

Statement of eurocom e.V.

dated 2 April 2026

on the European Commission's proposal for the revision of the Medical Device Regulation and In Vitro Diagnostic Medical Devices (MDR and IVDR, Regulations (EU) 2017/745 and (EU) 2017/746) of 16 December 2025

eurocom e.V. is the association of European manufacturers of compression therapy, orthopedic aids and digital health applications. These aids and applications are medical devices within the meaning of the MDR.

I. Introduction and General Remarks

Eurocom expressly welcomes the proposal of the revised MDR. In particular, eurocom highlights the timely submission of the proposal, which required a considerable amount of work from the European Commission, Directorate-General SANTE, within a short timeframe. At the same time, early completion is necessary to ensure that the new regulations come into force in a reasonably timely manner.

In terms of content, eurocom particularly welcomes the objectives of the revision, namely the simplification of regulatory requirements, the reduction of bureaucratic burdens and the enhancement of planning certainty for stakeholders. It is also very positive that the European Commission is focusing especially on small and medium-sized enterprises among the manufacturers in order to promote their competitiveness and thus prevent negative impacts on patient care and public health.

In particular, eurocom views the new regulations on the following topics very positively:

- **UDI direct marking** (Annex VI, Section 4.10 MDR proposal): eurocom welcomes the proposed clarifications and simplifications relating to the UDI system. In particular, the planned exemption for reusable devices intended solely for use on or by a single patient (single patient multiple use) with regard to direct marking in Annex VI, Section 4.10 of the MDR proposal is to be viewed as entirely positive.
Further comments regarding the new regulation are set out under "II. In detail". Eurocom would like to emphasize here the **urgent need for appropriate clarification**, subject to the MDR revision, as otherwise UDI direct marking must be introduced by 27 May 2027, even though this obligation is expected to be lifted again in the near future. Guidance at MDCG level, for example, could be a suitable means of providing such clarification.
- **Clinical evaluation of Class I medical devices**: eurocom welcomes the simplifications and simplifications regarding the clinical evaluation of Class I medical devices (for example in Article 2(48) and Article 61 of the MDR proposal), as this reduces the burden on small and medium-sized enterprises without compromising patient safety.

- **Involvement of Notified Bodies for Class I medical devices** (Article 16 MDR proposal): The new regulation avoids the considerable but unnecessary burden caused by the involvement of Notified Bodies in cases of repackaging, relabeling or niche Class I devices.

In this paper, eurocom addresses individual aspects of the proposal. It is primarily based on eurocom's detailed position paper of 19 September 2024. In doing so, eurocom remains committed to overarching objectives such as the **final regulation of medical devices within the MDR** or the **tighter control of national regulations on medical device law** (demands No. 1 and 8 of the paper). In particular, the demand to make the MDR the definitive legal act for medical devices remains highly relevant in view of the ever-increasing number of directives or regulations under EU environmental law that also affect medical devices. This is even more so given that Recital (98) of the MDR continues to regard this Regulation as the 'sole legal act' for the placing on the market of medical devices. However, this demand will not be discussed further here.

II. In detail

1. Outstanding demands of eurocom

a. UDI direct marking

Eurocom **welcomes** the proposed clarifications and simplifications relating to the UDI system.

In view of the proposed new provision in Article 17(2) of the MDR proposal in conjunction with Annex I, Section 23.4(n) of the MDR proposal, it should be clarified in this context that such 'single patient, multiple use' devices – in particular medical devices such as compression stockings or orthoses – are **not** subject to **reprocessing** within the meaning of Article 2(39) of the MDR. Consequently, they do not require any guidance on suitable reprocessing procedures. To this end, a corresponding clarification for 'single patient, multiple use' Class I devices should be included in Annex I, Section 23.4(n) of the MDR proposal or in the definition in Article 2(39) of the MDR.

It is also worth noting positively that the Commission is to be tasked, by means of implementing acts, with providing further **appropriate simplifications** for highly customised or customisable devices, taking into account their risk class, the number of devices on the market and the burden associated with the UDI rules (Article 27(11)(c) of the MDR proposal). Custom-made or customisable Class I medical devices in particular are currently subject to a disproportionate burden under the UDI system. At the same time, they compete for comparable indications with custom-made devices that are not subject to any UDI requirements. The Commission should therefore take prompt action in the context of the MDR reform to remedy this distortion of competition to the detriment of CE-marked devices.

There is a need for action through a **provisional regulation** due to the **obligation for direct UDI marking** that remains in force. From 27 May 2027, manufacturers of Class I devices will be obliged to apply this marking and must adapt their production accordingly. With the amendment to Annex VI, Section 4.10 of the MDR proposal, this obligation is expected to lapse shortly thereafter upon the entry into force of the revised MDR. Manufacturers of devices already available on the market for 'single patient multiple use' would therefore have to formally implement a provision through changes to the device design, which the legislator already considers, as is foreseeable, to be ineffective and obsolete. This

would result in unnecessary implementation costs, whereas the new regulation is intended to avoid such costs. In view of the transitional period still in force, during which the MDR reform will not yet enter into force, a clarifying provisional regulation is necessary, subject to the entry into force of the new wording. A clarifying MDCG Guidance may already be suitable for this purpose.

b. Distinction between custom-made and made-to-measure devices (Article 2(3) MDR and other provisions)

Eurocom's call for a **legally clear distinction** between custom-made devices on the one hand and CE-marked custom-made devices on the other has not yet been incorporated into the reform proposal.

Currently, there is only a definition of a custom-made device in Article 2(3) of the MDR. Adaptable medical devices and patient-matched medical devices, each of which requires CE marking, are addressed only in a negative sense, in the form of a specific exception in Article 2(3) of the MDR, the details of which are unclear. Internationally recognised definitions are now available in the IMDRF PMD WG/N49 FINAL: 2018. The Q&A in MDCG 2021-3 also refers to these, although it is not legally binding.

In the interests of legal certainty and clarity of the MDR, these definitions must be regulated in a binding manner in accordance with the IMDRF. eurocom therefore maintains its call for a statutory regulation and demarcation of the various device categories in connection with Article 2(3) of the MDR. This demand is particularly necessary in view of the planned new provision in Article 27(11)(c) of the MDR, in order to establish a legally certain distinction from custom-made devices in relation to highly individualised devices (*'highly individualised characterisation of those devices'*).

c. Classification of medical software (Annex VIII, Chapter III, Section 6.3 of the MDR Proposal)

Eurocom welcomes, in principle, the fact that the reformulation of Rule 11 clearly follows a **risk-based approach**. The aim is to allow software with a low risk profile to be classified as a Class I device once again.

However, eurocom sees a clear risk that, due to ambiguities in the reformulation, medical software in borderline cases might even have to be classified as at least Class IIa. This is inappropriate and does not correspond to the risk-based approach.

As a starting point, the clear alignment of the reformulation of Rule 11 with the IMDRF guidelines (IMDRF/SaMD WG/N12FINAL:2014 and IMDRF/SaMD WG/N81 FINAL: 2025) is to be expressly welcomed and medical software should, in principle, be classified as Class I. In the exceptional cases listed in indents 1–3, it must be made absolutely clear, in accordance with the IMDRF guidelines, that the first criterion in each case refers to the intended purpose of 'to treat or diagnose'. This is already laid out in the proposal for the new Rule 11, particularly with regard to the distinctions in Chapter 5 of IMDRF/SaMD WG/N12FINAL:2014 between 'treat and diagnose', 'drive clinical management' and 'inform clinical management', but the wording is not clear or legally certain. At the same time, it is unclear why the proposal for a new Rule 11 once again lists all medical purposes specific to Article 2(1) of the MDR at the outset, given that the classification can only be relevant for software that constitutes a device within the meaning of the MDR.

Eurocom calls for a clarifying revision of Rule 11 with the aim of enabling the classification of the following software applications in Class I in future: monitoring of wearing behaviour, feedback on wearing duration, exercise instructions, training plans and hygiene instructions for Class I medical devices, which themselves belong to the lowest risk class.

Rule 11 should therefore be worded as follows (this is a revised proposal based on the position paper of 19 September 2024; changes are shown in bold or struck through):

*„Software which is ~~intended to generate an output that confers a clinical benefit and is used for diagnosis, treatment, prevention, monitoring, prediction, prognosis, compensation or alleviation of a disease or condition~~ **a device in accordance with Article 1 (4) of this Regulation** is classified as class I, unless the output is intended for ~~a disease or condition~~ **one of the following situations:***

- **to treat and diagnose** in a critical situation with a risk of causing death or an irreversible deterioration of a person's state of health, in which case it is classified as class III;
- **to treat and diagnose** in a serious situation with a risk of causing a serious deterioration of a person's state of health or a surgical intervention, or to drive clinical management in a critical situation in which cases it is classified as class IIb;
- **to treat and diagnose** in a non-serious situation, or to drive clinical management in a serious situation or to inform clinical management in a critical or serious situation in which cases it is classified as class IIa.”

Furthermore, for reasons of legal certainty, it is imperative to define the respective key terms 'to treat and diagnose', 'drive clinical management' and 'inform clinical management', as well as 'critical situation', 'serious situation' and 'non-serious situation', in the MDR in accordance with the IMDRF's risk-based approach. This can be done within the definitions in Article 2 of the MDR or in the general part of Annex VIII to the MDR. Furthermore, legally certain classification can be facilitated by providing examples in a dedicated borderline document.

Incidentally, eurocom welcomes the Commission's efforts to finally centralise the regulation of **medical AI systems**, including high-risk AI systems, in the MDR on a sector-specific basis. A prerequisite here is also the harmonisation of the currently ongoing transition periods of the AI Act, as currently envisaged in the Digital Omnibus AI.

d. Electronic Instructions for Use (eIFU) (Annex I Section 23.1 lit. f MDR)

Eurocom does not consider the regulations to be sufficient, as **devices intended for use by lay person** are exempt from the eIFU.

This is inconsistent with both the goal of reducing bureaucracy and that of protecting the environment. Furthermore, accessibility is insufficient in pure paper format, as there is neither a read-aloud function nor a search or translation function. Patient safety is also enhanced by the rapid provision of updates (for example, new contraindications) in the instructions for use. An eIFU can be updated in all EU languages within a few weeks and provided with the necessary information to ensure patient safety. Replacing the paper version, by contrast, can take up to six months.

Similarly, eurocom points out that, according to the proposal 'Directive of the European Parliament and of the Council establishing a Union Code on Medicinal Products for Human Use and repealing Directive 2001/83/EC and Directive 2009/35/EC', of 23 April 2023, an electronic version with the option to request a printout is envisaged. As medicinal products are regularly dispensed directly to patients, there is a high degree of comparability with medical devices intended for use by the general public.

A good interim step would therefore be the hybrid option for these medical devices as well: eIFU as the norm, paper format on demand. Eurocom therefore stands by this demand. Implementation should take place immediately as part of the MDR reform in Annex I, Section 23.1(f) MDR, to the effect that the eIFU is regarded as the norm in future. Although an amendment to Implementing Regulation (EU) No 207/2012 is also a viable option, a future-proof solution should preferably be implemented at the level of the higher-ranking MDR, and the current MDR revision should be used as a good opportunity to adapt the instructions for use.

2. Further content of the proposal

a. Simplifications regarding the qualifications and availability of the person responsible (Article 15(1) and (2) MDR proposal)

Eurocom welcomes the simplification of the **availability** of the person responsible for regulatory compliance (PRRC) for SMEs under Article 15(2) of the MDR proposal.

However, eurocom criticises the planned removal of requirements regarding the PRRC's **qualifications**, as this could significantly weaken the PRRC's position within the company and in their cooperation with the authorities. This cooperation must take place on an equal footing and be based on professional competence. This applies particularly in the context of vigilance tasks. Furthermore, relaxed and ultimately unclear qualification standards render the PRRC interchangeable, which hinders the fulfilment of their important duties within the company. Without strict and substantively appropriate qualification requirements, there is also a risk of distortions of competition, particularly and above all to the benefit of manufacturers in third countries, for whom circumventing the rightly stringent requirements for the PRRC would effectively be made easier.

b. Ombudsperson for conflicts between manufacturers and notified bodies (Article 35 MDR proposal)

Eurocom **welcomes** this new provision on general grounds. Proceedings before ombudspersons can be an effective way of countering undesirable developments.

Eurocom strongly encourages consideration of establishing a **comparable procedure** for cooperation between **manufacturers and the competent national authorities**. This is because, here too, it is evident that administrative practices in the Member States often differ significantly from one another, and manufacturers are confronted with differing official interpretations (particularly in national language versions) of the MDR. Furthermore, national authorities in Member States naturally have varying levels of practical experience with European medical device regulation. Consequently, manufacturers are in most cases unable to enforce the legal protection to which they are theoretically entitled within the framework of a multitude of different national administrative procedures and procedural laws, or can do

so only at immense cost, and are thus at a massive disadvantage compared to markets which, unlike the European Union, also have uniform administrative and procedural legal structures.

c. Expert panels to advise the European Commission (Article 106, 106a MDR proposal)

Eurocom welcomes the expansion of the role of *expert panels* to bring greater expertise in the field of medical devices to bear. A boundless expansion of procedures and costs should be avoided in this regard.

In this context, too, consideration should be given to whether the selective establishment of expert panels for specific subject areas, primarily concerning higher-class devices, might not be better addressed through access to ombudsman offices, which are also more widely accessible to Class I manufacturers.

d. Digital versions of the technical documentation and other documents (Article 19 MDR proposal, Article 110a MDR proposal)

Eurocom welcomes the new regulation as a procedural simplification. At the same time, eurocom suggests a clarification to protect trade secrets in the event of any evaluation by the authorities using AI.

e. Requirements for other clinical investigations (Article 82 MDR proposal)

Eurocom takes a **critical view** of the repeal of Article 82 of the MDR, as this could lead to even greater divergence between national regulations governing other clinical investigations than has been the case to date. There are concerns that this could result in further distortions of competition between national research centres.

At the same time, it should be clarified that the Commission's proposed rewording of the introductory sentence in Article 62(1) of the proposed MDR does not mean that what have hitherto been termed 'other clinical investigations' – namely those conducted for scientific purposes – will, following the repeal of Article 82 of the MDR, be subject without distinction to the requirements of Article 62 et seq. Rather, the recent implementation of other clinical investigations, which is largely left to national legislators, should at least be retained. There appears to be no grounds for stricter regulation of other (scientific) clinical investigations.

f. Trend reporting (Article 88(1) MDR proposal)

Eurocom considers that the new wording of Article 88(1) of the MDR poses a risk of generating a **higher volume of trend reports that are of no real relevance to patient safety**. According to the unanimous view of eurocom member companies, the obligation to report trends that are not serious incidents has, since the MDR came into force, proven to be of no significance for patient safety requirements regarding low-risk medical devices. Nevertheless, even manufacturers of Class I devices must implement such reporting processes, which are irrelevant to them in practical terms.

Eurocom therefore calls for Class I medical devices to be exempted from the obligation to report trends.

**eurocom e. V. – European Manufacturers Federation
for Compression Therapy and Orthopaedic Devices**

Reinhardtstr. 15, D-10117 Berlin

Telefon: 030 – 25 76 35 060

Email: info@eurocom-info.de

www.eurocom-info.de