Bundesverband Medizintechnologie e.V.

Position

Medical devices –uniform application of the requirements for notified bodies | Annex VII

January 2026

Introduction

BVMed welcomes the European Commission's proposal of 12 December 2025 to introduce concrete implementing provisions for Annex VII of Regulation (EU) 2017/745 (MDR). The draft Implementing Act represents an important step towards strengthening the efficiency, predictability and overall functioning of conformity assessment procedures for medical devices in the Union and thereby supporting timely and reliable market access.

To ensure that the conformity assessment system continues to evolve towards a future-proof, efficient and innovation-friendly framework, BVMed considers the following elements of the Draft Implementing Act to be particularly relevant:

- **Transparent and predictable quotations (Article 1)**
  Harmonised and detailed requirements for quotations issued by notified bodies improve cost transparency, comparability and planning certainty for manufacturers and thereby contribute to a robust and reliable conformity assessment system.

- **Predictable and flexible timelines (Article 2)**
  The introduction of maximum timelines for conformity assessment activities, combined with the possibility to agree shorter and case-specific timelines, provides the necessary structure and flexibility to ensure reliable planning and to accommodate time-critical changes in a risk-based manner.

- **Effective stop-the-clock mechanism (Article 3)**
  A clearly defined stop-the-clock system allows timelines to be suspended only where this is justified by missing information, while ensuring that parallel assessment activities continue wherever possible, thereby preventing unnecessary delays.

- **Targeted and life-cycle-based re-certification (Articles 6 and 7)**
  The focus on requirements that are genuinely relevant for re-certification strengthens efficiency and predictability by avoiding duplicate assessments and by fully reflecting the MDR's life-cycle approach based on continuous oversight of manufacturers, their quality management systems and devices.

On this basis, the following sections set out BVMed's detailed assessment of the draft Implementing Act and provide targeted recommendations to further refine and strengthen the proposed framework.

1.
Article 1 Quotations

With regard to Article 1, BVMed welcomes the introduction of specific requirements for the content of quotations to be issued by notified bodies to manufacturers, as this constitutes a key element for improving transparency and increasing planning certainty for manufacturers, while harmonised and uniform requirements for such quotations also enhance comparability.

BVMed suggestions:

Article 1(1)(b) – SME status

- **Clarify and streamline the indication of SME status** by allowing manufacturers to indicate if they intend to leverage any potential benefits for SMEs with a simple yes/no question, in order to reduce administrative burden for non-SMEs. Only if there are any special provision for SMEs and the manufacturer wants to leverage those, additional data shall be required.
- **Limit the requirement for detailed SME information** to the data necessary to determine SME status in accordance with Commission Recommendation 2003/361/EC and only where the manufacturer declares itself as an SME.

Article 1(1)(j) – "Any other information"

- **Restrict the scope of "any other information" to strictly necessary** data that is indispensable for the preparation of a quotation, in order to avoid the early and disproportionate request of extensive information from manufacturers. In general, the information in (a) to (i) should be sufficient for a quotation, however it is welcomed that the manufacturer has the option to add information that it deems relevant.
- **Ensure that product-related evidence requirements remain proportionate**, recognising that the relevant MD code should generally be sufficient to substantiate information related to the medical device at the quotation stage.

Article 1(4) – Cost increases

- **Ensure consistency with the initial cost transparency objective** by applying the same principles of detailed cost breakdown and mutual confirmation to any subsequent cost increases arising during the conformity assessment process.

2.
Article 2 Timelines

BVMed welcomes the introduction of maximum timelines for conformity assessment procedures, as this is a key step towards improving the predictability of market access for manufacturers and accelerating procedures overall. This is essential to ensure concrete planning reliability, to close potential gaps between the individual steps of the defined conformity assessment activities, and to provide for a risk-based flexibility that allows time-critical changes to be agreed and implemented between manufacturers and notified bodies where needed. BVMed therefore also welcomes that the quotation issued by the notified body must specify the concrete timelines agreed for the individual conformity assessment, as this further enhances planning certainty for manufacturers and may foster competition among notified bodies to the benefit of the system.

BVMed suggestions:

Article 2(2) – Maximum duration of conformity assessment activities

- **Ensure a complete and gap-free framework of maximum timelines** by explicitly defining a maximum period between the conclusion of the contract between the manufacturer and the notified body (end of Article 2(2)(a)) and the start of the first audit program activity (beginning of Article 2(2)(b)). A lack of clarity at this stage risks undermining the objective of predictability and could lead to unjustified delays before conformity assessment activities effectively start.

Article 2(3) – Substantial changes

- **Close regulatory gaps by setting a maximum duration between the notification of the decision on a planned substantial change and the start of the corresponding audit or technical documentation assessment.** Without such a limit, significant delays may occur despite the existence of maximum timelines for subsequent assessment steps.
- **Maintain a single, combined maximum timeline of 90 days for the assessment of substantial changes, covering both the preliminary review and the subsequent conformity assessment activities, whereas within the first 30 days, the notified body shall inform the manufacturer if further assessment and approval is required.** In practice, manufacturers are generally able to assess whether a change requires notified body involvement. Hence, most of the changes submitted to the notified body will require further assessment. Adding an extra step for the notified body's assessment if the change requires approval will cause redundant review of information (first to assess if the change requires approval and secondly to review it) and thus increase administrative burden and duration of the process. When assessing a change, notified bodies will be able to determine if the change requires approval in the beginning of the assessment and be able to potentially cancel the assessment during the first 30 days. A combined 90-day maximum timeline is proportionate, reflects established practice, and supports international competitiveness.

3.
Article 3 Interruption of work on conformity assessment

BVMed welcomes the introduction of a mechanism to stop-the-clock on the defined timelines when the notified body cannot continue their work without the requested information. We emphasize that the work which is not dependent on the missing information should continue.

BVMed suggestions:

Article 3 – stop-the-clock mechanism

- **Clarify the concept by consistently referring to a "stop-the-clock" mechanism rather than an "interruption of work".** The purpose of Article 3 is to suspend the running of timelines, not to mandate a general halt of all conformity assessment activities. Where possible, parallel activities should continue in order to avoid unnecessary delays.

Article 3(2) – Conditions for stop-the-clock

- **Define clear and objective criteria for triggering a stop-the-clock.** Clear grounds are necessary to prevent stop-the-clock from becoming routine practice rather than an exception.
- **Link the use of stop-the-clock to a concrete and clearly defined action required from the manufacturer.** Any suspension of timelines should be explicitly tied to a specific and actionable request, such as the submission of a clearly identified document or report, ensuring transparency and proportionality.

4.
Article 4 Monitoring of the duration and costs

BVMed welcomes the planned monitoring of activities carried out by notified bodies and the envisaged publication of the corresponding data, as this enhances transparency and enables a meaningful comparison of notified bodies' performance.

BVMed suggestions:

- **Ensure that published data is categorised in a way that is meaningful and allows for comparability** for example by linking activities related to the products concerned to an appropriate level of EMDN codes, in order to allow for genuinely comparable and informative insights into notified bodies' activities.
- **Maintain proportionality of monitoring and reporting obligations** to ensure that the administrative burden for notified bodies remains reasonable and that sufficient resources can continue to be allocated to core conformity assessment activities. The overall burden for notified bodies should not exceed the level associated with the GÖG Survey, which is planned to end in December 2025 after a 36-month mandate, thereby freeing up reporting resources at notified bodies that can be reallocated to the new monitoring requirements.

5.
Article 6 & 7 – Re-certification

BVMed welcomes that **Articles 6 and 7** of the Implementing Act establish clear rules on which additional requirements are relevant for re-certification. This provides an important framework to limit administrative burden, avoid duplicate assessments of elements that are already continuously verified through manufacturers' quality management systems and notified bodies' regular surveillance audits, and to focus re-certification activities on the most necessary and risk-relevant aspects. In this way, the Implementing Act appropriately reflects the MDR's life-cycle approach based on continuous oversight of manufacturers, their quality management systems and their devices.

BVMed suggestions:

Article 6(1)(a) – Changes in the context of recertification & Article 7

- **Clarify that no new reporting obligations for changes are introduced in the context of recertification.** Requiring manufacturers to submit a comprehensive list of all changes, including those that were not notified to the notified body, goes beyond existing MDR requirements and is neither necessary nor proportionate. The assessment of changes is a continuous process within the manufacturer's QMS; changes that require notification are duly reported, while non-notifiable changes remain subject to review by notified bodies during audits.

Article 6(2) – Purpose and scope of change-related obligations

- **Clarify the objective and scope of Article 6(2) to avoid introducing additional or unclear obligations regarding the notification of changes during recertification.** Manufacturers already continuously assess planned changes as part of their QMS and report them to the notified body if necessary. It remains unclear which specific types of changes are intended to be captured under this provision and how it differs from existing processes.

Article 6(3) – Continuity of certification during recertification & Article 7

- **Ensure uninterrupted marketability of medical devices during recertification where delays are not attributable to the manufacturer**. Certificates should not lapse solely due to procedural delays on the part of the notified body. Clear consequences must be defined where the 60-day deadline is not met. BVMed suggests that, if the notified body is unable to take a decision on recertification within the prescribed timeline, the decision shall be deemed positive and the certificate shall be issued. If, after consultation with the manufacturer, the notified body subsequently concludes that recertification is not possible, it may withdraw the certificate in accordance with the applicable MDR procedures.

7.
Additional considerations on Annex VII

BVMed notes that the measures introduced by the draft Implementing Act represent an important step towards a more future-proof conformity assessment system under the MDR. However, to fully realise a system that can support innovation, medical needs and regulatory sustainability over time, additional structural elements will be required and should be implemented without delay e.g. in the context of the ongoing MDR revision.

A genuinely future-proof framework should be based on the following two pillars:

- **Structured dialogue in clinical strategy**
  A regulatory framework that allows for early, structured and legally secure dialogue between manufacturers and notified bodies on key aspects, including clinical strategy, is essential to ensure efficient, predictable and innovation-friendly conformity assessment pathways.
- **Coherence with future differentiated conformity assessment pathways**
  The conformity assessment system must be designed in a way that it can accommodate future pathways for highly innovative products, such as breakthrough and orphan devices, including about quotations, timelines and procedural steps, without creating legal uncertainty or procedural fragmentation.

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