

## **Position of eurocom e.V. of September 19, 2024**

### **Evaluation of the Medical Device Regulation**

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

#### **I. Introduction and summary**

As manufacturers of medical aids, eurocom's member companies are part of a very good healthcare system in Germany and many other countries in the European Union (EU). They are the driving force behind many innovations in the medical aid sector, ensuring rapid healing, less pain, fewer costly operations, and a faster return to work. In Germany alone, around 25 million patients benefited from medical aids for compression therapy, orthopaedic insoles, bandages, orthoses, prosthetic aids, and breast care devices, i.e., the medical aids manufactured by eurocom's member companies.<sup>1</sup>

EU-wide regulations, such as the Medical Device Regulation (EU) 2017/745 (MDR) and numerous other EU regulations, ensure equal standards and requirements within the EU. At the same time, they impose a straitjacket of specific provisions for medical devices or general rules that also apply to medical devices. eurocom's members are mostly small and medium-sized companies with limited financial and human resources. For these companies in particular, the numerous regulatory requirements of the MDR represent a significant burden. In our 2024 Member Survey, 89.7 percent of members saw the MDR as the number one cost-increasing regulation.

Furthermore, it is now generally acknowledged that the Medical Device Regulation often creates excessive regulatory hurdles, particularly with regard to long-standing and well-established medical devices in the lowest risk class. Cost and effort will render production uneconomical and thus hinder health care provision and the development of innovative devices. Especially with these low-risk devices in class I the increased effort required for regulatory compliance would not contribute towards achieving increased patient safety.

eurocom therefore expressly welcomes the EU Commission's decision to bring forward the evaluation of the MDR to 2024 and calls for an appropriate revision of the MDR to reduce hurdles, simplify processes, and resolve ambiguities.

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<sup>1</sup> Representative survey by the Allensbach Institute for Public Opinion Research commissioned by eurocom e.V.: Survey results 2023, page 6: 5.9 million users of medical compression stockings, 12.1 million users of orthopaedic insoles, 6.8 million users of bandages/orthoses. Furthermore, 150,000 prosthesis users are affected, as are 75,000 women with recently diagnosed breast cancer in need of breast care devices.

**eurocom is calling for the following measures:**

- **A final MDR:** The Medical Device Regulation should be the central regulatory framework for the manufacture of medical devices, which is undermined by numerous cross-sectoral “horizontal” legal acts. This results in less appropriate provisions and uncertainty about applicable regulations. This is why the MDR must become the final regulatory framework for medical devices at the EU level. Other regulatory frameworks either exclude medical devices entirely or include additional provisions in the MDR.
- **UDI direct marking:** The UDI direct marking requirement for devices used multiple times on a single individual (single patient, multiple use) is excessive. eurocom calls for the necessary clarifications in the MDR to avoid the UDI direct marking requirement for these devices.
- **Differentiation between custom-made and patient-matched devices:** 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. eurocom calls for clear definitions of the terms “patient-matched,” “custom-made,” and “mass-produced devices” in the MDR.
- **Clinical evaluation for class I medical devices:** For class I medical devices, the requirements for clinical evaluation are higher than necessary for patient safety. Therefore, clear rules should be set under which a clinical evaluation for class I medical devices is only required to a limited extent, for example, if the device corresponds to similar devices already on the market or if it is based on simple physical principles.
- **classification of medical software:** If medical software provides the medical doctor or therapist with information which is used to take decisions with diagnosis or therapeutic purposes, it will be classified as at least class IIa and a notified body is required. This imposes a disproportionate burden on the companies and strains the limited capacities of the notified bodies. The classification of software as a medical device needs to be adjusted: classification should be based on the risk level. Medical software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes should be strictly classified as a class I medical device.
- **Involvement of notified bodies for class I medical devices:** The MDR requires distributors of class I medical devices to involve a notified body in certain cases, such as breaking down, repackaging, relabelling or translating instructions for use of medical devices. This is often very time-consuming and uneconomical for distributors, without significantly increasing patient safety. Many distributors shy away from this effort, with the result that these services are not available to patients. eurocom calls for class I medical devices to be exempted from the necessary involvement of notified bodies regarding the above-mentioned activities of distributors.
- **Electronic instructions for use:** Exclusively electronic instructions for use of medical devices are still only permitted in very few exceptional cases. In this case, systematic digitization is necessary by allowing exclusively electronic instructions for use. For patients without access to the electronic instructions for use, a short-term non-electronic option for sending the printed instructions for use by post must be created.

- **National regulations:** The MDR is binding and directly applicable in every EU member state. However, there are specific national regulations in the Member States. Although the MDR provides for such opening clauses for national law, this leads to numerous special national regulations in practice. eurocom therefore calls for a review of the opening clauses for the Member States for their necessity and effectiveness. National supplementary rules must be reduced to a minimum. The priority of the MDR over conflicting national regulations must be more strictly monitored and sanctioned.

## II. Individual demands

### 1. A final MDR

#### a) Problem

The primary objective of the MDR is to ensure a high level of protection of health for patients and users. Consequently, the MDR sets high standards of quality and safety for medical devices in order to meet common safety concerns as regards such products. Due to the specific regulatory matter, the given complexity, and the high safety relevance resulting from the use of the products on and in humans, the objective of the MDR is, according to Recital (98), to constitute a single legislative act for medical devices.

This very positive and, in the past, fundamentally successful approach is increasingly coming under pressure due to the increasing dynamics and quantity of cross-sectoral legislation on product safety and product-related environmental protection. In particular, Regulation (EU) 2023/988 on general product safety and Regulation (EU) 2023/1542 concerning batteries and waste batteries are representative of countless horizontal issues. This will weaken the innovative capacity of the European medical technology industry, at least in the medium term. Moreover, the availability of innovative and high-quality medical devices will be permanently jeopardised. The member companies of eurocom take aspects of environmental pollution and waste of resources very seriously. However, the field of medical devices is concerned with sick people in need of care who are supported with closely monitored products, for example, by alleviating illnesses, compensating for disabilities, or treating injuries. The objective is to keep the patient in focus and to find a balance between sensible regulations for medical devices and the impact on the environment.

#### b) eurocom's demands:

In this area of conflict, eurocom is advocating for a path that is both constructive and proactive. Since the path of largely integrated life cycle regulation has already been taken in numerous other product areas, this path should also be considered for medical devices. Since the path of largely integrated life cycle regulation has already been taken in numerous other product areas, this path should also be considered for medical devices. A prime example of this is pharmaceuticals, which are very successfully regulated at the European level with a largely self-contained regulatory framework. Medical devices may be more heterogeneous and complex in their design and the associated requirements, but they essentially differ from pharmaceuticals only in their mode of action.

By focusing more strongly on the MDR as the only regulatory framework for medical devices, there is a unique opportunity to combine the innovative capacity of the medical technology industry for the benefit of maximum patient protection with the undoubtedly essential issues of environmental and climate protection. This also has the advantage that new regulations are processed from the start by the EU authorities responsible for the MDR with specialist expertise in medical devices. This saves time and effort by reducing coordination among EU authorities. Integrated regulation is the right way to ensure that the MDR's requirements for transparency, legal certainty, and protection are sustainable and environmentally friendly, even in the face of increasing volatility, complexity, and ambiguity, for the benefit of patients and users of medical devices.

eurocom's demands: The MDR becomes the final regulatory framework for medical devices at the EU level. Other regulatory frameworks either exclude medical devices completely or include additional provisions in the MDR.

## **2. Definition of reuse – Consequences for UDI direct marking on the device**

### **a) Problem**

The MDR pursues two objectives with equal intensity:

First, the establishment of clear standards of quality and safety for medical devices to protect patients (Recitals (1) and (2) MDR). Second, the establishment of a smooth functioning internal market, explicitly taking into account small and medium-sized enterprises (SMEs) (Recital (2) MDR). eurocom strongly supports these objectives and emphasises that patient protection and fair competition in the internal market are the foundations for high-quality and innovative medical device provision.

The majority of medical devices provided to patients are class I devices (in the lowest risk class). In Germany, these devices are predominantly produced by medium-sized enterprises. For these companies, the implementation of the MDR, which class I products have had to fully comply with since 26 May 2021, has shown that the financial and human resources required to implement the new regulations are disproportionate to the risk associated with products that have often been successful in the market for decades. A typical example is the supply of medical compression stockings, bandages, orthoses, or prosthetic components. In this case, additional regulatory hurdles will often not result in improved safety for patients, but would lead to higher costs for medical devices, which would put additional strain on the solidary financed health care system and may even jeopardise high-quality and innovative patient care in the future.

The problems posed by the requirements of the MDR for the medical aids sector can be exemplified by the excessive requirements for direct marking of devices for unique device identification purposes (Unique Device Identifier - UDI).

### **Excessive requirements for UDI direct marking for devices used multiple times on a single individual (single patient, multiple use)**

Medical aids classified as class I devices are typically intended to be used multiple times by a single patient but are subject to UDI direct marking requirements that are not justified by improved safety. This

leads to unnecessarily increased development and manufacturing costs, making the provision of medical aids to patients more expensive and distorting competition in the medical aid market.

The UDI system introduced by the MDR requires affixing a UDI in addition to the existing labelling requirements for medical devices.<sup>2</sup> The so-called UDI carrier (AIDC and HRI representation of the UDI) must be placed on the label or on the device itself and on all higher levels of device packaging.<sup>3</sup>

However, special requirements apply to reusable devices, as set out in Annex VI, Part C, Section 4.10 MDR:

- Pursuant to Annex VI, Part C, Section 4.10, Sentence 1 MDR, devices that are reusable shall bear a UDI carrier on the device itself.
- Pursuant to Annex VI, Part C, Section 4.10, Sentence 2, and Section 6.2 MDR, additional special requirements apply to reusable devices that require cleaning, disinfection, sterilisation, or refurbishing between uses. In this case, the UDI carrier shall be permanent and readable after each process performed to make the device ready for the subsequent use throughout the intended lifetime of the device (“direct marking”). Typical examples of this are reusable surgical instruments that require cleaning and sterilisation after each surgical use with a specific reprocessing cycle as set out in Article 2(39) MDR.

Considering Sentence 1 and Sentence 2 of Annex VI, Part C, Section 4.10 MDR together, we can conclude that reusable devices that do not require cleaning, disinfection, sterilisation, or refurbishing between uses with a specific reprocessing cycle as set out in Article 2(39) MDR shall also bear a UDI carrier on the device itself. Pursuant to Annex VI, Part C, Section 4.10, Sentence 3 MDR, exemptions from the direct marking requirements are only made in exceptional circumstances, i.e., if direct marking would interfere with the safety or performance of the device or if the device cannot be directly marked because it is not technologically feasible.<sup>4</sup>

The obligation to place the UDI carrier on the device itself applies to all class I devices that are reusable as of 26 May 2021 (Article 123(3)(g)(iii) MDR).

Which products are considered to be reusable is not defined in the MDR. This can only be concluded by reversing the definition of single-use devices as set out in Article 2(8) MDR, according to which “single-use device” means a device that is intended to be used on one individual during a single procedure.

The classification as a reusable device or as a single-use device is primarily made by the manufacturer. If a device is not explicitly intended for single-use according to the manufacturer's indication,<sup>5</sup> it is a reusable device (in this case, the manufacturer must include appropriate information in accordance with Annex I, Section 23.3, Subparagraph n and, if necessary, Subparagraph o MDR, in particular care instructions to extend the life of the product as well as, e.g., signs of wear and tear indicating that the product is no longer safe to use).

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<sup>2</sup> Annex VI, Part C, Section 2.1 MDR.

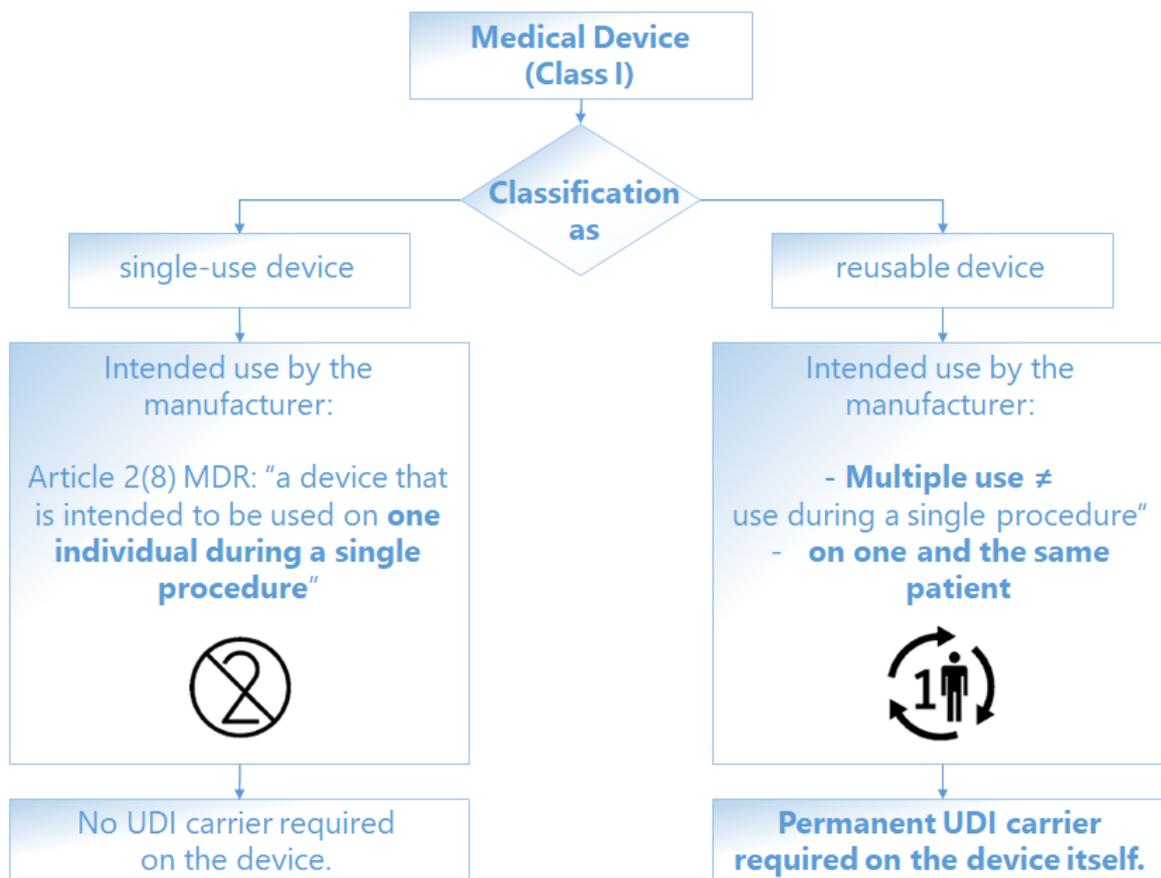
<sup>3</sup> Article 27(4) MDR, Annex VI, Part C, Section 4.1 MDR.

<sup>4</sup> See also the Unique Device Identifier (UDI) FAQs, Helpdesk, Number 5, available at [https://eu-udi.zendesk.com/hc/article\\_attachments/5309461882641/Factsheet\\_Helpdesk\\_UDI\\_FAQs\\_EN\\_FINAL.pdf](https://eu-udi.zendesk.com/hc/article_attachments/5309461882641/Factsheet_Helpdesk_UDI_FAQs_EN_FINAL.pdf), version of 1<sup>st</sup> March 2022.

<sup>5</sup> Annex I, Section 23.2, Subparagraph n MDR.

According to this reverse definition, devices intended to be used multiple times on one individual (“single-patient, multiple-use”) are reusable devices within the meaning of the MDR. Pursuant to Annex VI, Part C, Section 4.10, Sentence 1 MDR, such devices shall also bear a UDI carrier on the device itself.

The following chart illustrates the different consequences of classifying devices as “single-use devices” and “reusable devices.”



**Result: Increased consumer costs**

For certain class I devices essential to the provision of high-quality, affordable medical aids, compliance with this requirement necessitates costly changes to the products’ design and manufacturing process. These include, for example, medical compression stockings, bandages, orthotics, or orthopaedic insoles. In these cases, direct marking is not possible by simply sticking a label on the product. This kind of class I device is typically used by a single patient over an extended period of time and should be cleaned on a regular basis for hygienic reasons. A label sticker would quickly peel off due to cleaning or daily use. In practice, manufacturers of such devices are required to develop complex technical solutions and complete a conformity assessment procedure to place a permanent and readable UDI carrier on a product that is only being used by a single individual. Please note that this is in addition to the UDI placed on the first level of packaging, which is also provided to the patient.

This means that the aforementioned aids are de facto subject to significantly higher technical requirements for “direct marking” that, as can be concluded from Annex VI, Part C, Section 4.10, Sentence 2, are only intended for reusable devices used on multiple patients in professional settings for which a specific reprocessing cycle, including testing and restoring the technical and functional safety of the used device, is required between patient uses. For such products (e.g., reusable surgical instruments), direct marking also ensures that the number of reprocessing cycles can be tracked by recording the UDI in the Central Sterile Services Department to facilitate easier traceability.

The direct marking requirements for established class I devices lead to increased costs for consumers and the solidary system without improving the safety of the medical devices. There are no known relevant incidents that would require improved traceability through direct marking for single patients. The desired traceability of the number of reprocessing cycles is equally unnecessary for the aforementioned aids, which are intended to be used by a single patient. On the contrary: the aim of increasing patient safety is even jeopardised by unnecessarily increasing consumer costs and the resulting imminent decrease in the supply of high-quality medical aids, as these can no longer be produced economically at the prices previously reimbursed by the health insurance funds.

### **Result: Distortion of competition in relation to single-use and custom-made devices**

For manufacturers of CE-marked medical aids intended for reuse by a single patient, direct marking leads to distortion of competition in two respects:

- They are disadvantaged compared to single-use devices. Single-use devices are not subject to the direct marking requirements.<sup>6</sup> This is why single-use devices can be offered at cheaper prices. However, in the interest of sustainability, manufacturers should not be encouraged to classify more and more products in the home healthcare sector as single-use and thus disposable products.
- They are disadvantaged compared to custom-made devices within the meaning of Article 2(3) MDR. Custom-made devices are also defined as intended for the sole use of a particular patient. The intended purpose and indications for use of custom-made devices and devices requiring CE marking are often identical in the medical aids sector. One example of this would be orthopaedic insoles or orthoses, which are available as custom-made products and as CE-marked products that can be adapted to suit an individual patient’s features.<sup>7</sup> Custom-made devices have been exempted from the UDI requirements from the start and therefore require no direct marking.

Obviously, the fact that the direct marking requirements are limited to CE-marked, reusable products cannot be justified by differences in patient safety.

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<sup>6</sup> As stated in the last sentence of Number 5 of the Unique Device Identifier (UDI) FAQs, Helpdesk, available at [https://eu-udi.zendesk.com/hc/article\\_attachments/5309461882641/Factsheet\\_Helpdesk\\_UDI\\_FAQs\\_EN\\_FINAL.pdf](https://eu-udi.zendesk.com/hc/article_attachments/5309461882641/Factsheet_Helpdesk_UDI_FAQs_EN_FINAL.pdf), version of 1 March 2022.

<sup>7</sup> As defined in MDCG 2021-3 – Q&A on Custom-Made Devices.

#### **b) eurocom's demands:**

eurocom calls for the necessary clarifications in the MDR to avoid the UDI direct marking requirement for single-use devices intended to be used multiple times on one individual. eurocom makes the following suggestions:

- 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.
- In addition, the definition in Article 2(39) MDR should be worded more precisely:  
"Reprocessing" means a process carried out on a used device under the responsibility of a professional reprocessor so that it can be safely reused by a non-layman user. These processes include cleaning, disinfection, sterilisation, and related procedures, as well as testing and restoring the technical and functional safety of the used device.

### **3. Definition and differentiation of custom-made / patient-matched**

#### **a) Problem**

As a general rule, medical devices and their accessories bear the CE marking, with the exemption of custom-made devices as defined in Article 2(3) MDR. In addition, custom-made products are privileged in many respects compared to medical devices with CE marking requirements by excluding manufacturers of custom-made products from certain general obligations; in fact, manufacturers of custom-made devices shall follow the procedure set out in Annex XIII MDR.

Even though 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 are significant ambiguities in the MDR in particular with regard to class I devices in the field of compression aids as well as the provision of prostheses and orthoses. In particular, the differentiation between custom-made devices as defined in Article 2(3) MDR, and patient-matched medical devices, which do not fall under the definition in Article 2(3) MDR, is often not clear. Furthermore, the term "patient-matched" is not defined in the MDR. Merely reversing the definition of custom-made devices in the second subparagraph of Article 2(3) MDR often does not allow a clear classification. In practice, different language versions and preconceptions in particular lead to a completely different classification and regulatory handling of the same product by the market surveillance authorities of the Member States. For example, the criterion that mass-produced devices shall not be considered to be custom-made devices laid down in the second subparagraph of Article 2(3) MDR in the English language version suggests that patient-matched medical devices are mass-produced, where it is only a matter of potential reproducibility in serial industrial processes.

Besides, the general obligations of manufacturers under Article 10 MDR also apply to manufacturers of custom-made devices. Although custom-made devices are explicitly excluded from some obligations or subject to special regulations (e.g., in Article 10(4) and (5) in conjunction with Annex XIII, Article 10(6),

and (7) in conjunction with Article 27(1) MDR). Furthermore, a large part of the general obligations also apply to manufacturers who exclusively produce custom-made devices. Practice has shown that many of the remaining obligations, which are designed solely for industrially developed and manufactured products, cannot be fulfilled appropriately or at all by typically artisanal manufacturers of custom-made products. The specific characteristics of custom-made devices are not sufficiently considered in Article 10 MDR, e.g., the development documentation pursuant to Article 10(9)(g) MDR, or the overly complex requirements for clinical evaluation, including clinical follow-up, pursuant to Article 10(3) MDR.

#### **b) eurocom's demands:**

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 (Recital (2), Sentence 1). To remedy this situation, eurocom calls for:

#### **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. 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.

*Proposed wording for “custom-made devices”:*

*‘Custom-made device’ means any device specifically made in accordance with a written prescription which gives specific design characteristics, is specifically adapted to meet 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. Mass-produced devices, which only need to be adapted or assembled at the point of care, in accordance with the manufacturer’s validated instructions, to suit an individual patient’s specific anatomic-physiological features, or which are manufactured in accordance with a written prescription, within a certain design scope specified by the manufacturer, to suit an individual patient’s anatomic-physiological features, shall not be considered to be custom-made devices.*

*Proposed wording for “mass-produced devices”:*

*‘Mass-produced device’ means any device which is reproducibly produced by means of industrial manufacturing processes; the number of products manufactured is 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 is at risk if manufacturers of custom-made devices find themselves forced to cease their activities due to non-transparent and inappropriate regulatory requirements.

eurocom thus calls for a 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 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 could be remedied in a targeted and legally compliant manner through special regulations in Annex XIII MDR.

## **4. Clinical evaluation and proof of clinical benefits**

### **a) Problem**

The clinical evaluation of medical devices is an extremely complex and costly process. It includes the systematic evaluation and analysis of relevant clinical data to confirm the safety and performance of the product. Especially for class I medical devices, the requirements are set too high for the following reasons:

*Established safety and performance data:* For established therapeutic methods and class I medical devices, there is often extensive safety and performance data from many years of clinical use. These data demonstrate that the product is safe and effective, reducing the need for additional clinical evaluations.

*Low risk profile:* class I medical devices are classified as low risk and typically require less stringent regulatory requirements compared to higher-class devices. Since the risk profile is low, conducting complex clinical evaluations and, where required, clinical trials is disproportionate.

*Available literature and data:* For established therapeutic methods, extensive scientific literature and databases may already exist that prove the effectiveness and safety of the product. As this information is already available, an additional clinical evaluation is redundant.

*Resource optimisation:* Conducting clinical trials is time-consuming and costly. For products with a long history of clinical use and a low risk profile, resources could be more efficiently invested in other areas such as product improvement/innovation, training of medical personnel, or quality assurance.

*Harmonisation with international standards:* In some cases, international regulatory authorities and standards may already have established recognised safety and performance standards for class I products. A clinical evaluation may be unnecessary in such cases and may not contribute to additional safety or performance.

*Equivalence:* The equivalence approach in the clinical evaluation of class I devices is currently too limited. In its current form, it often hinders manufacturers' individual innovations and delays the introduction of new products to the market.

#### **b) eurocom's demands:**

To remedy this situation, eurocom calls for:

##### **Lowering the requirements for clinical evaluation**

The requirements for the clinical evaluation of class I devices must be reduced. Instead, clear rules should be laid down under which clinical evaluation is only required to a limited extent, for example, if the product corresponds to similar products already on the market or is based on simple physical principles. This would reduce the burden on manufacturers and facilitate market entry without compromising the safety of patients and users. It is important that these changes continue to ensure the protection of public health through increased monitoring of other aspects of product quality and safety. For example, post-market surveillance (PMS), including post-market clinical follow-up (PMCF), could provide adequate confirmation of safety and performance.

##### **Facilitating clinical evaluation using data from similar devices (equivalence pathway)**

The experience gained to date with the equivalence pathway, which is very limited under the MDR, must be used as an opportunity to significantly facilitate the use of clinical data from similar products, especially for products with a low (risk) class. For example, by reducing the equivalence criteria or replacing the equivalence pathway with approval based on scientific literature reviews, the capacity for innovation in the medical device sector, which is under pressure due to sometimes excessive requirements in clinical evaluation, can be promoted again.

By integrating PMS and PMCF processes, manufacturers can continue to monitor and ensure the safety and performance of their products. This can help support innovation processes and facilitate access to new and improved medical devices.

##### **Exemptions from the clinical evaluation process for devices with a low risk profile**

Furthermore, for devices in the lowest risk class I, fundamental consideration should be given to introducing a product listing system based on established, similar product categories. The structure of the US FDA's Medical Device Exemptions 510(k) could be used as an example. This could also contribute to the standardisation of international requirements and, thus, to supporting the international competitiveness of EU manufacturers, which is under pressure.

## 5. Software

### a) Problem

Since the MDR came into force, the classification of software as a medical device has led to significant obstacles to innovation without creating any added value in terms of patient safety through the virtually consistent higher classification of software. According to the implementing rules of Annex VIII, Chapter II, Section 3.3 MDR, stand-alone software shall be classified in its own right.

The provision in Section 3.3 reads as follows:

*“Software, which drives a device or influences the use of a device, shall fall within the same class as the device.*

*If the software is independent of any other device, it shall be classified in its own right.”*

For stand-alone software, a new classification rule was introduced under Rule 11 of the MDR (Annex VIII, Chapter III, Section 6.3 MDR). Rule 11 reads as follows:

*“Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause:*

- *death or an irreversible deterioration of a person's state of health, in which case it is in class III; or*
- *a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb.*

*Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb.*

*All other software is classified as class I.”*

As soon as medical software provides the medical doctor or therapist with information which is used to take decisions with *diagnosis* or *therapeutic* purposes, it will be classified as at least class IIa and a notified body is required. No distinction is made as to whether the software merely provides information, or makes decisions itself, or provides recommendations to support healthcare professionals in making diagnostic or therapeutic decisions. Based on the wording and structure of Rule 11, there is consequently no software with a diagnostic or therapeutic purpose that can still fall into class I. The last paragraph of Rule 11, which provides for classification in class I as a catch-all measure, is virtually meaningless, since software that qualifies as a medical device but has no diagnostic or therapeutic purpose is virtually non-existent.

Rule 11 is explained in the MDCG 2019-11 guidance. In Annex III of the MDCG 2019-11 guidance, Rule 11 is explained in a table based on the IMDRF risk categories. However, the MDCG 2019-11 guidance does not solve the problem with Rule 11. By referring to the IMDRF risk categories in Annex III of the MDCG 2019-11 guidance, an explanation of the categories of critical, serious, and non-serious is provided. However, no distinction is made as to whether the software itself makes decisions or merely provides information for decision-making to healthcare professionals. For diagnostic or therapeutic software, the severity of the healthcare situation or patient condition is the only factor taken into account. The probability of occurrence is not accounted for. Even if the software provides information

used to make decisions with diagnostic or therapeutic purposes, the probability of a hidden risk potential is much lower if the information is only provided, but a healthcare professional must make the decision as an intermediary and the software is used only to support the decision, alongside other sources of information. In this situation, the probability of identifying potential risk factors should also be taken into account, which is not possible under Rule 11.

The scope of application of Rule 11 itself is also problematic, as it is not limited to so-called stand-alone software, but also covers embedded software in devices, provided that it has functions that go beyond simply controlling the device. According to the wording, this could also include software applications related to the manufacturing of a (physical) medical device, e.g., for 3D printing technologies. Furthermore, the distinction between diagnostic, therapeutic, and other purposes is very fuzzy, which consistently leads to completely different interpretations by the competent authorities, where a legally sound basis for decision-making would actually be necessary.

In practice, the misconstruction of Rule 11, namely a clear separation of software types, has led to disproportionately high costs and effort for software products that are actually very low-risk. Since practically every piece of software is now considered a medical device and requires the involvement of a notified body, this also increases the burden on the already chronically inadequate capacities in the system of notified bodies. Digitization in the healthcare sector, which will be particularly important in the future, is being unnecessarily slowed down by such mis- and over-regulation, without the regulatory requirements showing any added value for patients. Rather, software types that pose a real risk to patients should be reviewed by notified bodies. On the other hand, software with a low risk or severity potential should be subject to self-certification by the manufacturer, like other class I medical devices. The misguided regulation of medical software is increasingly proving to be an obstacle to innovation. Reality shows that new software products are now primarily marketed in the US FDA system, which intentionally promotes innovation, and are therefore only made available to patients on the Union market much later or not at all.

#### **b) eurocom's demands:**

The classification of software as a medical device must be more clearly regulated in the relevant, legally binding classification rules. In particular, it is essential to restore the possibility for software with therapeutic or diagnostic purposes to be classified as a class I device. The classification must follow a clear risk-based approach and take into account not only the severity of possible harm but also the likelihood of an error being discovered by the healthcare professional. Medical decision support software that provides healthcare professionals with supporting information for diagnostic or therapeutic purposes should, in contrast to the current wording of Rule 11, generally be classified in class I and only in the case of higher risk profiles in classes IIa and above.

In view of the technological advances, particularly in 3D printing, there is also a need for a clear distinction between medical stand-alone software and software that is used in manufacturing.

### Specific suggestions for amendments:

- Annex VIII “Classification Rules”, Chapter I “Definitions Specific to Classification Rules” MDR should be supplemented by the following definitions:  
*“Stand-alone software applications” are devices in their own right that are brought to market without hardware, for example, as a download, and have an intended purpose.*  
*“Embedded software” is software that is part of a medical device, used as an operating system, or for controlling the device.*  
*“Diagnosis” means the evaluative summary of a patient’s symptoms and diagnostic findings, including the identification and designation of the underlying disease or injury.*  
*“Therapy” means the treatment of an illness in the broadest sense. The overall goal of therapy is to restore the patient’s normal physiological and psychological functions as completely as possible.*
- Chapter II “Implementing Rules”, Section 3.3 MDR should be amended as follows:  
*“Software, which drives a device or influences the use of a device, shall fall within the same class as the device (software as an accessory).*  
*Software that is intended to be used in combination with other devices (embedded) and that is intended to fulfil one or more specific medical purposes shall be classified according to the following rules.*  
*If the software is independent of any other device (stand-alone), it shall be classified in its own right.*  
*Software that does not itself have a medical purpose is not covered by this Regulation, for example, digital construction documents and control software for machines.”*
- Proposed wording for Rule 11 (Annex VIII, Chapter III, Section 6.3 MDR):  
*“Medical software which only provides information used to take decisions with diagnosis or therapeutic purposes by health professionals is classified as class I.*  
*Software that uses a self-learning algorithm to produce results that health professionals can use to make their own decisions is also classified as class I.*  
*Software that qualifies as an AI system within the meaning of Article 3(1) of Regulation (EU) 2024/1689 and that provides decisions without confirmation by health professionals is classified as class IIa.*  
  
*If the decisions taken by the software or by the healthcare professionals have an impact that may cause:*
  - *a serious deterioration of a person’s state of health or a surgical intervention, in which case it is classified as class IIb,*
  - or*
  - *death or an irreversible deterioration of a person’s state of health, in which case it is in class III.*  
*Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb.”*

## 6. Involvement of notified bodies (Article 16 MDR)

### a) Problem

The bar is set extremely high for the translation of the information supplied by the manufacturer or changes to the outer packaging by distributors and importers. While manufacturers of class I devices do not even have to certify a Quality Management System (QMS) according to Article 10(9) MDR, distributors or importers that carry out any of the activities mentioned in Article 16(2)(a) and (b) are subject to various requirements. This involves considerable effort and costs and is disproportionate compared to the requirements for manufacturers. For example, manufacturers may declare the conformity of a class I product under their sole responsibility do not require a certified QMS and only have to notify the competent authority of the product before placing it on the market. When carrying out the corresponding marking procedures, dealers/importers must first go through a complex process with the notified bodies, which causes constant follow-up costs (re-certification, monitoring, changes, cost increases, etc.).

The involvement of notified bodies required under Article 16(4) MDR also exacerbates their existing capacity constraints. In addition to the certification of medical devices in higher risk classes, they must also accompany, accept, certify, and monitor activities in accordance with Article 16(2) MDR. The tasks do not only relate to the formal acceptance of processes but also include on-site audits, surveillance audits, deep dives into overarching and specific activities within the scope of packaging / translation / labelling and evaluation of changes to activities, as well as the implementation of the resulting actions (e.g., validation of modified processes). To this end, notified bodies must establish new resources and divert existing resources during the transition period. This results in a lack of resources, e.g., for the aforementioned capacity constraints for the certification of higher-class medical devices. Here, the transitional periods have already been adjusted, as they were too short. With currently only 49 notified bodies for the EU and the end of the transitional periods for higher-class medical devices in 2027 and 2028, respectively, the priorities are therefore being set differently, and important capacities are instead being channelled into the involvement of notified bodies in accordance with Article 16(4) MDR. In addition, the authorities of the Member States must increase their capacities and expertise in order to be able to handle the corresponding requests, including market surveillance.

The involvement of notified bodies also causes considerable expenditures of time and money (for example for audits and certificates, but also internal capacities and resources). As in case of doubt, the distributors bear the costs for their activities under Article 16(2) MDR as well as for the materials (e.g., packaging and labelling), the costs of involving the notified bodies make the procedure uneconomical. Small distributors or importers in particular cannot bear such costs and expenses.

This procedure may lead to the discontinuation of niche products. Small companies that manufacture niche products with low sales volumes do not write instructions for use in 24 languages. The distributors, in turn, shy away from the effort of obtaining a certificate according to Article 16(4) MDR just to be allowed to translate a few instructions for use.

The involvement of a notified body is required, for example, for the activities of repackaging, relabelling or translating instructions for use of medical devices. This results in the following disadvantages:

Niche products: Since distributors are not always certified according to ISO 13485 and a certificate according to Article 16(4) MDR is probably only offered in combination with ISO 13485 (statement from

a notified body: the scope of certification according to Article 16 MDR corresponds to approximately 95 percent of an ISO 13485 certification), this would require a great deal of time and effort on the part of the distributors. In the foreseeable future, this will lead to products (niche products and other products with low margins) being discontinued, particularly in smaller national markets within the EU, as distributors are unable to carry out the necessary activities (attachment of IFUs, labelling, etc.) to place the product on the market due to the certification requirements.

Breaking down bulk products: Distributors usually purchase small-scale products such as CE-marked screws, adhesive buffers, pads, orthotic joints or splints, and other small-scale accessories in bulk from manufacturers and deliver small quantities to individual customers. The distributor does not know beforehand whether the customer orders one, two, or three of the products. Since distributors will not accept the effort required under Article 16(3) and (4) MDR for these products, all manufacturers must be informed that even the smallest medical devices must be individually packaged and individually labelled, as the distributor is not allowed to make any changes to the product. Each screw must be delivered individually packaged, otherwise, the distributor cannot break down the bulk product and resell it and must send it back to the manufacturer.

**b) eurocom's demands:**

eurocom calls for class I medical devices to be exempted from the required involvement of notified bodies in the cases mentioned. For this purpose, Article 16(4) MDR should be amended as follows (amendment underlined):

*(4) 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 in classes IIa, IIb, III and for devices in 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.*

## 7. Electronic instructions for use

### a) Problem

Exclusively electronic instructions for use of medical devices are still only permitted in very few exceptional cases. Annex I, Section 23.1, Point f MDR refers to the conditions and modalities under Article 3 of the Commission Implementing Regulation (EU) 2021/2226 of 14 December 2021. According to Article 3 of this Implementing Regulation, instructions for use in electronic form instead of in paper form may only be provided for

- implantable and active implantable medical devices,
- fixed installed medical devices, as well as
- devices fitted with a built-in system visually displaying the instructions for use

under the condition that the devices are intended for exclusive use by professional users and the use by other persons is not reasonably foreseeable. In addition, instructions for use in electronic form are permitted for software as a medical device if they are displayed by means of the software itself.

The obligation to provide instructions for use in paper form, apart from these very narrow exceptions, is having an increasingly negative impact:

- Patient-relevant changes to the instructions for use (IFU) must first be printed and replaced for stored products. An exchange requires a long transition period during which relevant information is withheld from the patient. This reduces patient safety.
- Including printed IFU in all mandatory language versions in the distribution countries or a precise allocation of the IFU in the corresponding/required language version causes high material and operating costs (increased paper usage, larger packaging/boxes, increased storage costs, etc.). Moreover, IFUs in paper form damage the environment.

Conclusion: Mandatory provision of the IFU in paper form decreases the potential for rapid transfer and update of information in the digital age; it therefore clearly runs counter to the goal of improving patient and user safety. In view of the increasing digitalization in all areas of life, concerns about the general admissibility of exclusively electronic instructions for use (e.g., with regard to accessibility for users) no longer appear to be up-to-date and are, in any case, negligible compared to the advantages of electronic instructions for use. In addition, the extensive requirement for IFUs in paper form leads to increasing costs and creates unnecessary waste.

A general transition to instructions for use in electronic form (eIFUs) for medical devices would, however, bring tangible benefits.

eIFUs

- contribute to resource and climate protection:
  - less use of paper
  - smaller packaging systems due to the elimination of printed IFUs
  - lower packaging weight reduces CO<sub>2</sub> emissions during shipping
  - no unnecessary waste/paper waste when changing the IFU
- keep information up-to-date in real time and are more easily available:
  - new eIFUs can be made available to all patients and users in real time
  - new warnings are immediately available online to all patients and users (regardless of the time of purchase)
  - no lengthy detour via the distributor

- still available as a printed version, which can be requested from the manufacturer
- easy access to the IFU via QR code on the packaging or product
- are more user-friendly:
  - digital versions can be provided with features (for example, explanatory videos, visualisations of various processes, or spoken word)
- make medical devices safer:
  - no delay for important updates
- meet the EU's objectives in terms of reducing bureaucracy, the Green Deal, and digitalization.

For patients without access to the electronic instructions for use, a short-term non-electronic option for sending the printed instructions for use by post must be created - for example, by providing a telephone number or a postal contact address.

#### **b) eurocom's demands:**

Considering patient and user safety as well as sustainability, much more consistent digitalization is required. This can be done through an updated implementing regulation or an adjustment of the MDR.

*Proposed wording for an amendment to Annex I MDR (amendments struck through and underlined):*

*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 exclusively 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").*

## 8. No additional national regulations

### a) Problem

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 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 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).

### b) eurocom’s demands:

To rectify this, eurocom calls for the following:

- 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 minimum 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 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).

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