Position of Pharma Deutschland e.V. on the Proposal for a Regulation amending Regulation (EU) 2017/745 as regards the simplification and reduction of regulatory burdens for medical devices (COM(2025) 1023 final)

date: 30 April 2026

Pharma Deutschland e.V. represents the interests of the pharmaceutical and medical device industry at both federal and state levels to politics, authorities, and institutions in the healthcare sector. With around 400 member companies, it is the largest association in the pharmaceutical and medical device sector. The political advocacy and member support extend to the area of prescription and non-prescription drugs as well as medical devices, such as medical apps and digital health applications.

General Support for the EU Proposal to Simplify and Streamline Medical Device Regulation

Pharma Deutschland welcomes the European Commission's initiative to simplify the EU regulatory framework for medical devices and to enhance the competitiveness of the European medical device sector within the internal market and at global level.

The majority of the measures proposed by the European Commission are suitable for simplifying procedures, increasing predictability, and reducing administrative burdens, without compromising the high level of patient safety, and should therefore be retained. These include in particular:

- abolition of the maximum validity period of conformity certificates,
- facilitation of the conformity assessment procedure,
- establishment of a structured dialogue,
- support for micro, small and medium-sized enterprises,
- digitalisation,
- facilitations in the field of vigilance,
- facilitations in the field of clinical evaluation,
- provisions for Well-Established Technology Devices (WET),
- establishment of regulatory sandboxes.

BERLIN
Friedrichstraße 134
10117 Berlin, Germany
T. 030 | 308 75 96 - 0
F. 030 | 308 75 96 - 111

BONN
Ubierstraße 71–73
53173 Bonn, Germany
T. 0228 | 957 45 - 0
F. 0228 | 957 45 - 90

BRÜSSEL
Rue Marie de Bourgogne 58
1000 Brüssel
T. +49-170-6133687

Pharma Deutschland e. V.

info@pharmadeutschland.de
www.pharmadeutschland.de

Need for further improvements and addressing unresolved issues under the MDR

Nevertheless, several areas require further improvement. The following analysis focuses on those proposed changes that are of greatest relevance and necessity for Pharma Deutschland members, namely manufacturers of substance-based medical devices, dental medical devices and software.

The sections below set out specific topics and elements of the proposal that would benefit from further refinement. Pharma Deutschland therefore proposes amendments to the following legal provisions:

- **Article 1 (8) – Subject matter and scope**
- **Article 2 – Definitions**
- **Article 4 – Regulatory Status of Products**
- **Article 4a – Opinion on and determination of the regulatory status of a product**
- **Article 10 – General obligations of manufacturers**
- **Article 15 – Person responsible for regulatory compliance**
- **Article 60 – Certificate of free sale**
- **Article 97 – Other non-compliance**
- **Article 106 – Expert panels**
- **Article 106b – Support by the EMA**
- **Annex I – Requirements regarding the information supplied with the device**
- **Annex VI – Information to be submitted upon the registration of devices and economic operators in accordance with articles 29(4) and 31, and core data elements to be provided to the UDI database together with the UDI-DI in accordance with articles 28 and 29, and the UDI system**
- **Annex VIII – Classification Rules**
  - ***Rules 6 and 7***
  - ***Rule 11***
  - ***Rule 14***
  - ***Rule 21***

- **Subject matter and scope**

Article 1(8)

Article 1(8) has not been amended by the Commission proposal. This provision sets out the concept of ancillary medicinal substances and is, therefore, linked to Classification Rule 14 that is applicable to medical devices incorporating an ancillary medicinal substance. As also explained further below on the Classification Rule 14 practical challenges in interpreting this classification rule persist, notably when it comes to the determination of an ancillary medicinal substance.

Commission Proposal	**Article 1(8)**

Original Text	**Proposed Change**
8. Any device which, when placed on the market or put into service, incorporates, as an integral part, a substance which, if used separately, would be considered to be a medicinal product as defined in point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma as defined in point 10 of Article 1 of that Directive, and that has an action ancillary to that of the device, shall be assessed and authorised in accordance with this Regulation.	8. Any device which, when placed on the market or put into service, incorporates, as an integral part, a substance which, if used separately, would be considered to be a medicinal product as defined in point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma as defined in point 10 of Article 1 of that Directive, and that has ~~an action~~ **clinically relevant** ancillary **action in order to achieve the intended medical purpose** ~~to that~~ of the device shall be assessed and authorised in accordance with this Regulation.

Justification

Substance-based medical devices often contain substances which, if used separately, can be considered to be medicinal products. However, the amounts of those substances present in substance-based medical devices are often not clinically relevant to the fulfilment of the intended medical purpose. An example constitutes substances having merely the function to preserve the formulation and are therefore used as preservatives. Consequently, they do not contribute to the intended medical purpose. This proposed change intends to clarify that a substance can only be considered as an ancillary medicinal substance if it has a clinically relevant ancillary action in order to achieve the intended medical purpose of the device.

This change must be read in conjunction with the proposed change to the classification Rule 14 further below.

- **Definitions**

Article 2(7)

The European Commission proposes to amend the definition of the term "generic device group" by replacing the current alternative conditions with cumulative ones. The existing definition is more proportionate and better aligned with the regulatory objectives.

Commission Proposal	**Article 2(7)**

Original Text	**Proposed Change**
(7) 'generic device group' means a set of devices having the same or similar intended purposes and a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics.	(7) 'generic device group' means a set of devices having the same or similar intended purposes **or** ~~and~~ a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics.

Justification

Replacing alternative conditions with cumulative conditions narrows the scope of the definition set in Article 2(7) and increases the internal homogeneity of the product group concerned. As a consequence, this approach would lead to a larger number of products being subject to conformity assessment activities under the applicable sampling plan.

The proposition would maintain the current provision of Article 2(7), which is based on alternative conditions.

- **Definitions**

Article 2(72)

The European Commission's proposal introduces a new definition of the term "well-established technology device" and removes the current list of products. This initiative is welcomed. However, a limited clarification or minor amendment would still be necessary to ensure legal certainty and consistent application.

Commission Proposal	**Article 2(72)**

Original Text	**Proposed Change**
(72) 'well-established technology device' means a device that belongs to a generic device group, which fulfils the following criteria:	(72) 'well-established technology device' means a device that belongs to a generic device group, which fulfils the following criteria:
a) it has simple, common and stable design;	a) it has simple, common and stable design;
b) it has not been associated with safety issues in the past;	b) it has **a well-known safety history** ~~not been associated with safety issues in the past~~;
c) it has well-known clinical performance characteristics and comprises standard of care devices with little evolution in indications and the state of the art;	c) it has well-known clinical performance characteristics and comprises standard of care devices with little evolution in indications and the state of the art;
d) it has a long history on the Union market;'	d) it has a long history on the Union market;'

Justification

It is proportionate and appropriate to extend the regulatory simplifications to all devices that demonstrably qualify as well-established technology device independent of the risk class. This proposal reflects their proven clinical performance, safety and low-risk profile. This approach would enhance regulatory efficiency while maintaining high standards of patient safety.

However, the term "safety issues" is not defined in the Regulation, which may lead to divergent interpretations by notified bodies.

- **Regulatory Status of Products**

Article 4

The current version of Article 4 includes a legally binding procedure for the determination of the regulatory status of a product. Such a procedure has been missing under the former Directive 93/42/EEC on medical devices and therefore it is an appreciated improvement. As no procedure according to the current Article 4 MDR has been conducted yet, it remains unclear why the European Commission suggests an amendment to this provision.

Commission Proposal	**Article 4**

Original Text	**Proposed Change**
Regulatory Status of Products 1. The competent authorities of the Member States shall coordinate their activities when determining whether a specific product, or category, or group of products, falls within the definition of 'medical device' set out in Article 2, point (1), or the definition of 'accessory for a medical device' set out in Article 2, point (2), or whether a product falls within the scope of Annex XVI or is an accessory for a product listed in that Annex. 2. The Member States shall ensure an appropriate level of consultation of the relevant competent authorities of the Member States in the fields of in vitro diagnostic medical devices, medicinal products, substances of human origin (SoHO), biocides, food products, cosmetics or other products subject to Union legislation, where the determination of whether a product has the regulatory status of a device involves aspects concerning the borderline with any of those types of products. If that is the case, Member States shall also ensure an appropriate level of consultation of the relevant advisory or regulatory bodies established in the relevant Union legislation, such as the European Medicines Agency (EMA), the SoHO Coordination Board, the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA).	Deletion of proposed Article 4

3. Where a competent authority of a Member State, after having performed an evaluation in accordance with Article 94, considers that a product that is CE marked in accordance with Article 20, does not fall within the scope of this Regulation, it shall consult the competent authorities of the other Member States regarding its envisaged measure determining the regulatory status of the product in question.

4. Where a competent authority of a Member State raises a substantiated disagreement regarding the envisaged measure referred to in paragraph 3, the consulting authority shall refer the matter to an expert panel as referred to in Article 106 and give utmost consideration to the opinion of that expert panel.

5. The results of the coordination activities of the competent authorities in accordance with this Article and the opinions of the expert panel delivered in accordance with paragraph 4 of this Article and Article 4a(2) shall be made publicly available, without disclosing any confidential information as referred to in Article 109.

6. The Commission may, by means of implementing acts, lay down the procedure, including timelines, for the application of paragraphs 1 to 4 of this Article and of Article 4a. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Justification

The reform proposal appears to seek to legally entrench the so-called Helsinki procedure, a decision-making mechanism characterized by limited transparency and an insufficient scientific basis.

The formally structured procedure proposed in the revised version of Articles 4 and 4a is highly questionable, as a decision on the regulatory status of a product initiated by a single competent authority becomes decisive unless another authority of a Member State raises a substantiated objection.

Particularly critical is the new proposed provision in Article 4(3), which allows Member States to adopt measures affecting the regulatory status of products that already bear the CE marking. This significantly relativizes the principle of free movement of goods enshrined in Article 24 MDR, the Blue Guide as well as Articles 34 and 36 TFEU and undermines legal certainty and legitimate expectations.

In the absence of clearly defined substantive criteria, procedural safeguards and effective mechanisms for the protection of vested rights, there is a substantial risk that individual national decisions may de facto undermine EU-wide market access.

Moreover, the specific wording of the new provisions raises fundamental questions regarding the role and legal effect of the expert panels referred to in the proposed Article 106. The risk of divergent assessments under identical EU-wide conditions is therefore not fully eliminated, particularly since there is no obligation to apply the procedures set out in proposed Articles 4 and 4a. As a result, the intended strengthening of legal certainty is unlikely to be achieved in practice. In addition, unresolved issues remain regarding technical coverage and the long-term availability of sufficient expertise, especially for complex demarcation and classification questions. In this context, the mandatory involvement according to proposed Article 4(2) of other European bodies (e.g. EMA, ECHA or EFSA) does not remedy the structural deficit resulting from the lack of systematic involvement of independent scientific, technical and industry expertise, which may lead to isolated and inconsistent outcomes.

Proposed Article 4(6) MDR grants the European Commission the power to specify, by means of implementing acts, the procedure, including binding deadlines, for the coordination and demarcation mechanisms referred to in proposed Articles 4(1) to (4) and proposed Article 4a. While this allocation of powers would be welcome in principle, the general procedural framework already reflects key elements of the Helsinki procedure, which has been subject to justified criticism. Moreover, there is a risk that, despite formal legal restructuring, the demarcation process will continue in practice to be marked by delays, isolated positions and divergent national approaches.

- **Opinion on and determination of the regulatory status of a product**

Article 4a

The analysis of the proposed Article 4 also applies for the proposed Article 4a.

Furthermore, although the decision-making process appears to be more closely aligned with democratic principles, the mandatory involvement of industry experts remains absent. Such expertise could provide essential technical and scientific input to the assessment. The possible involvement of the newly established expert panels cannot adequately compensate for this structural deficit.

At least the procedure concludes with the adoption of a formal legal act.

Commission Proposal	**Article 4a**

Original Text	**Proposed Change**
Opinion on and determination of the regulatory status of a product	Opinion on and determination of the regulatory status of a product
1. A competent authority, a notified body, a manufacturer, a developer of a product or the Commission may submit a substantiated request for an opinion from an expert panel referred to in Article 106 on the question whether a specific product, or category or group of products, falls within the definitions of 'medical device' or 'accessory for a medical device', or whether a product falls within the scope of Annex XVI or is an accessory for a product listed in that Annex. Where, in such a request, the requester considers that the product in question is a device, the request shall also specify the proposed classification of the device in accordance with Article 51 and Annex VIII.	1. A competent authority, a notified body, a manufacturer, a developer of a product or the Commission may submit a substantiated request for an opinion from an expert panel referred to in Article 106 on the question whether a specific product, or category or group of products, falls within the definitions of 'medical device' or 'accessory for a medical device', or whether a product falls within the scope of Annex XVI or is an accessory for a product listed in that Annex. Where, in such a request, the requester considers that the product in question is a device, the request shall also specify the proposed classification of the device in accordance with Article 51 and Annex VIII.
2. The expert panel shall provide its opinion without undue delay. The requester shall give utmost consideration to the opinion of the expert panel.	2. *(proposed Article 4(3))* Where a competent authority of a Member State, after having performed an evaluation in accordance with Article 94, considers that a product that is CE marked in accordance with Article 20, does not fall within the scope of this Regulation, it shall consult **the competent authority of the Member State where the manufacturer or the authorized representative has its registered place of business and the manufacturer** ~~other Member States~~ regarding its ~~envisaged measure~~
3. Having regard to the expert panel opinion referred to in paragraph 2 or in Article 4(4), a Member State may submit a substantiated request to the Commission to determine whether a specific product, or category or group of products, falls within the definitions of 'medical	

device' or 'accessory for a medical device', or whether a product falls within the scope of Annex XVI or is an accessory for a product listed in that Annex.

The Commission shall decide on the substantiated request of the Member State or on its own initiative, by means of implementing acts, which shall be adopted in accordance with the examination procedure referred to in Article 114(3).

The Commission may ask the expert panel for clarifications or refer the opinion back to the expert panel for further consideration, including in cases where a Member State's substantiated request raises new questions of a scientific or technical nature.

4. This Article shall not apply where within the framework of another Union legislation the regulatory status of the product, or category or group of products concerned has been determined as falling within the scope of that other Union legislation, or where a procedure for the determination of the regulatory status is ongoing within the framework of another Union legislation.

~~determining the~~ **justification** on the regulatory status of the product in question**, before submitting a substantiated request for an opinion of an expert panel as referred to in paragraph 1. The competent authority of the Member State where the manufacturer or the authorized representative has its registered place of business and the manufacturer shall provide their justifications within 30 days.**

3. *(proposed Article 4(2))*The ~~Member States~~ **expert panel** shall ensure an appropriate level of consultation of the relevant competent authorities of the Member States in the fields of in vitro diagnostic medical devices, medicinal products, substances of human origin (SoHO), biocides, food products, cosmetics or other products subject to Union legislation, where the determination of whether a product has the regulatory status of a device involves aspects concerning the borderline with any of those types of products. If that is the case, ~~Member States~~ **the expert panel** shall also ensure an appropriate level of consultation of the relevant advisory or regulatory bodies established in the relevant Union legislation, such as the European Medicines Agency (EMA), the SoHO Coordination Board, the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA). **The expert panel shall consult if applicable the notified body, the manufacturer and the developer of the product concerned.**

4. *(proposed Article 4a(2))* The expert panel shall provide its opinion **within 30 days** ~~without undue delay~~. The requester shall give utmost consideration to the opinion of the expert panel.

(proposed Article 4a(4)) ~~4. This Article shall not apply where within the framework of another Union legislation the regulatory status of the product, or category or group of products, concerned has been determined as falling within the scope of that other Union legislation or where a procedure for the determination of the~~

~~regulatory status is ongoing within the framework of another Union legislation.~~

5. *(proposed Article 4(5))* ~~The results of the coordination activities of the competent authorities in accordance with this Article and~~ The opinions of the expert panel delivered in accordance with paragraph 4 of this Article ~~and Article 4a(2)~~ shall be made publicly available, without disclosing any confidential information as referred to in Article 109.

6. *(proposed Article 4a(3))* Having regard to the expert panel opinion referred to in paragraph **4** ~~2 or in Article 4(4)~~, a ~~Member State~~ **requester as referred in paragraph 1** may submit a substantiated request to the Commission to determine whether a specific product, or category or group of products, falls within the definitions of 'medical device' or 'accessory for a medical device', or whether a product falls within the scope of Annex XVI or is an accessory for a product listed in that Annex.

The Commission shall decide on the substantiated request of the **requester** ~~Member State or on its own initiative~~, by means of implementing acts, which shall be adopted in accordance with the examination procedure referred to in Article 114(3).

The Commission may ask the expert panel for clarifications or refer the opinion back to the expert panel for further consideration, including in cases where a ~~Member State's~~ substantiated request raises new questions of a scientific or technical nature.

Justification

The following assumptions are necessary to ensure legal certainty for manufacturers, to enable their willingness to place devices on the market, and to guarantee the availability of devices on the Union market:

- Apart from a decision of the Commission adopted by means of an implementing act, only the competent authority of the Member State in which the manufacturer has its registered place of business should be empowered to determine the regulatory status of a product of that manufacturer.

- The free movement of CE-marked medical devices must be safeguarded, as guaranteed by Article 24 MDR, the Blue Guide as well as Articles 34 and 36 TFEU.
- National authorities responsible for market surveillance in Member States where a CE-marked device is merely distributed should be empowered to carry out market surveillance activities in accordance with Article 93 ff. MDR. Any concerns regarding the correct regulatory status of a CE-marked device should be referred to the Commission by means of a duly substantiated request after opinion of an expert panel or to the Member State in which the manufacturer has its registered place of business.
- Expert panels should demonstrate proven and up-to-date clinical, scientific, technical or regulatory expertise in the field of medical devices, as well as impartiality, objectivity and transparency. For the determination of the regulatory status of products, it must be ensured that the expert panel has access to all relevant information necessary to fulfil its tasks. This includes, in particular, information provided by the manufacturer and, if applicable, the manufacturers of equivalent CE marked devices, who possesses the most comprehensive knowledge of the products concerned.
- The expert panel should also assess whether a previous determination of a product, and the underlying reasoning of such a determination by authorities or administrative or civil courts, remains applicable under the current and amended Union legislation.

An amendment would also be necessary to Recital 11.

- **General obligations of manufacturers**

Article 10

Article 10 sets out the general obligations of manufacturers and specifies, in paragraph 11, the language requirements for the information to be provided by the manufacturer. It provides that such information must be supplied in the official language(s) determined by the Member State in which the device is made available. However, this provision does not distinguish between information intended for lay users and information intended for professional users.

Commission Proposal	**Article 10(11)**
Original Text	**Proposed Change**
11. Manufacturers shall ensure that the device is accompanied by the information set out in Section 23 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient. The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient. When determining the official language of the Union in which the information set out in Section 23 of Annex I or other information to be provided by the manufacturer shall be made available, Member States shall consider accepting another official language of the Union in which the information is made available, taking into consideration the technical knowledge, experience, education or training of the average intended user(s).	11. Manufacturers shall ensure that the device is accompanied by the information set out in Section 23 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient. The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient. When determining the official language of the Union in which the information set out in Section 23 of Annex I or other information to be provided by the manufacturer shall be made available, Member States shall consider accepting another official language of the Union in which the information is made available, taking into consideration the technical knowledge, experience, education or training of the average intended user(s). **Where a device is made available exclusively to professional users, the information referred to in Section 23 of Annex I shall be provided by the manufacturer in English.**
Justification	
Where a device is made available exclusively to professional users, the information referred to in Section 23 of Annex I should be provided in English. Providing translations into additional languages does not lead to an increase in patient safety. Healthcare professionals in the European Union can reasonably be expected to understand English, as they undergo extensive professional education and training. English is a commonly understood working language among healthcare professionals across the EU. An amendment would be also necessary to Recital 15.	

- **Person responsible for regulatory compliance**

Article 15

The European Commission has amended Article 15 by removing the obligation for a person seeking to become the Person Responsible for Regulatory Compliance (PRRC) to demonstrate specific formal qualifications. While the deletion of the requirement for a specific diploma, certificate, or other formal qualification is welcomed, the tasks assigned to the PRRC nevertheless require that this person possesses appropriate and sufficient professional experience.

Commission Proposal	**Article 15**

Original Text	**Proposed Change**
1. Manufacturers shall have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices. Without prejudice to national provisions regarding professional qualifications, manufacturers of custom-made devices may demonstrate the requisite expertise referred to in the first subparagraph by having at least two years of professional experience within a relevant field of manufacturing. […]	1. Manufacturers shall have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices. **The requisite expertise shall be demonstrated by four years of professional experience in regulatory affairs or in quality management systems relating to medical devices.** Without prejudice to national provisions regarding professional qualifications, manufacturers of custom-made devices may demonstrate the requisite expertise referred to in the first subparagraph by having at least two years of professional experience within a relevant field of manufacturing. […]
6. Authorised representatives shall have permanently and continuously at their disposal at least one person responsible for regulatory compliance who possesses the requisite expertise regarding the regulatory requirements for medical devices in the Union.	6. Authorised representatives shall have permanently and continuously at their disposal at least one person responsible for regulatory compliance who possesses the requisite expertise regarding the regulatory requirements for medical devices in the Union. **The requisite expertise shall be demonstrated by four years of professional experience in regulatory affairs or in quality management systems relating to medical devices.**

Justification

The functions assigned to the PRRC require a certain level of qualification. The requirement set out in the current Article 15(1)(a) for a diploma, certificate or other evidence of formal qualification appears to be superfluous. Nevertheless, the PRRC must possess a basic understanding of regulatory and quality management matters, which is indispensable for the proper fulfilment of their responsibilities. Therefore, the requirement laid down in the current version of Article 15(1)(b) should not be deleted. The same applies to the current version of Article 15(6)(b).

The removal of the obligation for micro and small enterprises relying on an external PRRC to ensure that this person is available "permanently and continuously", replacing it with a general availability requirement in Article 15(2), is welcomed. This change better reflects the operational realities of these manufacturers while maintaining an adequate level of regulatory oversight.

- **Certificate of free sale**

Article 60

The European Commission has amended Article 60 by introducing a new paragraph 1b, which establishes an obligation for competent authorities to publish certificates of free sale in EUDAMED. This additional requirement is critical and raises significant concerns.

Commission Proposal	**Article 60(1b)**

Original Text	**Proposed Change**
1b. The competent authority shall make the certificates of free sale issued in accordance with paragraphs 1 and 1a publicly available in Eudamed.	Deletion of the proposed Article 60(1b).

Justification

Certificates of free sale typically contain information on the manufacturer, the product trade name, the Basic UDI-DI and the third country for which the certificate is issued.

The disclosure of the information contained in certificates of free sale does not provide any added value for patient safety or public health. Moreover, trade relations with third countries shall fall outside the scope and purpose of Eudamed.

Manufacturers have a legitimate interest in not disclosing sensitive information on their commercial relationships with non-EU trade partners.

- **Other non-compliance**

Article 97

Article 97 lays down provisions applicable in cases of "other non-compliances" concerning CE-marked devices that do not present an unacceptable risk to the health or safety of patients, as identified by national authorities in the course of their market surveillance activities.

From the perspective of legal certainty for manufacturers of CE-marked devices, as well as the principles of proportionality and feasibility of corrective measures and the clear allocation of roles and responsibilities between authorities and economic operators, the proposed amendments to Article 97 raise concerns. In particular, they may give rise to divergent interpretations and potentially conflict with the principles of the New Legislative Framework and the free movement of goods within the European Union, notably in situations involving differing views on the regulatory status or classification of a CE-marked device.

Commission Proposal	**Article 97**
Original Text	**Proposed Change**
1. Where, having performed an evaluation pursuant to Article 94, the competent authorities of a Member State find that a device or an economic operator does not comply with the requirements laid down in this Regulation but does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, they shall require the relevant economic operator to bring the non-compliance concerned to an end within a reasonable period that is clearly defined and communicated to the economic operator and that is proportionate to the non-compliance.	1. Where, having performed an evaluation pursuant to Article 94, the competent authorities of a Member State find that a device or an economic operator does not comply with the requirements laid down in this Regulation but does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, they shall require the relevant economic operator to bring the non-compliance concerned to an end within a reasonable period that is clearly defined and communicated to the economic operator and that is proportionate to the non-compliance. **The assessment of compliance shall take due account of the respective roles and responsibilities of economic operators as set out in Articles 10, 11, 13, 14 and 16. In the case of device-related non-compliances, the relevant economic operator shall be the manufacturer.**
2. Where the economic operator does not bring the non-compliance to an end within the period referred to in paragraph 1, the Member State concerned shall, without delay, take all appropriate measures to restrict or prohibit the product being made available on the national	2. Where the economic operator does not bring the non-compliance to an end within the period referred to in paragraph 1, the Member State concerned shall, **where the non-compliance relates to the device, and after consulting the competent authority responsible for the**

market or to ensure that it is recalled or withdrawn from the national market. That Member State shall inform the Commission and the other Member States, without delay, of those measures, by means of the electronic system referred to in Article 100.	**manufacturer,** without delay, take all appropriate measures to restrict or prohibit the product being made available on the national market or to ensure that it is recalled or withdrawn from the national market. That Member State shall inform the Commission and the other Member States, without delay, of those measures, by means of the electronic system referred to in Article 100.
2a. The economic operator shall take any appropriate corrective action pursuant to paragraph 1 or 2 throughout the Union in respect of all the devices concerned that they have made available on the market, unless a competent authority takes other appropriate measures.	~~2a. The economic operator shall take any appropriate corrective action pursuant to paragraph 1 or 2 throughout the Union in respect of all the devices concerned that they have made available on the market, unless a competent authority takes other appropriate measures.~~ **3. By way of derogation from paragraphs 1 and 2, where a competent authority holds a dissenting view on the regulatory status or the classification of a CE-marked device, it shall follow the procedures laid down in Articles 4 and 51b of this Regulation. Pending the outcome of those procedures, the free movement of the CE-marked device shall remain protected in accordance with Article 24 of this Regulation.**

Justification

It is acknowledged that market surveillance activities may include an assessment of the regulatory status or classification of a CE-marked device. However, in light of the CE marking and the protection of the free movement of goods pursuant to Article 24, measures restricting or prohibiting the making available of a device on the market, or requiring its recall or withdrawal, must remain the responsibility of the competent authority of the manufacturer. This applies insofar as the device does not present an unacceptable risk to the health or safety of patients that would justify immediate action by other national authorities.

Where a national authority holds a dissenting view on the regulatory status or classification of a CE-marked device, and where no consensus can be reached following consultation with the manufacturer and its competent authority, the national authority may initiate the applicable legal procedures for the determination of the regulatory status in accordance with Article 4 and, where relevant, for the determination of the classification under Article 51b.

By contrast, where a product has already been classified as a device and bears a CE marking in another Member State, a national authority must first apply the procedures laid down in the legal framework for medical devices before applying classification procedures under other Union legislation (see judgment

of the European Court of Justice of 3 October 2013, Case C-109/12). Any national measure taken without a transparent and objective procedure in accordance with Article 4 (and by analogy Article 51ff.) would therefore be contrary to the case law of the Court and would infringe the manufacturer's rights under the principle of the free movement of goods.

Finally, with regard to proportionality, it must be emphasised that the application of Article 97 presupposes that the CE-marked device concerned does not present an unacceptable risk to health or safety. Where such a risk exists, Article 95 applies. Consequently, in the absence of a safety concern, there is no justification for immediate national measures without awaiting the outcome of the legal procedures provided for under Articles 4 and 51 ff.

- **Expert panels**

Article 106

Article 106 describes the general principles pertaining to the role and tasks of independent expert panels. The significantly revised provision by the Commission proposal intends to expand the type of expertise available in expert panels given the broader range of areas in which expert panels provide advice and their involvement in the regulatory system.[1]

Commission Proposal	**Article 106**

Original Text	**Proposed Change**
[…]	[…]
4. Expert panels shall take into account relevant information provided by stakeholders including patients' organisations and healthcare professionals' associations. […]	4. Expert panels shall take into account relevant information provided by stakeholders including patients' organisations ~~and~~**,** healthcare professionals' associations, **notified bodies' organisations and manufacturer's associations.** […]
Justification	
To meet the objective of giving impartial and objective opinions, expert panels shall have access to information provided by all relevant stakeholders, including notified bodies' organisations and manufacturer's associations.	

[1] Cf. recital 45 of the Commission Proposal.

- **Support by the EMA**

Article 106b

Since 2022, the EMA has provided the secretariat for the expert panels. The Commission's proposal includes support from the EMA to the competent authorities to improve coordination between them, especially with regard to borderline cases and classification issues, derogations from applicable conformity assessment procedures and possibly other requirements, clinical evaluations and investigations, vigilance and market surveillance.

Commission Proposal	**Article 106b**

Original Text	**Proposed Change**
1. The EMA shall, on behalf of the Commission, provide scientific, technical and administrative support to the national competent authorities designated under this Regulation and under Regulation (EU) 2017/746 to facilitate the exchange of experience, cooperation and coordination with a view to ensuring a uniform application of such Regulations, in particular in the following areas: (a) regulatory status of products and classification of devices in accordance with Articles 4, 4a, 51, 51a and 51b of this Regulation and Articles 3, 3a, 47, 47a and 47b of Regulation (EU) 2017/746; (b) derogations from the applicable conformity assessment procedures in accordance with Articles 59 and 59a of this Regulation and Articles 54 and 54a of Regulation (EU) 2017/746; (c) clinical evaluation, clinical investigations, performance evaluation and performance studies in accordance with Chapter VI of this Regulation and Chapter VI of Regulation (EU) 2017/746, including support to the coordinating Member State for the coordinated assessment procedure for clinical investigations and performance studies referred to in Article 78 of this Regulation and Article 74 of Regulation (EU) 2017/746; (d) vigilance and market surveillance in accordance with Chapter VII of this Regulation and Chapter VII of Regulation (EU) 2017/746, including support to the coordinating competent	Deletion of proposed Article 106b. Given the specific characteristics of the medical device sector, establishing a separate, truly impartial, specialised Office for medical devices may be a more effective long-term solution than transferring these tasks to the EMA.

authority for the coordinated procedure referred to in Article 89(9) of this Regulation and Article 84(9) of Regulation (EU) 2017/746.

2. The EMA shall provide scientific, technical and administrative support to the Commission for the establishment of Union regulatory sandboxes in accordance with Article 59c of this Regulation and Article 54c of Regulation (EU) 2017/746.

3. The EMA shall set up a support scheme for manufacturers of medical devices and in vitro diagnostic medical devices, which are micro, small and medium-sized within the meaning of Recommendation 2003/361/EC, regarding the requirements of this Regulation and Regulation (EU) 2017/746.

4. The EMA shall have access to Eudamed and any electronic system referred to in Article 33(2) of Regulation (EU) 2017/745 or Article 30(2) of Regulation (EU) 2017/746 that is not included in Eudamed.

Justification

The EMA's technical and human resources are of particular concern. The agency currently has only limited specific expertise in the field of medical devices, especially when compared with its many years of experience in the regulation of medicinal products. Without a substantial expansion of its technical expertise, there is a risk that the EMA will formally assume a central role while being unable in practice to fulfil this role with the necessary depth and quality. This poses a particular risk for substance-based medical devices, combination products and complex demarcation issues.

Furthermore, the role of the EMA in the decision-making process remains unclear. The agency is expected to coordinate, support and promote exchange without being granted any decision-making powers of its own. This intermediate position risks leading to a diffusion of responsibility, as national authorities may rely on the EMA while it remains unclear who ultimately bears responsibility for substantive assessments and potential incorrect decisions. Furthermore, there is little reason to believe that the EMA would refrain from actively influencing decisions regarding the regulatory status of products.

Access to EUDAMED and other electronic systems also presents a mixed picture. While it allows for improved coordination and analysis of vigilance and market surveillance data, it simultaneously raises questions regarding data sovereignty, the allocation of responsibilities and practical integration into existing national workflows.

- **Annex I – Requirements regarding the information supplied with the device**

Chapter III 23.1

The European Commission has amended the provisions on instructions for use supplied in a non-paper format by referring to the Commission Implementing Regulation (EU) 2021/2226 allowing manufacturers of medical devices intended for professional users to provide instructions for use in electronic format. While this adaptation is welcomed, it remains necessary to extend this possibility to all medical devices, irrespective of the intended user.

Commission Proposal	**Annex I Chapter III 23.1(f)**

Original Text	**Proposed Change**
23.1. General requirements regarding the information supplied by the manufacturer	23.1. General requirements regarding the information supplied by the manufacturer
[...]	[...]
(f) Instructions for use may be provided to the user in non-paper format (e.g. electronic) to the extent, and only under the conditions, set out in Commission Implementing Regulation (EU) 2021/2226 or in any subsequent implementing rules adopted pursuant to this Regulation.	(f) Instructions for use may be provided to the user in non-paper format (e.g. electronic) ~~to the extent, and only under the conditions, set out in Commission Implementing Regulation (EU) 2021/2226 or in any subsequent implementing rules adopted pursuant to this Regulation~~. **Users shall have the possibility to obtain instructions for use in paper format upon request**.

Justification

Implementing Regulation (EU) 2021/2226 has been overtaken by technological developments. The risks it seeks to address with regard to internet availability for professional and lay users no longer reflect the current state of the art. These assumptions have remained largely unchanged since Regulation (EU) No 207/2012, despite the significant progress in the availability, reliability and robustness of internet connections over the past decade.

Providing instructions for use in electronic form offers several significant advantages. First, it reduces environmental impact by cutting down on paper consumption. Second, it lowers costs for the medical device industry by eliminating printing and distribution expenses. A further benefit is increased flexibility: electronic IFUs can be updated easily, ensuring that users always have access to the most current information. This not only maintains but can even enhance the level of safety.

Practical experience from other jurisdictions that allow electronic instructions for use (eIFU) confirms this assessment. For example, the United States of America permits the provision of eIFU for all medical devices, irrespective of whether they are intended for professional or lay use.

The option to provide instructions for use in electronic form should therefore be available for all medical devices and accessories. At the same time, users should always retain the right to obtain the instructions for use in paper form upon request.

- **Annex VI – Information to be submitted upon the registration of devices and economic operators in accordance with articles 29(4) and 31, core data elements to be provided to the UDI database together with the UDI-DI in accordance with articles 28 and 29, and the UDI system**

Part B Core data elements to be provided to the UDI database in accordance with articles 28 and 29

The European Commission has proposed to expand the list of core data elements to be submitted to the UDI database under Articles 28 and 29 by adding information on the Member States in which a device is, or is intended to be, made available.

Commission Proposal	**Annex VI Part B 4.**

Original Text	**Proposed Change**
The manufacturer shall provide to the UDI database the following information relating to the manufacturer and the device:	The manufacturer shall provide to the UDI database the following information relating to the manufacturer and the device:
[...] 4. Member States where the device is or is to be made available,	[...] ~~4. Member States where the device is or is to be made available~~,
[...]	[...]

Justification

The further expansion of the scope of core data elements to be provided to the UDI database beyond the existing requirements is inappropriate. In the event of a serious incident, the competent authorities of the affected Member States are already duly informed through established vigilance mechanisms. Against this background, the mere provision of distribution-related information does not provide any tangible additional regulatory value and therefore cannot justify the significant additional administrative burden imposed on manufacturers.

- **Annex VIII - Classification Rules**

Rules 6 and 7

Classification Rules 6 and 7 have been amended in the Commission's proposal to clarify that reusable surgical instruments should be classified as class I, regardless of the part of the body with which they come into contact. This clarification is welcomed. However, it should be extended to cover all surgical instruments and should not be limited to reusable instruments only.

Commission Proposal	**Rule 6**

Original Text	**Proposed Change**
All surgically invasive devices intended for transient use are classified as class IIa unless they:	All surgically invasive devices intended for transient use are classified as class IIa unless they:
- are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class III;	- are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class III;
- are reusable surgical instruments regardless of the body part with which they come into contact, in which case they are classified as class I;	- are ~~reusable~~ surgical instruments regardless of the body part with which they come into contact, in which case they are classified as class I;
- are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class III;	- are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class III;
- are intended to supply energy in the form of ionising radiation in which case they are classified as class IIb;	- are intended to supply energy in the form of ionising radiation in which case they are classified as class IIb;
- have a biological effect or are wholly or mainly absorbed in which case they are classified as class IIb; or are intended to administer medicinal products by means of a delivery system, if such administration of a medicinal product is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are classified as class IIb.	- have a biological effect or are wholly or mainly absorbed in which case they are classified as class IIb; or are intended to administer medicinal products by means of a delivery system, if such administration of a medicinal product is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are classified as class IIb.

Commission Proposal	Rule 7

Original Text	Proposed Change
All surgically invasive devices intended for short-term use are classified as class IIa unless they:	All surgically invasive devices intended for short-term use are classified as class IIa unless they:
- are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class III;	- are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class III;
- are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class III;	- are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class III;
- are intended to supply energy in the form of ionizing radiation in which case they are classified as class IIb;	- are intended to supply energy in the form of ionizing radiation in which case they are classified as class IIb;
- have a biological effect or are wholly or mainly absorbed in which case they are classified as class III;	- have a biological effect or are wholly or mainly absorbed in which case they are classified as class III;
- are intended to undergo chemical change in the body in which case they are classified as class IIb, except if the devices are placed in the teeth; or	- are intended to undergo chemical change in the body in which case they are classified as class IIb, except if the devices are placed in the teeth; or
- are intended to administer medicines, in which case they are classified as class IIb;	- are intended to administer medicines, in which case they are classified as class IIb;
- are reusable surgical instruments regardless of the body part with which they come into contact, in which case they are classified as class I;	- are ~~reusable~~ surgical instruments regardless of the body part with which they come into contact, in which case they are classified as class I;

Justification

Under the current framework, a surgical instrument supplied sterile and intended for single use is classified in a higher risk class (class IIa) than an otherwise identical device that is labelled as reusable (class I) and therefore must be cleaned, disinfected and sterilised by the user prior to first use and before each subsequent use. This differentiation is neither comprehensible nor risk-based and leads to a contradictory regulatory outcome. Reuse of a device requires additional reprocessing steps by the user and entails a higher risk of improper handling or contamination than a device that is supplied sterile and intended for single use only.

The proposed change affects not only the Classification Rules 6 and 7 but also Annex VIII Chapter I Nr. 2.3 and the regulations for the conformity assessment in Article 52 (7, first paragraph).

- **Annex VIII - Classification Rules**

Rule 11

Classification Rule 11 has been amended in the Commission's proposal with the aim of assigning lower risk classes to software. This objective is very welcome. However, the proposed revision of Rule 11 does not achieve its stated goal of simplification. On the contrary, it risks increasing legal uncertainty and may ultimately discourage innovation in digital health solutions within the EU market.

Commission Proposal	**Rule 11**

Original Text	**Proposed Change**
Software which is intended to generate an output that confers a clinical benefit and is used in a non-serious situation for diagnosis, treatment, prevention, monitoring, prediction, prognosis, compensation or alleviation of a disease or condition is classified as class I, unless the output is intended for a disease or condition:	Software which is intended to generate an output that confers a clinical benefit and is used in **a non-serious situation** for diagnosis, treatment, prevention, monitoring, prediction, prognosis, compensation or alleviation of a disease or condition is classified as class I, unless the output is intended for a disease or condition:
- 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; - 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; - 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;	- 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; - 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; - ~~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;

Justification

The Commission's proposal to introduce a default class I classification under the revised Rule 11 is welcomed, as it aims to introduce greater proportionality for clinical benefit software.

However, a fundamental inconsistency remains within Rule 11. While the opening part of the rule allows for a class I classification, the final indent effectively makes it almost impossible for software to be classified as class I in practice.

In particular, the final indent referring to software intended "to inform clinical management in a critical or serious situation" renders the identification of class I software ineffective. In practice, virtually all software outputs relate to situations beyond "non-serious", thereby triggering a default classification as class IIa.

Illustrative examples include:

– BMI calculators used for obesity risk screening → Class IIa

– Dyscalculia exercise applications → Class IIa

This approach results in trivial, low-risk software tools being placed in the same risk class as genuinely medium- or high-risk software, such as ECG analysis software. Consequently, such products would be subject to full conformity assessment procedures involving a notified body, leading to disproportionate time and cost burdens. Low-risk and non-critical products should be made available to patients and users without unnecessary regulatory obstacles.

Moreover, the proposal would create international regulatory divergence:

– FDA: Simple clinical calculators and certain clinical decision support tools are excluded from active regulation, whereas they would fall under Class IIa in the EU.

– UK MHRA: Simple clinical calculators are excluded from medical device classification, while they would be Class IIa under the proposed EU approach.

As a result, the proposed revision of Rule 11 for software fails to achieve its stated objective of simplification and risks discouraging digital health innovation within the EU market.

- **Annex VIII - Classification Rules**

Rule 14

Classification Rule 14 has not been amended by the Commission proposal. Nonetheless, practical challenges in interpreting this classification rule persist, which could be addressed by refining and clarifying its wording.

Commission Proposal	**Rule 14**

Original Text	**Proposed Change**
All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as defined in point 10 of Article 1 of that Directive, and that has an action ancillary to that of the devices, are classified as class III.	All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as defined in point 10 of Article 1 of that Directive, and that **has** ~~an~~ **a clinically relevant** ancillary ~~to that of the devices~~ **action in order to achieve the intended medical purpose**, are classified as class III.

Justification

According to Recital (59) of the MDR, the objective of the regulation is to obtain a suitable risk-based classification of devices. This should also be the case for products falling under Rule 14.

The classification rule should consider if the respective substance has an impact on the intended medical purpose of the device. If this is not the case, it is not justifiable to classify those products under the highest risk class.

To illustrate, many substance-based medical devices contain substances which, if used separately, can be considered to be medicinal products. However, those substances present in the amount in medical devices are not clinically relevant to the fulfilment of the intended medical purpose. An example constitutes substances having merely the function to preserve the formulation and are therefore used as preservatives - but do not contribute to the intended medical purpose.

However, these substances are currently sometimes considered as ancillary medicinal substances without considering whether the substances are clinically relevant to achieve the intended medical purpose with the effects that products containing them are incorrectly classified as Class III products due to the wording of Classification Rule 14. As a result, this classification requires a disproportionate amount of resources, bureaucracy and costs for manufacturers and Notified Bodies.

- **Annex VIII - Classification Rules**

Rule 21

Per the Commission proposal, Rule 21 has been slightly modified with regard to its wording. In particular, the terms "on or" have been added to the introductory sentence of this classification rule.

Commission Proposal	**Rule 21**

Original Text	**Proposed Change**
Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed on or in the human body are classified as:	Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed ~~on or~~ in the human body are classified as:
– class III if they, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose;	– class III if they, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose;
– class III if they achieve their intended purpose in the stomach or lower gastrointestinal tract and they, or their products of metabolism, are systemically absorbed by the human body;	– class III if they achieve their intended purpose in the stomach or lower gastrointestinal tract and they, or their products of metabolism, are systemically absorbed by the human body;
– class IIa if they are applied to the skin or if they are applied in the nasal or oral cavity as far as the pharynx, and achieve their intended purpose on those cavities; and	– class IIa if they are applied to the skin or if they are applied in the nasal or oral cavity as far as the pharynx, and achieve their intended purpose on those cavities; and
– class IIb in all other cases.	– class IIb in all other cases.

Justification

The proposed change would have the effect of bringing certain devices within the scope of Rule 21 that are currently classified under other rules, in particular Rule 1, as class I devices. In particular, this affects devices that are locally dispersed on the human body, such as electrode gel, ultrasound gel and ultrasound cream. Currently, these devices are consistently classified as class I devices according to MDCG Guidance 2021-24 Rev. 1 on classification.

Without a doubt, these devices are low-risk preparations. Reclassifying them from class I (Rule 1) to class IIa (Rule 21) would be disproportionate to their actual risk posed. In addition, such products would have to undergo a conformity assessment involving a notified body entailing significant additional time and cost for manufacturers. In other words, the proposed change concerning Rule 21

would increase administrative burden, including costs, for manufacturers of these products rather than reducing them.

Therefore, the wording of Rule 21 should be left unchanged.