Position of eurocom e.V.

of October 1, 2025

to the initiative of the European Commission „Medical devices and in vitro diagnostics – targeted revision of EU rules" (Ares (2025) 7425764)

eurocom e.V. is the European Manufacturers Federation for compression therapy, orthopaedic devices and digital health applications, which are medical devices within the meaning of the Medical Device Regulation (MDR).

I. Introduction and general information

eurocom welcomes the European Commission's initiative to make rapid changes to the MDR with the aim of simplifying and strengthening the competitiveness of economic operators in relation to medical devices, as well as making the regulations more proportionate. eurocom considers it very positive that the European Commission is paying particular attention to the concerns of small and medium-sized enterprises (SMEs). The majority of eurocom's member companies are SMEs whose competitiveness depends on moderate regulatory and bureaucratic requirements, as they do not have the same human and financial resources as large corporations. As the European Commission also notes, this can increase the availability of medical devices for patients.

Among the stated objectives of the initiative, eurocom particularly highlights the goal of reducing administrative burdens and the intention to make regulatory requirements for low-risk products more proportionate, which must also apply to requirements beyond conformity assessment. Medical aids for compression therapy and orthopedic devices are typically class I medical devices, where many simplifications are possible without compromising patient safety. eurocom is aware of the importance of patient safety and reviews each requirement to determine whether its implementation would compromise patient safety.

In any case, eurocom calls on the EU Commission to stick to the complete revision of the MDR, as EU Commissioner Oliver Várhélyi already confirmed in his opening statement after his appointment. eurocom shares the position that the MDR needs fundamental reform in order to increase the competitiveness of the medical device sector in the EU. It must not be limited to a quick but minor revision of a few points.

eurocom therefore expressly refers to its lengthy position paper on the evaluation of the Medical Device Regulation dated September 19, 2024. This position paper, which was submitted as part of the public consultation for this project (running until December 15, 2024) and also sent directly to Commissioner Várhélyi, remains valid. From the demands contained therein, eurocom refers to the overarching objectives of the need to implement the MDR as the definitive EU regulatory framework for medical devices

and to restrict further national regulations (demands No. 1 and No. 8 of the paper dated September 19, 2024). Both are in line with the aim of the present initiative to "better align the legal framework with other relevant regulations." EU legal acts, for example from environmental legislation, must be better aligned with the specificities of healthcare and medical device law and, for this purpose, should ideally be accommodated in a separate section of the MDR. Similarly, divergent or even contradictory national regulations must be restricted, and essential national regulations must be examined more closely for their conformity with the MDR.

II. Individual demands

1. Definition of reuse – Consequences for UDI direct marking on the device

a) Problem

Due to the lack of a definition of reusable products, which are only distinguished from single-use products within the meaning of Art. 2 (8) MDR, medical devices that are regularly washed at home after use on a single patient (such as medical compression stockings or bandages) must also be classified in the same category as reusable medical devices that must be reprocessed before reuse on other patients within the meaning of Art. 2 (39) MDR. It is already unclear whether the definition of reprocessing within the meaning of Art. 2 (39) MDR covers such simple household washing processes. What makes sense for reusable surgical instruments, which must be cleaned and sterilized after each surgical use in specific reprocessing procedures within the meaning of Art. 2 (39) MDR, is unnecessary for household washing by laypersons.

For reusable medical devices, stricter requirements also apply in accordance with Annex VI, Part C, Section 4.10, Sentence 1 MDR, even if they do not have to be reprocessed in accordance with Annex VI, Part C, Section 4.10, Sentence 2 MDR, due to the application of the UDI carrier to the product itself (known as direct marking). In the case of devices intended for the care of a single patient, which are typically intended for multiple use by that one patient (*single patient multiple use)*, the requirement for direct marking increases the cost of manufacture and thus the cost of supplying devices to patients. On the other hand, patient safety is not increased; rather, the requirement leads to distortions of competition in the medical device market. This applies in particular to custom-made devices within the meaning of Art. 2 (3) MDR, which are often identical to CE-marked products in the medical device sector, but whose manufacturers are not required to implement the obligations associated with the UDI system and thus direct marking.

However, according to Annex VI, Part C, Section 4.10, sentence 1 MDR, the obligation to place the UDI carrier on the product itself applies to all CE-marked reusable class I products from May 26, 2027 (Art. 123 (3) (g) (iii) MDR).

b) eurocom's demand

eurocom calls for the necessary clarifications in the MDR to avoid mandatory UDI direct marking for single-patient, multiple-use products. eurocom makes the following suggestions:

- Annex VI, Part C, Section 4.10, sentence 1 of the MDR should be deleted without replacement.

- In addition, the definition in Art. 2 (39) MDR must be specified as follows:
  "reprocessing" means a process carried out on a used device under the responsibility of a professional reprocessor in order to allow its safe reuse by a user who is not a layperson These processes include cleaning, disinfection, sterilisation, and related procedures,, as well as testing and restoring the technical and functional safety of the used device.

2. Definition and differentiation of custom-made / patient-matched

a) Problem

Although the distinction between custom-made devices and other medical devices is of considerable importance for the regulatory obligations to be fulfilled by the manufacturer, there is considerable uncertainty under the MDR, particularly with regard to class I products in the field of compression therapy and the supply of prostheses and orthoses. In particular, the distinction between *custom-made devices* within the meaning of Art. 2 (3) MDR and made-to-measure products that do not fall under the definition in Art. 2 (3) MDR (*patient-matched medical devices)*, which are therefore subject to CE marking, is often unclear. Furthermore, the term "patient-matched medical devices" is not defined in the MDR. In practice, differences in language versions and preconceptions in particular lead to completely different classifications and regulatory treatment of the same product by market surveillance authorities in the Member States. For example, in contrast to custom-made devices, the term "*devices which are mass-produced*" in the English language version of Art. 2 (3) MDR suggests that custom-made devices are mass-produced, whereas they are merely potentially reproducible in serial industrial processes.

EU legislation does not take into account the distinction made in the guidelines of the International Medical Device Regulators Forum (IMDRF) and thus does not enable the EU medical device sector to benefit from international cooperation, including, where appropriate, by relying on the decisions of other trustworthy bodies ("reliance"). By implementing eurocom's demand, the EU Commission would fulfill this objective, according to the call for comments.

Without compromising public health or patient safety, a minimal change in the wording of the law would significantly reduce the administrative burden and increase predictability and cost efficiency for low-risk medical devices, as also envisaged in the call for evidence.

b) eurocom's demand

Clear definitions of the terms "custom-made device" and "mass-produced devices" are required within the MDR. To this end, the definition of a custom-made device needs to be clarified. The term "mass produced devices," which has not yet been defined, needs to be defined in order to better distinguish between custom-made devices and made-to-measure devices. Consistent definitions must be ensured across all language versions of the MDR.

Proposed wording for "custom-made device" (Art. 2 (3) MDR) (changes marked):
'custom-made device' means any device specifically made in accordance with a written prescription of any person authorised by national law by virtue of that person's professional qualifications which gives, under that person's responsibility, specific design characteristics of the product, which is adapted to the specific requirements of a particular patient, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs.
However, mass-produced devices which only need to be adapted at the point of care in accordance with the manufacturer's validated instructions ~~to meet the specific requirements of any professional user and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of any authorised person,~~ or which are adapted to the anatomical characteristics of an individual patient within a certain range of design specified by the manufacturer on the basis of a written prescription, shall not be considered custom-made devices.

Proposed wording for "mass-produced devices" (Art. 2 (3) MDR):
Mass-produced devices refer to products that are manufactured in a reproducible manner using industrial processes; the quantity of devices manufactured is irrelevant.

3. Involvement of notified bodies (Article 16 MDR)

a) Problem

The bar for the translation of manufacturer information or changes to packaging by distributors or importers is set extremely high. While manufacturers of c lass I products do not even have to certify their quality management system (QMS) in accordance with Art. 10 (9) MDR, distributors and importers who carry out activities in accordance with Art. 16 (2) (a) and (b) MDR are subject to various requirements that entail considerable effort and costs.

The involvement of notified bodies in certain activities of importers and distributors in connection with the repackaging of medical devices and the provision of instructions for use in the correct language version, as required by Art. 16 (4) MDR, also exacerbates the existing capacity bottlenecks there. In addition to certifying medical devices in higher risk classes, these bodies must also accompany, approve, certify, and monitor (on-site audits, packaging activities, translation, labeling, etc.) the quality management system in accordance with Art. 16 (3) MDR in relation to the activities specified in Art. 16 (2) MDR. With currently only 50 notified bodies for the EU and the end of the transition periods for higher-class medical devices in 2027 and 2028, priorities are thus being set differently and important capacities are instead being directed towards integration in accordance with Art. 16 (4) MDR.

The involvement of notified bodies also entails considerable time and financial expenditure (e.g. for audits, certificates, internal capacities, and resources). Since, in case of doubt, distributors bear the costs of their activities pursuant to Art. 16 (2) MDR as well as for the materials, the involvement of notified bodies makes the procedure uneconomical for them. The involvement of a notified body is necessary, for example, for activities such as repackaging, relabeling, or translating instructions for use of medical devices. This leads to the disadvantages mentioned below.

Niche products: Since distributors are not always certified according to ISO 13485 and a certificate according to Art. 16 (4) MDR is probably only offered in combination with ISO 13485, this is a very large

expense for distributors. This will foreseeably lead to niche products being discontinued, especially in smaller national markets within the EU, as distributors will be unable to carry out the necessary activities (enclosing IFUs, labeling, etc.) for market availability due to the certification requirements.

Breaking down bulk products: Distributors normally purchase small items such as CE-marked screws, adhesive pads, cushions, orthotic joints, and other small accessories in large quantities from manufacturers and deliver small quantities to individual customers. The distributor does not know in advance whether the customer will order only one, two, or three of the products. Since distributors will not accept the expense for these products in accordance with Article 16 (3) and (4) MDR, even the smallest medical devices would have to be individually packaged and labeled by the manufacturer, as the distributor is not allowed to/will not change anything on the product packaging. If each screw is not delivered individually packaged, resale by the distributor is no longer possible.

b) eurocom's demand

eurocom requests that class I medical devices be exempted from the necessary involvement of notified bodies in the cases mentioned. To this end, Art. 16 (4) MDR should be amended as follows (addition underlined):

„At least 28 days prior to making the relabelled or repackaged device available on the market, distributors or importers carrying out any of the activities mentioned in points (a) and (b) of paragraph 2 shall inform the manufacturer and the competent authority of the Member State in which they plan to make the device available of the intention to make the relabelled or repackaged device available and, upon request, shall provide the manufacturer and the competent authority with a sample or mock-up of the relabelled or repackaged device, including any translated label and instructions for use. For devices of classes IIa, IIb, III and for devices of classes Ir, Is and Im, the distributor or importer shall submit to the competent authority within the same period of 28 days a certificate, issued by a notified body designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 2, attesting that the quality management system of the distributor or importer complies with the requirements laid down in paragraph 3. "

4. Electronic instructions for use

a) Problem

The instructions for use for medical devices must be available in paper form on a regular basis. Exceptions in the form of electronic instructions for use are only possible in a few cases. Even the amendment to Implementing Regulation (EU) 2021/2226 of June 25, 2025, which essentially enabled electronic instructions for use for medical devices intended for use by professional users, has no effect on the majority of medical devices. Firstly, most class I medical devices are intended for use by laypersons or patients. Secondly, the requirements in the form of a documented risk assessment with eleven prerequisites are too high and therefore hardly feasible.

The negative effects of paper-based instructions for use therefore remain. These include:

- Changes to the instructions for use that are relevant to patients must first be printed and replaced for stored products. Replacement requires a long transition period during which relevant information is withheld from patients. This reduces patient safety.

- The inclusion of printed instructions for use in all mandatory language versions in the countries of distribution or the precise allocation of instructions for use in the corresponding/required language version result in high material and operating costs (increased paper use, larger packaging/boxes, increased storage costs, etc.) and, in paper form, harm the environment due to the high consumption of resources for paper production and the large amount of waste generated during disposal.

An electronic instruction for use, on the other hand, offers several advantages for patients and the environment:

- New instructions for use can be made available to all patients and users in real time.
- New warnings, such as newly discovered contraindications, are immediately available online to all patients and users (regardless of when they purchased the product).
- There is no lengthy detour via the retailer; instead, all important updates reach patients without delay.
- Digital versions have clear advantages in terms of accessibility and patient guidance: adjustable font size, read-aloud function, search function, and even explanatory videos on how to use the device.

For patients without access to electronic instructions for use, a short-term non-electronic option for sending printed instructions by mail should be created, for example, by providing a phone number or postal address.

These options would represent real progress towards greater digitalization.

b) eurocom's demand

eurocom calls for the possibility of widespread use of electronic instructions for use, including for medical devices intended for use by laypersons. If a risk assessment is necessary, it should be carried out as part of general quality and risk management. At the same time, there must be a possibility to take or request the instructions for use in paper form at short notice.

Proposed wording for an amendment to Annex I MDR (changes marked):

"Annex I

Requirements regarding the information ~~supplied~~ provided with the device

23. Label and instructions for use

23.1. General requirements regarding the information ~~supplied~~ provided by the manufacturer

f Instructions for use for medical devices of all risk classes may be provided to the user in non-paper format (e.g. electronic) ~~to the extent, and only under the conditions, set out in Regulation (EU) No 207/2012 or in any subsequent implementing rules adopted pursuant to this Regulation,~~ provided that, following a risk analysis, the residual risks are considered acceptable.

i) *If the instructions for use are provided in electronic form, a direct link to the relevant website must be provided on the device itself or on the next higher packaging level. Links shall be provided in a human-readable format and may be supplemented by machine-readable information, such as Quick Response codes ("QR codes").*"

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