excessive reporting of false positives for potentially serious incidents	For a potential serious incident, where nobody was actually harmed but where there is only a suspicion that the product could pose a risk, the MDR reduced the nofification period from 30 days (MDD) to 15 days. As the investigation of such cases often takes longer than 15 days (e.g. if a device must be sent to the manufacturer for analysis), manufactureres are obliged to report many cases of potential incidents many of which later turn out to be unsubstantiated. This is exasperated by the fact that the MDR does not really address the likelihood of harm in the definition of serious incident ("might have led or might lead") which can lead to the reporting of events with only insignificant risk.	The short notififaction period in unconfirmed cases has no safety benefits but leads to a high volume of false-positive or unsubstantiated reports, burdening both manufacturers and competent authorities, while diluting the focus on high-risk events. For incidents with real harm, appropriate a shorter notification period (10 days) is already in place. Returning to a 30-day reporting obligation for cases without realized harm would be appropriate, at least for cases where the risk is low. 30 day is also a timeframe that is used in may other jurisdictions without there being any evidence in the literature that this has any disadvantage. The 15 days notification period should be retained for cases with high risk i.e. when the likelyhood of severe harm is high. A graduated approach would align with the risk-based vigilance system laid out in Articles 83 to 89 of the MDR, support more targeted, higher-quality reporting improve the usefulness and signal value of vigilance data	Change MDR Article 87 (3) to introduce a risk-based, tiered reporting timeline: A shorter deadline (15 days) remains in place for events with a high probability of serious harm under normal or foreseeable conditions. A longer deadline (30 days) allows time for a substantiated assessment in cases with low or uncertain risk and no actual harm.	Proposed Text: 3. ***Manufacturers shall report any serious incident as referred to in point (a) of paragraph 1 immediately after they have established the causal relationship between that incident and their device or that such causal relationship is reasonably possible and not later than 30 days after they become aware of the incident. However, where it appears likely that an identical or similar incident could lead to death or serious deterioration of health under normal or foreseeable conditions of use, the manufacturer shall submit the report not later than 15 days after becoming aware of the incident.***	1, 2, 3

				and would be in line with Recitals 5, 59 and 61 of the MDR, which call for a vigilance system that is effective, proportionate, and focused on real safety signals, while avoiding unnecessary public concern and administrative burden.			

3.	Clinical evaluation updates	MDR requirement Parallel PMS- and clinical evaluation update processes lead to redundant work	Currently, manufacturers of legacy and well-established devices need to update the clinical evaluation throughout the life cycle of the device concerned with clinical data obtained from the implementation of the manufacturer's PMCF plan in accordance with Part B of Annex XIV and the post-market surveillance plan referred to in Article 84. However, the PMS/ PMCF process should be proportionate to the expectable risk, and capable of being automated and statistics driven to ensure that costs for compliance are kept at reasonable levels and processes are appropriate for the devices concerned. Article 61 MDR shall be amended to eliminate the requirement for a Clinical Evaluation Plan (CEP) and Clinical Evaluation Report (CER) update for legacy and well-established devices in Classes I, I* (Ir, Is, Im), and selected nonactive Class IIa devices with a proven safety record. PMS and PMCF should be about detecting signals relevant to PMS and PMCF. Targeted clinical safety evaluation will perform better than periodic clinical evaluation updates,	According to MEDDEV 2.7.1 rev. 4 clinical evaluation shall be actively updated every 2 to 5 years if the device is not expected to carry significant risks and is well established. However, updates of clinical evaluation reports are extremely time consuming and costly process, which need to be conducted also if there are no relevant changes to report from PMS and PMCF activities. We propose a clinical safety based “Legacy Safety Summary File” instead for the monitoring of the compliance with state of the art and of clinical safety. This can be implemented by means of a small amendment to Article 61 (11) MDR or could be done by means of an implementing act based on article 61 (13) MDR, supported by MDCG guidance.	Amendment to article 61 (11) 1st paragraph MDR. Amend MEDDEV 2.7.1 rev. 4.	Article 61 (11) 1st paragraph is amended as follows: ***For legacy and well-established devices, subsequent to an initial clinical evaluation, clinical evaluation documentation updates are not required. Manufacturers shall maintain a Legacy Safety Summary File containing:*** ***a. Product description and classification.*** ***b. Risk management report (ISO 14971).*** ***c. Post-market surveillance (PMS) summary for ≥ 5 years.*** ***d. Declaration of conformity with relevant standards.*** ***e. Test reports (biocompatibility, mechanical, reprocessing/sterilisation as applicable).*** ***f. State-of-the-art alignment and acceptance criteria for clinical safety.*** ***The Legacy Safety Summary File shall be updated every 5 years on the basis of clinical data regarding the state of the art and the post-market surveillance plan referred to in Article 84.***	1, 2, 3

			especially for legacy and well-established devices.				
4.	Eudamed content	MDR and IVDR requirement Repeated depiction of EUDAMED content (e.g. EMDN codes) in technical documentation and certificates	The administration of multiple copies of product content (e.g. EMDN codes) in technical documentation and certificates is coupled to a tremendous effort, especially for large product portfolios. With EC-intended annually routine rework of EMDN database a good example of artificial workload on a mass of documents and risk for invalid certificates is set up by the EC.	Since the content to be delivered for each product to the Eudamed database for administrative reasons is to be released either by the Notified Body or in responsiveness of the legal manufacturer anyway. Thus, the ultimate lifecycle of these data shall be exerted in the database – fully accessible for all instances and transparent to the world. It is not reasonable to depict such data again on several documentation instances, unless BASIC UDI-DI and UDI-DI is annotated. The current situation lead to unnecessary burden by reissuance of documents or certificates with direct impact on product availability and human ressources.	Identify the content in the EUDAMED database, that is a necessary copy of product data (e.g. warnings) and those data, that are sufficient to be available in the database solely, since they are released there anyway for certification by the relevant parties. Restrict duplication of data outside EUDAMED on the necessary content.	Ideally, the attributes depicted in EUDAMED have a specific reason (maybe risk mgmt driven as for storage temperatures etc.) to be depicted outside of the data set in the technical documentation. In fact the EUDAMED data are extended certification data.	

5.	SSP for IVD	IVDR Requirement	SSP is to be made available over EUDAMED especially with the purpose of informing lay users of assay performance and safety aspects. For professional use assays the patient has no connection to the assay and therefore, no ability to access the SSP. Professional users have a much deeper understanding of assay performance, limitation and risks. In addition they often have contact to the manufacturers expert not available to lay persons. Potential additional information gained from the SSP as compared to IFU and other product information material is negligible to non-existent.	This legal requirement is an example of copy-and-paste from the MDR to the IVDR. The SSCP was intended for implantable MDs that remain in the body for years of decades, potentially posing ongoing risks to patient safety. A test that is used outside the human body, providing a one-time result is not comparable and should be handled differently. Equating these very different product types in terms of risk communication is disproportionate and misaligned with the intended purpose of the SSCP.	Option 1 Removal of IVDR article 29 and annex VI (A) 2.11 Option 2 Amendment to article 29 (1) IVDR as follows: 1. For class C and D lay use devices, except for devices for performance studies, the manufacturer shall draw up a summary of safety and performance.		

6.	Classification of class B devices IVDR | Self-assessment	IVDR requirement	Removal of surveillance audits for class B devices with the exception of review of PMS material to reduce the burden on the system and eliminate bureaucratic reports with no patient benefit)	For the IVDR the policy choice was made to enormously increase the devices under the requirement for notified body conformity assessment where these devices were subject to self-assessment under the IVDD This policy decision has not been motivated by safety or performance issues with IVDs under the IVDD and does not serve a purpose of increasing patient safety or test performance. As a result, the continued conformity assessment system under the IVDR is congested with a large amount of low risk (class B) devices that used to be subject to self-assessment. For these devices the notified body capacity under the IVDR is scarce and of which the added value of notified body continued conformity assessment identical to C and D is questionable. This creates an enormous extra cost to the healthcare system that is not justified by any benefits in terms of increased performance or safety of tests. The replacement of surveillance reviews for class B with reduced technical file reviews focused only on PMS data would underline the different inherent risks to class C/D devices.	Add to Article 49 the following point: ***for class B in vitro diagnostic devices the involvement of the notified body in surveillance shall be limited to quality management system audits and review of post-market surveillance data. No surveillance audits involving product sampling or technical documentation file checks shall be required for class B devices.*** Add to Article 78 (1): ***For Class B devices, the post-market surveillance system shall be subject to review by the notified body solely concerning post-market surveillance data, without the requirement for routine surveillance audits.*** Amend Annex IX, Section 3.3: ***3.3. Notified bodies shall periodically, at least once every 12 months, carry out appropriate audits and***		

				Furthermore, current Class A devices are being monitored by national competent authorities. The Impact Assessment predicted a significant increase in costs for manufacturers (which indeed took place) but justified these based on “enhanced robustness of the classification system, as well as international harmonization”. So far the advantages that underlay this policy choice have not materialized and industry does not expect them to materialize without recalibration of the IVDR’s certification process.	***assessments to ensure that the manufacturer applies the approved quality management system and the post-market surveillance plan. For Class B devices, the notified body's assessment shall be limited to the review of post-market surveillance data provided by the manufacturer, without conducting routine surveillance audits***. Amend Annex IX, Section 3.5: ***3.5. In the case of Class C devices, the surveillance assessment shall include an assessment of the technical documentation as specified in Section 4 for the device or devices concerned on the basis of further representative samples chosen in accordance with the rationale documented by the notified body in accordance with the third paragraph of Section 2.3. For Class B devices, the surveillance assessment shall be***		

					limited to the review of post-market surveillance data, without the requirement for routine surveillance audits or additional assessments of technical documentation. Amend Annex VII Section 4.10: ***The notified body shall have documented procedures:... (b) for screening relevant sources of scientific and clinical data and post-market information relating to the scope of their designation. For Class B devices, such information shall be taken into account solely in the review of post-market surveillance data provided by the manufacturer, without conducting routine surveillance audits***.		

7.	Abolition of the Helsinki Procedure	Non-functioning of the Helsinki procedure	The following issues are associated with this procedure: • Lack of transparency and legitimacy • Inadequate competence and expertise of the assessors involved • Absence of consultation with manufacturers or the notified body of the product concerned before a decision is made • Inclusion of new cases in the Borderline Manual even when no simple majority among all 27 Member States is reached • Lack of timely conclusions, with no adherence to defined timelines • Products being trapped in regulatory "limbo" for years.	In the context of product qualification and classification under the MDR and IVDR, the Helsinki procedure should be abolished.	Instead, the formal legal procedure to determine the regulatory status of products should be used, as it requires structured presentation and evaluation of arguments. We advocate for the consistent application of existing legal instruments, particularly Article 4 MDR and Article 3 IVDR for decisions on the regulatory status of a product and Article 51 (3) MDR and Article 47 (3) IVDR for decisions on the classification of a device.		2, 5

8.	Sampling of technical documentation of class IIa and IIb products (Art. 52, 4-6, Ann. IX, Ch I, Section 2, 3)	MDR requirement Dispro-portionate and repeated sampling of technical documentation	Article 52, paragraphs 4-6 MDR, and Annex IX, Chapter I, No. 3, specify the assessment of technical documentation on the basis of representative samples. The sampling shall take into account MDCG-Guidances, technological novelty, similarities in design, technology, manufacturing and sterilization processes, the intended purpose and the results of any relevant previous assessments, e.g. with regard to physical, chemical, biological or clinical properties. (Annex IX Section 2.3) Before issuing the certificate, the notified body must examine the technical documentation of at least one representative product per category (for Class IIa) or per generic product group (for Class IIb), Art. 52 (4) and (6) MDR. Specifically, this means that for each category covered by the manufacturer's application (Class IIa) or for each generic product group (Class IIb), a representative product must be randomly selected, and the corresponding technical documentation must be fully evaluated. These evaluations are required <u>before the QMS certificate is issued</u> and are included in the	In cases where there is little to no change in the Technical Documentation reexamining the same Technical Documentation provides no substantiative value and places an undue burden on the manufacturer. Sampling activities should follow the rationale of proportionality. The principle of proportionality is central to the decision on sampling – not only how, but whether and how deeply testing is carried out. MDCG 2019-13 equates the depth of assessment for a technical documentation of a Class IIa / IIb device with the assessment of a class III device. Especially in the case of repeated review of the same file this is directly opposed to the principles of risk-based assessment.	• Amend Annex IX, Chapter I, No. 3.5 to exclude Class IIa devices from sampling obligation during surveillance audits. (Delete "***~~class IIa and~~***"). • Amend Annex IX, Chapter I, No. 3.5 to exempt WET from sampling obligation during surveillance audits. (add: ***Well Established Technologies shall be exempt from this obligation***) • Amend Annex IX 3.5 to make clear that the surveillance audit only includes an assessment of the technical documentation where appropriate and necessary. And that prior assessment activities in regard to technical documentations need to be taken into account when determining if another review is necessary. • Amend Annex IX to make clear that the same technical documentation does	• Class IIa products should only be sampled within the initial review. Additional sampling during surveillance audits is unnecessary. Only in the event of changes, anomalies, vigilance data or trends, should further TDs be reviewed. • For WET, a reduced or waived testing rate should be possible. • There is no reason why a yearly review of a technical documentation is necessary, if no issues arise from vigilance/changes/anomalies etc. • Repeated checks of documents that have already been assessed should not take place without cause. A yearly review of the same or comparable technical documentations is not proportionate. • Change back the focus of the review of technical documentation on clinical. Sections 4.4-4.8, as specified in the first published version of the legal act, and not on the complete TD as introduced withCorrigendum, OJ L 117, 3.5.2019, p. 9 (2017/745) • • The generic product group should no longer be defined via the 4th EMDN level (Class IIb). Instead, it should be	2, 3, 5

			final assessment in accordance with MDR Annex VII Section 4.7. In Annex IX Chapter 3.5 it is further specified that the surveillance audit shall also include an assessment of the technical documentation on the basis of the representative samples and the rationale in Section 2.3. The scope of the random samples is further specified in the guideline MDCG 2019-13 (Rev1, Dec 2024). This defines the criteria on a flat-rate basis using minimum quantities specified as percentages based on generic product groups (Class IIb) or product categories (Class IIa). It is also specified, that due to its inclusion in the surveillance audit, it is the opinion of the MDCG that one random sample is required every year. Issues: While the generic device group is defined in Article 2 (7), there is no definition in the MDR for a category of products. The MDCG has determined to use the 4th level of EMDN Codes (3rd level for IVDR) and the MDA/MDN Codes respectively. This approach is not practical in many cases the 4th level of		not need to be assessed twice if no significant change has occurred. This can be achieved by adding language stating that prior (years / certification cycles) assessment of comparable technical documentation is to be taken into account. • TechDoc Review should be focused on clinical not the complete TechDoc. Change Annex IX 3.5 to only reference 4.4-4.8 instead of complete section 4. • Amend Article 2 (7) and include a definition for category of products. Amend Article 52 to make clear, that the manufacturer and the notified body jointly come to an individual determination on groupings, determined among other factors by the MDA / MDN scopes.	determined individually and by mutual agreement with the notified body at the start of certification in accordance with Art. 2 No. 7 MDR. Medical devices are too complex in their variety to be captured in a generic manner.	

			EMDN-Codes is partially stratified to an extent where technologically nearly identical products with a similar intended purpose can have different codes, triggering additional, duplicative TD-Reviews. The MDCG additionally only takes one certification period into account. In the event of recertification, some notified bodies interpret this to mean that the sampling plan is reset. So a TD that was already reviewed in last year's surveillance audit, and has not been changed, can be subject to review again. In the case of SME's or other companies with a small product portfolio, TD's that already have been sampled are often reviewed again, even if there have been little to no changes to the product or the documentation. This does not lead to patient safety but causes administrative burden, blocks capacities for other important topics and leads to significant costs, especially for SMEs				

9.	Adapt to Modern Formats of Documentation	MDR/IVDR Requirement Divergent Notified Body practice	Documentation historically is understood to be made up by structured content (e.g. pages in a PDF) However, in more recent years, technology has allowed for more modular approaches toward documentation. For example, Technical Documentation can be viewed as a collection of content/data managed in own lifecycles according QMS processes. These pieces of content are repeated in many different sections within technical documentation (e.g. intended use) for legibility. This setting is highly prone to errors as information´s lifecycle elicits delays in revision of documents depending on it´s individual information compilation with simultaneously review. In a more modular or data-driven approach, the intended use and other parts of the documentation could be sent as separate modular datapoints. The Notified Body could then generate a complete sequential Technical Documentation from these datapoints. This way of submitting information for technical documentation has	The current situation is replicating data/information within documentation according to the specific needs of the individual reader. More advanced methods of structuring information in documents are available and should be permitted to be used. It is possible to manage and consent to the release of legally binding information via the data itself, as shown by EUDAMED content.	Harmonize the Understanding of Documentation within the MDR and IVDR to make clear that e.g. modular or data driven submission is legally permitted. This would for example with regard to technical documentation. Enable a compilation in a modular, data-driven resp. digital format according manufacturers processes (audited and certified) towards Notified Bodies instead of compilation of pdf documents.	Make clear in what cases Documentation can refer to (signed, validated, approved, released) information and not a certain structure of information. Allow for the possibility of data-driven submissions.	2

			multiple advantages over a classical approach. The same is true for various other kinds of documentation (Clinical, Biocomp etc.). At the moment Notified Bodies often do not accept data-driven submissions. In part, because they see the legal obligation, for a document to be generated in a structured manner, to be eligible for submission.				