

Position 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: 1st October 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 Commissions' 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.

Most of the amendments proposed in the Draft Report of the Committee on Public Health of the European Parliament are well suited to achieve these objectives. These amendments should therefore be retained. In particular, this applies to:

- **Digitalisation** – enabling the broader use of electronic instructions for use (eIFU)
- **Simplification for products intended for professional users** – allowing certain information to be provided in English
- **Increased transparency and stakeholder involvement** – strengthening the participation of manufacturers, notified bodies and industry associations in various regulatory procedures
- **Greater legal clarity** – revising classification Rule 14 for medical devices incorporating a medicinal substance and classification Rule 21 for substance-based medical device

In addition, several amendments tabled by Members of the European Parliament merit support.

Need for further improvements and addressing unresolved issues under the MDR

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. It considers both the Draft Report of the Committee on Public Health of the European Parliament and the amendments tabled by Members of the European Parliament. 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:

- **Recitals 11 and 39**
- **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 60 – Certificate of free sale**
- **Article 94 – Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance**
- **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*

▪ Recital 11

The European Commission seeks, through its proposed Recital 11, to enhance legal certainty and safeguard the principle of the free movement of goods. However, these objectives cannot be fully achieved through the coordination mechanism proposed by the Commission. **The Draft Report proposes an amendment to Recital 11 (Amendment 3), which Pharma Deutschland fully supports.**

Commission Proposal	Draft Report of the Committee on Public Health of the European Parliament	Recital 11
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Original Text	Amendment 3	Proposed Change by Pharma Deutschland
(11) To ensure legal certainty and to safeguard the principle of free movement of goods, the coordination mechanism between national competent authorities for decisions on the regulatory status of a product and on the classification of a device, should be streamlined and, where appropriate, involve external expertise from an expert panel, supported by the European Medicines Agency (EMA). The decision on the regulatory status, however, should remain with the national authorities or, where appropriate, with the Commission acting through implementing acts.	(11) To ensure legal certainty and to safeguard the principle of free movement of goods, the coordination mechanism between national competent authorities for decisions on the regulatory status of a product and on the classification of a device, should be streamlined and, where appropriate, involve external expertise from an expert panel, supported by the European Medicines Agency (EMA). The decision on the regulatory status, however, should remain with the competent authority of the Member State in which the manufacturer has its registered place of business national authorities or, where appropriate, with the Commission acting through implementing acts.	(11) To ensure legal certainty and to safeguard the principle of free movement of goods, the coordination mechanism between national competent authorities for decisions on the regulatory status of a product and on the classification of a device, should be streamlined and, where appropriate, involve external expertise from an expert panel, ~~supported by the European Medicines Agency (EMA).~~ The decision on the regulatory status, however, should remain with the competent authority of the Member State in which the manufacturer has its registered place of business national authorities or, where appropriate, with the Commission acting through implementing acts.

Justification

It clarifies that decisions on the regulatory status of products should be taken by the competent authority of the Member State in which the manufacturer has its registered place of business. This approach enhances legal certainty, reduces the risk of divergent assessments by different competent authorities and promotes a more predictable regulatory framework.

▪ Recital 39

Recital 39 explains the rationale for the Commission's proposal to make the equivalence concept more practical and workable under the MDR. In particular, it recognises that clinical data are often available for equivalent devices and that the current requirement to obtain a contract with the manufacturer of the equivalent device granting access to its technical documentation has proven to be extremely difficult, if not impossible, to fulfil in practice.

Commission Proposal	Amendment 210	Recital 39
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Original Text	Proposed by Laurence Trochu	Proposed Change by Pharma Deutschland
(39) Clinical data are often available for devices that are equivalent to the device under conformity assessment. In order to make the conditions under which manufacturers can claim equivalence more flexible, the requirement in Regulation (EU) 2017/745 for a contract with the manufacturer of the equivalent device granting access to its technical documentation should therefore be removed and the equivalence criteria be adapted.	(39) Clinical data are often available for devices that are equivalent to the device under conformity assessment. In order to make the conditions under which manufacturers can claim equivalence more flexible, the requirement in Regulation (EU) 2017/745 for a contract with the manufacturer of the equivalent device granting access to its technical documentation should therefore be removed and the equivalence criteria be adapted, without compromising the competitiveness of the most innovative manufacturers, who are making the effort to be the first to produce clinical data. Assessment data obtained under Regulation (EU) 2021/2282 on health technology assessment may itself be used by manufacturers for their own (CE) marking file.	(39) Clinical data are often available for devices that are equivalent to the device under conformity assessment. In order to make the conditions under which manufacturers can claim equivalence more flexible, the requirement in Regulation (EU) 2017/745 for a contract with the manufacturer of the equivalent device granting access to its technical documentation should therefore be removed and the equivalence criteria be adapted, without compromising the competitiveness of the most innovative manufacturers, who are making the effort to be the first to produce clinical data. Assessment data obtained under Regulation (EU) 2021/2282 on health technology assessment may itself be used by manufacturers for their own (CE) marking file.

Justification

While the Commission proposal aims to make the equivalence concept more practical by removing the requirement to obtain access to a competitor's technical documentation, it is equally important to ensure that this increased flexibility does not undermine incentives for innovation and clinical evidence generation. Manufacturers that invest significant resources in generating clinical data should not be placed at a competitive disadvantage compared with competitors relying on equivalence. The proposed wording appropriately recognises the need to balance a more practical use of equivalence with the protection of innovation and investment in clinical research.

Furthermore, the reference to assessment data generated under Regulation (EU) 2021/2282 on Health Technology Assessment is welcomed. Where scientifically relevant and applicable, the use of such data may help avoid unnecessary duplication of evidence generation and contribute to a more efficient regulatory system.

The amendment therefore supports a proportionate application of the equivalence concept while preserving incentives for innovation, facilitating the use of existing evidence and reducing unnecessary regulatory burdens.

▪ Subject matter and scope

Article 1(8)

Article 1(8) has not been amended neither by the Commission proposal nor by the Draft Report of the Committee on Public Health of the European Parliament. However, **the Draft Report proposes an amendment to Rule 14 (Amendment 122), which Pharma Deutschland fully supports.** Since Article 1(8) establishes the concept of an ancillary medicinal substance and Rule 14 governs the classification of medical devices incorporating such substances, both provisions should be aligned to ensure legal certainty and consistent application.

Commission Proposal	Draft Report of the Committee on Public Health of the European Parliament	Article 1(8)
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Original Text	No amendment	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. The Draft Report of the Committee on Public Health of the European Parliament has already include an amendment to Rule 14 (Amendment 122) and therefore our proposition would align Article 1(8) with it, thereby enhancing legal certainty and ensuring consistent application of these provisions.

▪ **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 Draft Report of the Committee on Public Health of the European Parliament does not propose any amendments to this provision.** However, the existing definition is more proportionate and better aligned with the regulatory objectives.

Commission Proposal	Draft Report of the Committee on Public Health of the European Parliament	Article 2(7)
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Original Text	No amendment	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. **The Draft Report of the Committee on Public Health of the European Parliament foresees cumulative conditions in the wording of the second criterion (Amendment 13).** The wording of the second part of this criterion (has a well-known safety history and has not been associated with safety issues in the past) remains unclear and may lead to divergent interpretations. **Several amendments have been submitted on Article 2(72) (Amendments 235 ff.).**

Commission Proposal	Draft Report of the Committee on Public Health of the European Parliament	Article 2(72)
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Original Text	Amendment 13	Proposed Change by Pharma Deutschland
(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; b) it has 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; d) it has a long history on the Union market;	(b) it has a well-known safety history and has not been associated with safety issues in the past;	(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; 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; 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.

Commission Proposal	Amendments 236 and 237	Article 2(72)
Original Text	Proposed by Marie-Sophie Lanig, Angelika Niebler and by Andreas Glück, Stine Bosse, Billy Kelleher	Proposed Change by Pharma Deutschland
(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; b) it has 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; d) it has a long history on the Union market;’	(a) it has simple, common and stable design	(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; 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; d) it has a long history on the Union market;’

Justification

To provide legal certainty for manufacturers, it is essential to **establish clear criteria for well-established technologies directly in the MDR**. “Simple design” lacks sufficient legal certainty.

Commission Proposal	Amendment 240	Article 2(72)
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Original Text	Proposed by Laurent Castillo, Marie-Luce Brasier-Clain, Valérie Deloge	Proposed Change by Pharma Deutschland
(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; b) it has 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; d) it has a long history on the Union market;’	(b) it has not been associated with safety issues in the past within the meaning of Article 87 of this Regulation;	(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; 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; d) it has a long history on the Union market;’

Justification

To provide legal certainty for manufacturers, it is essential to establish clear criteria for well-established technologies directly in the MDR. The **reference to Article 87 MDR is welcomed**. The substance of this amendment is identical to that of Amendment 241, although the wording differs. Therefore, one of the two amendments should be accepted.

Commission Proposal	Amendment 241	Article 2(72)
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Original Text	Proposed by Aurelijus Veryga	Proposed Change by Pharma Deutschland
(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; b) it has 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; d) it has a long history on the Union market;'	(b) it has not been associated with safety issues in the past as defined by Article 87;	(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; 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; d) it has a long history on the Union market;'

Justification

To provide legal certainty for manufacturers, it is essential to establish clear criteria for well-established technologies directly in the MDR. The **reference to Article 87 MDR is welcomed**. The substance of this amendment is identical to that of Amendment 240, although the wording differs. Therefore, one of the two amendments should be accepted.

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 was absent under former Directive 93/42/EEC on medical devices and therefore represents a welcome improvement. As no procedure under Article 4 MDR has yet been conducted, it remains unclear why the European Commission considers it necessary to amend this provision.

The Draft Report of the Committee on Public Health of the European Parliament proposed some amendments to Article 4 (Amendments 17, 18, 19, 20 and 21). Several amendments concerning Article 4 have been submitted (Amendments 267 ff). Unfortunately, several of these amendments would make Article 4 disproportionate and inconsistent with its original objective of providing a clear and efficient procedure for determining the regulatory status of products.

Commission Proposal	Draft Report	Article 4
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Original Text	Amendments 17, 18, 19, 20 and 21	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.	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, that has been placed on the market 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.	Regulatory Status of Products 1. The consulting competent ~~authorities~~ authority of the Member States and the competent authority of the Member State in which the manufacturer has its registered place of business shall coordinate their activities when determining whether a specific product, ~~or category, or group of products,~~ that has been placed on the market 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

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).

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

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).

3. Where a competent authority of a Member State, after having performed an evaluation in accordance with Article 94, **has substantiated evidence** considers that a product that is CE marked in accordance with Article 20, does not

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

2. The **competent authorities** of the Member States **referred to in paragraph 1** 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).

3. Where a competent authority of a Member State, after having performed an evaluation in accordance with Article 94, **has substantiated evidence** ~~considers~~ that a product that is CE marked in accordance with Article 20, does not

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

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. **The consulting competent authority shall inform the concerned manufacturer and concerned notified body that has issued the certificate.**

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 shall be made publicly available, without

fall within the scope of this Regulation, it shall consult the competent ~~authorities~~ **authority** of the ~~other~~ Member States **in which the manufacturer has its registered place of business** regarding its envisaged measure determining the regulatory status of the product in question. **The consulting competent authority shall inform the concerned manufacturer and, where applicable, concerned notified body that has issued the certificate.**

4. In cases where no agreement concerning the determination of the regulatory status of a specific product can be reached within the coordination referred to in paragraph 3, the consulting authority shall, prior to implementing national measures in accordance with Article 97, submit a substantiated request for an opinion from an expert panel referred to in Article 106, in accordance with Article 4a.

5. deleted

5a. deleted

6. deleted

available, without disclosing any confidential information as referred to in Article 109.

disclosing any confidential information as referred to in Article 109.

5a. Where necessary, to ensure the uniform application of this Regulation, and taking into account the opinion of the expert panel referred to in paragraph 4, the Commission may, by means of implementing acts, determine whether a product, CE-marked in accordance with Article 20, falls within the scope of this Regulation.

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).

6. The Commission shall, by means of implementing acts, lay down the procedure, including timelines and involvement of concerned stakeholders, 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 European Commission proposal and the Draft Report appear to seek to legally entrench the so-called Helsinki Procedure, a decision-making mechanism characterised by limited transparency and an insufficient scientific basis. The formally structured procedure proposed in the revised version of Article 4 is disproportionate, as a decision on the regulatory status of a product initiated by a single competent authority becomes decisive unless another competent authority raises a substantiated objection.

For products that are CE-marked in accordance with Article 20, existing mechanisms already address situations where a device presents an unacceptable risk to patients or otherwise fails to comply with the requirements of the Regulation (Article 95). The principle of the free movement of goods, as laid down in Article 24 MDR and Articles 34 and 36 TFEU and further explained in the Blue Guide, should be safeguarded to the greatest extent possible in order to ensure legal certainty for manufacturers. A CE marking issued following a successful conformity assessment should provide

manufacturers with a high degree of regulatory certainty. Reopening questions regarding the regulatory status of a CE-marked product should therefore be limited to exceptional circumstances supported by robust evidence. Undermining the value of completed conformity assessments risks weakening confidence in the MDR framework, creating legal uncertainty for manufacturers and diminishing the role of notified bodies.

A proportionate approach would require a competent authority of a Member State that has substantiated evidence that a product which is CE marked in accordance with Article 20 does not fall within the scope of this Regulation, and which has conducted an evaluation pursuant to Article 94, to consult the competent authority of the Member State in which the manufacturer has its registered place of business, and inform the manufacturer and the notified body concerned. In the event of disagreement between the consulting competent authority and the competent authority of the Member State in which the manufacturer has its registered place of business, an expert panel should be consulted in accordance with Article 4a. There is no need to involve the competent authorities of all other Member States in such a procedure. Instead, those authorities should be informed of any expert panel opinions relating to the determination of the regulatory status of a CE-marked product in accordance with Article 4a.

▪ Opinion on and determination of the regulatory status of a product

Article 4a

The Draft Report of the Committee on Public Health of the European Parliament proposed some amendments to Article 4a (Amendments 22, 23, 24, 25 and 26). The amendments proposed in the Draft Report do not allow manufacturers, developers or notified bodies to submit a substantiated request to an expert panel for a scientific and technical opinion on the determination of the regulatory status of a product. Such a possibility is, however, provided for questions relating to the classification of devices under proposed Articles 51a and 51b. **Several amendments concerning Article 4a have been submitted (Amendments 281 ff.).** Unfortunately, several of these amendments would make Article 4a disproportionate and inconsistent with its original objective of providing a clear and efficient procedure for determining the regulatory status of products.

Commission Proposal	Draft Report	Article 4a
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Original Text	Amendments 22, 23, 24, 25 and 26	Proposed Change
Opinion on and determination of the regulatory status of a product	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	1. A competent authority, ~~a notified body, a manufacturer or 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	1. A competent authority, a notified body, a manufacturer ~~or~~ 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

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.

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

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 **within 30 days from receipt of a complete request**. The requester shall give utmost consideration to the opinion of the expert panel **when determining the regulatory status of the product. Any opinion of an expert panel in relation to the determination of the regulatory status, shall be made publicly available, without disclosing any confidential information as referred to in Article 109.**

device, the request shall also specify the proposed classification of the device in accordance with Article 51 and Annex VIII.

2. Where the request concerns a device that is CE marked in accordance with Article 20, the expert panel shall, before issuing its opinion, consult the competent authority of the Member State in which the manufacturer has its registered place of business, the manufacturer and, where applicable, the notified body concerned.

3. In determining whether a product may fall within a regulatory status other than that applicable to medical devices, the expert panel shall take due account of whether the product concerned is capable of complying with the requirements of the sector-specific legislation governing the proposed regulatory category.

Where the proposed regulatory status is that of a medicinal product, the assessment shall include consideration of whether, having regard to the mode of action described by the

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.

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.

manufacturer, the product is capable of obtaining the relevant marketing authorisation in accordance with the applicable legal requirements. The assessment shall further take into account the potential impact of the proposed reclassification on the availability of treatment options for patients.

4. The expert panel, referred to in Article 106, shall deliver an opinion on the determination of the regulatory status of the device within 90 days. The opinion shall include the reasons for the proposed regulatory status. The competent authority may ask the expert panel for clarifications on its opinion.

5. Within 30 days of receipt of the expert panel opinion, or any requested clarification, the competent authority shall adopt its decision. The competent authority shall follow the expert panel opinion, unless it provides duly justified reasons for departing from it. It shall notify the other Member States and the

Commission of its decision without undue delay.

6. The opinions of the expert panel in relation to the determination of the regulatory status of a product that is CE marked in accordance with Article 20 shall be made publicly available, without disclosing any confidential information as referred to in Article 109.

7. On the basis of an expert panel opinion issued under this Article, the Commission may, following a substantiated request, adopt an implementing act to clarify the regulatory status of a specific product. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Justification

It is essential that manufacturers and developers are entitled to request an opinion from an expert panel on questions relating to the regulatory status of a product. Such access promotes legal certainty, facilitates the development of innovative products and helps to ensure a more harmonised interpretation of the MDR throughout the Union. This would enhance legal certainty, increase confidence in regulatory decisions and help avoid situations where CE-marked devices are subsequently withdrawn from the market as a result of a reassessment of their regulatory status.

In accordance with the case law of the European Court of Justice, the regulatory status of a product shall be determined through a case-by-case assessment. Consequently, references to product categories or groups should be deleted, as they may undermine an individual assessment of each product.

Furthermore, our proposition aligns with the proposed Articles 51a and 51b on classification issues of devices, taking into account the amendments introduced by the Draft Report. It would strengthen the role of expert panels in addressing complex questions regarding the regulatory status of products

by enabling the submission of substantiated requests for scientific and technical opinions. This would enhance consistency and legal certainty while ensuring that final decisions on regulatory status remain within the established regulatory framework.

To ensure a proportionate and predictable approach, the assessment of the expert panel should take into account whether the product concerned is capable of complying with the requirements applicable to the proposed regulatory category. This would help prevent situations in which a product cannot subsequently obtain the authorisations required under the new regulatory framework, resulting in its withdrawal from the market and a potential reduction in the availability of treatment options for patients.

For innovative products that are still under development or undergoing conformity assessment, the publication of expert panel opinions may reveal commercially sensitive information and could negatively affect innovation and investment. The protection of business information should therefore be carefully balanced against transparency objectives.

The Commission would not be automatically involved, thereby preserving its resources and administrative capacity.

▪ 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.

The Draft Report of the Committee on Public Health of the European Parliament has already included our proposal (Amendment 31 in combination with Amendment 6).

Commission Proposal	Draft Report of the Committee on Public Health of the European Parliament	Article 10(11)
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Original Text	Amendment 31 in combination with Amendment 6	Proposed Change by Pharma Deutschland
11. [...] 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. [...] 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. [...] 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 intended exclusively for professional use, the information referred to in Section 23 of Annex I may be provided only in English.

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 (as proposed in the Draft Report of the Committee on Public Health of the European Parliament has already included our proposal (Amendment 6).

▪ **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. **The Draft Report of the Committee on Public Health of the European Parliament does not propose any amendments to this provision.** This additional requirement is critical and raises significant concerns. **No amendment concerning this provision has been submitted.**

Commission Proposal	Draft Report of the Committee on Public Health of the European Parliament	Article 60(1b)
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Original Text	No Amendment	Proposed Change by Pharma Deutschland
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.

▪ **Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance**

Article 94

Article 94 lays down the procedure for the evaluation of devices suspected of presenting an unacceptable risk or other non-compliance with the MDR. The Commission's proposal expands the scope of this provision in several respects. First, it extends the evaluation not only to the device concerned but also to the economic operator. Second, it requires, where applicable and upon request, the notified body that issued the certificate for the device to cooperate with competent authorities during the evaluation. Third, the proposal introduces an explicit power for competent authorities to request documentation from economic operators and notified bodies where such documentation is necessary in the interest of public health or patient safety. In addition, the proposal expressly provides for cooperation between competent authorities of different Member States when carrying out evaluations under Article 94.

The Draft Report of the Committee on Public Health of the European Parliament does not propose any amendments to this provision. One amendment concerning Article 94 has been submitted (Amendment 600).

Commission Proposal	Amendment 600	Article 94(2)
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Original Text	Proposed by Laurent Castillo, Margarita de la Pisa Carrión, Ondřej Knotek, Marie-Luce Brasier Clain, Valérie Deloge	Proposed Change by Pharma Deutschland
Article 94 Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance	Article 94 Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance	Article 94 Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance
The competent authorities of a Member State shall, alone or in cooperation with the competent authorities of other Member States, carry out an evaluation of a device of of an economic operator covering all the relevant	The competent authorities of a Member State shall, alone or in cooperation with the competent authorities of other Member States, carry out an evaluation of a device of of an economic operator covering all the relevant	The competent authorities of a Member State shall, alone or in cooperation with the competent authorities of other Member States, carry out an evaluation of a device of of an economic operator covering all the relevant

requirements laid down in this Regulation relating to the risk presented by the device, or to any other non-compliance of the device or of the economic operator, where they, based on data obtained by vigilance or market surveillance activities or on other information, have reason to believe either of the following:

(a) the device may 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;

(b) the device or the economic operator concerned otherwise does not comply with the requirements laid down in this Regulation.

The relevant economic operators and, where applicable and requested, the notified body that issued a certificate for the device in question shall cooperate with the competent authorities.

requirements laid down in this Regulation relating to the risk presented by the device, or to any other non-compliance of the device or of the economic operator, where they, based on data obtained by vigilance or market surveillance activities or on other information, have reason to believe either of the following:

(a) the device may 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;

(b) the device or the economic operator concerned otherwise does not comply with the requirements laid down in this Regulation.

The relevant economic operators and, where applicable and requested, the notified body that issued a certificate for the device in question shall cooperate with the competent authorities. **Before concluding the assessment, the competent authorities shall report their preliminary conclusions to the economic operator concerned and give it the opportunity to submit observations or additional technical information, except**

requirements laid down in this Regulation relating to the risk presented by the device, or to any other non-compliance of the device or of the economic operator, where they, based on data obtained by vigilance or market surveillance activities or on other information, have reason to believe either of the following:

(a) the device may 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;

(b) the device or the economic operator concerned otherwise does not comply with the requirements laid down in this Regulation.

The product's regulatory status shall not, in and of itself, constitute such evidence.

The relevant economic operators and, where applicable and requested, the notified body that issued a certificate for the device in question shall cooperate with the competent authorities. **Before concluding the assessment, the competent authorities shall report their preliminary conclusions to the economic operator concerned and give it the opportunity to submit observations or additional technical information, except**

The competent authorities of the Member States may request any economic operator or notified body to submit documentation available to them, where access to such documentation is needed in the interest of public health or patient safety or health.

where immediate action is necessary to remedy a significant risk to health or safety.

The competent authorities of the Member States may request any economic operator or notified body to submit documentation available to them, where access to such documentation is needed in the interest of public health or patient safety or health.

where immediate action is necessary to remedy a significant risk to health or safety.

The competent authorities of the Member States may request any economic operator or notified body to submit documentation available to them, where access to such documentation is needed in the interest of public health or patient safety or health.

Justification

This proposal **strengthens procedural fairness and transparency** during market surveillance evaluations under Article 94. Before reaching a final conclusion, competent authorities should provide the economic operator concerned with their preliminary findings and give it the opportunity to submit observations, clarifications or additional technical information. This helps ensure that decisions are based on a complete and accurate assessment of all relevant facts and evidence.

The proposed right to be heard enhances legal certainty and is consistent with the principles of good administration and due process. It may also help avoid unnecessary regulatory measures where additional information provided by the economic operator resolves the concerns identified during the evaluation.

The exception for situations where immediate action is necessary to remedy a significant risk to health or safety is appropriate and ensures that urgent public health concerns can continue to be addressed without delay.

The clarification made in Amendment 273 that a product's regulatory status should not, in and of itself, constitute evidence of an unacceptable risk is appropriate. The regulatory status of a product and the risks posed by that product are distinct issues and should not be conflated. **This clarification should therefore be added in Article 94.**

▪ **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.

The Draft Report of the Committee on Public Health of the European Parliament does not propose any amendments to this provision. No Amendment concerning this provision has been submitted.

Commission Proposal	Draft Report of the Committee on Public Health of the European Parliament	Article 97
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Original Text	No Amendment	Proposed Change by Pharma Deutschland
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		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.

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 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

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, **where the non-compliance relates to the device, and after consulting the competent authority responsible for the 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.

3. In order to ensure the uniform application of this Article, the Commission may, by means of implementing acts, specify appropriate measures to be taken by competent authorities to address given types of non-compliance. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

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

~~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.

4. In order to ensure the uniform application of this Article, the Commission may, by means of implementing acts, specify appropriate measures to be taken by competent authorities to address given types of non-compliance. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

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. A device that has successfully undergone a conformity assessment involving a notified body and has been CE-marked in accordance with Article 20 should benefit from a high degree of regulatory certainty. National market surveillance measures should not operate as a re-assessment of a device that has successfully undergone conformity assessment and obtained CE-marking.

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. **The Draft Report of the Committee on Public Health of the European Parliament already considers our proposal (Amendment 98).**

Commission Proposal	Draft Report of the Committee on Public Health of the European Parliament	Article 106(4)
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Original Text	Amendment 98	Proposed Change by Pharma Deutschland
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 and industry 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.

▪ 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. **The Draft Report of the Committee on Public Health of the European Parliament does not propose any amendments to this provision. Several amendments have been submitted concerning this provision by Letizia Moratti, Dolors Montserrat, Elena Nevado del Campo, by Ruggero Razza, Michele Picaro as well as by Ruggero Razza, Michele Picaro and by Letizia Moratti, Dolors Montserrat, Elena Nevado del Campo (Amendments 619 ff.).**

Commission Proposal	Amendments 619 and 620	Article 106b
Original Text	Proposed by Letizia Moratti, Dolors Montserrat, Elena Nevado del Campo, by Ruggero Razza, Michele Picaro	Proposed Change by Pharma Deutschland
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: [...]	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:	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.

Justification

Limiting the EMA's role to administrative support is appropriate and is welcomed. Removing the references to scientific and technical support helps to ensure a clear allocation of responsibilities and avoids any perception that the EMA may influence regulatory qualification decisions in areas beyond its primary field of competence. This is particularly important for substance-based medical devices and other complex borderline products.

Restricting the EMA's role to administrative support therefore contributes to legal certainty, preserves the existing regulatory framework and avoids unnecessary overlap of responsibilities.

Commission Proposal	Amendments 621 and 622	Article 106b
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Original Text	Proposed by Ruggero Razza, Michele Picaro and by Letizia Moratti, Dolores Montserrat, Elena Nevado del Campo	Proposed Change by Pharma Deutschland
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	Deletion of Article 106b(1a)	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.

and Articles 3, 3a, 47, 47a and 47b of Regulation (EU) 2017/746;

[...]

Justification

The Commission proposal would assign the EMA a role in supporting decisions on the regulatory status and classification of products. The deletion of this provision is welcomed.

The **EMA's primary mandate and expertise relate to medicinal products**. Removing this provision contributes to legal certainty, preserves a clear distribution of responsibilities and avoids unnecessary overlap between the regulatory systems for medicinal products and medical devices. Restricting the EMA's role to administrative support therefore contributes to legal certainty, preserves the existing regulatory framework and avoids unnecessary overlap of responsibilities.

▪ **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. **The Draft Report of the Committee on Public Health of the European Parliament already considers our proposal (Amendment 110).**

Commission Proposal	Draft Report of the Committee on Public Health of the European Parliament	Annex I Chapter III 23.1(f)
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Original Text	Amendment 110	Proposed Change by Pharma Deutschland
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.	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)~~ such as electronic format ~~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.	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.~~ 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.

The Draft Report of the Committee on Public Health of the European Parliament already considers our proposal (Amendment 112).

Commission Proposal	Draft Report of the Committee on Public Health of the European Parliament	Annex VI Part B 4.
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Original Text	Amendment 112	Proposed Change by Pharma Deutschland
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, [...]	deleted	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,~~ [...]

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. **The Draft Report of the Committee on Public Health of the European Parliament does not propose any amendments to these provisions. Two amendments concerning Rules 6 and 7 have been submitted by Ondřej Dostál (Amendments 820 f.).**

Commission Proposal	Amendment 820	Rule 6
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Original Text	Proposed by Ondřej Dostál	Proposed Change by Pharma Deutschland
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 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	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 ~~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	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 ~~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 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.

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;

- 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.

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;

- 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.

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).

Commission Proposal	Amendment 821	Rule 7
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Original Text	Proposed by Ondřej Dostál	Proposed Change by Pharma Deutschland
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 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; - 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	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 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; - 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	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 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; - 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

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| - 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 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; | - 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. **The proposed amendments in the Draft Report of the Committee on Public Health of the European Parliament (Amendments 117, 118, 119 and 120) are partially achieving the objective of simplification and proportionality.**

Commission Proposal	Draft Report of the Committee on Public Health of the European Parliament	Rule 11
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Original Text	Amendments 117, 118, 119 and 120	Proposed Change by Pharma Deutschland
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 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 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 to:
- 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 treat or diagnose 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;	- treat or diagnose 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;

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| <ul style="list-style-type: none"> - 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; | <ul style="list-style-type: none"> - in treat or diagnose a disease or condition 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 of a disease or condition in a critical situation in which cases it is classified as class IIb; | <ul style="list-style-type: none"> - treat or diagnose a disease or condition 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 of a disease or condition in a critical situation in which cases it is classified as class IIb; |
| <ul style="list-style-type: none"> - 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; | <ul style="list-style-type: none"> - in treat or diagnose a disease or condition in a non-serious situation, or to drive clinical management of a disease or condition in a serious situation or to inform clinical management of a disease or condition in a critical or serious situation in which case it is classified as class IIa; | <ul style="list-style-type: none"> - treat or diagnose a disease or condition in a non-serious situation where clinical management is required, or to drive clinical management of a disease or condition in a serious situation, or to inform clinical management of a disease or condition in a critical or serious situation, in which case 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, we would like to draw attention to one aspect of Rule 11 that, in its current drafting, may not yet deliver the intended effect.

The opening sentence sets class I as the default classification for clinical-benefit software. However, this default no longer applies once the output is intended for a disease or condition in one of the three situations listed in the indents that follow:

- a critical situation
- a serious situation

– a non-serious situation.

These three situations cover every possible case; no fourth category exists. The final indent assigns even the mildest of the three, the non-serious situation, to class IIa. As a result, every clinical-benefit software output falls into one of the three situations, and none of them currently leads to class I in practice.

We would therefore welcome a clarification ensuring that the class I pathway set out in the opening sentence retains a genuine scope of application.

Illustrative examples that would currently suffer from the current proposal include:

– Dyscalculia exercise applications → Class IIa

– Motion sickness exercise applications, guiding lay users through standardised breathing and gaze-stabilisation exercises → Class IIa

Neither example concerns a critical or serious situation, and neither requires clinical management in the sense of ongoing monitoring, dose titration, or a change in a healthcare professional's treatment decision: both generate a tailored treatment (e.g. clinically well-established exercises), intended for direct use by lay users without the need of a healthcare professional. Yet under the current wording of Rule 11, both default to class IIa.

This approach results in trivial, low-risk software tools being placed in the same risk class as genuinely medium- or high-risk devices, such as ECG analysis software. Consequently, such devices would be subject to 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.

For these reasons, we believe the proposed revision of Rule 11 for software does not yet fully achieve its stated objective of simplification and proportionality, and risks discouraging investment in digital health solutions within the EU.

Our proposition restores a **genuine class I pathway for low-risk treatment software that neither relates to critical or serious conditions nor requires clinical management**, consistent with the default classification rule in Annex I, point 6.6(g). The proposed approach ensures that low-impact treatment-support software is not subject to disproportionate regulatory requirements, while preserving a cautious classification in line with established risk-based classification principles, including the IMDRF framework. The proposal is **largely inspired by the amendments of the Draft Report of the Committee on Public Health of the European Parliament**.

▪ **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.

The Draft Report of the Committee on Public Health of the European Parliament already considers our proposal (Amendment 122).

Commission Proposal	Draft Report of the Committee on Public Health of the European Parliament	Rule 14
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Original Text	Amendment 122	Proposed Change by Pharma Deutschland
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 action~~ a clinically relevant action contributing to the intended medical purpose of the ~~devices~~ device , 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 action~~ has a clinically relevant 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.

The Draft Report of the Committee on Public Health of the European Parliament already considers our proposal (Amendment 121).

Commission Proposal	Draft Report of the Committee on Public Health of the European Parliament	Rule 21
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Original Text	Amendment 121	Proposed Change by Pharma Deutschland
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 achieve their intended purpose in the stomach or lower gastrointestinal tract and they, or their products of metabolism, are	Deleted	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 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 IIb in all other cases.

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 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.