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

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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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