

ANALYSIS

of the Pharma Deutschland e.V.

on the Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and in vitro diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I (COM(2025) 1023 final)

date: 11 February 2026

Preliminary Note

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.

Pharma Deutschland e.V. welcomes the European Commission's initiative aimed at simplifying the EU regulatory framework for medical devices and enhancing the competitiveness of the European medical device sector within the internal market and at global level. Nevertheless, we see several areas where further improvements are needed. The following analysis focuses on the changes that are of greatest relevance and necessity for our member companies.

	<p align="center">European Commission legal proposal Dated December 2025</p> <p>Commission proposed amendments within the MDR/IVDR text, showing:</p> <ul style="list-style-type: none"> Deleted text in strikethrough (example: text) New text in bold (example: text) 	<p>Impact & Gap analysis</p> <p><i>What is positive, what are issues (missing, unclear...)? Add a brief rationale</i></p>	<p>Redlines: Critical negative or positive? Colour code R or G</p> <p><i>Indicate where the amendment is critically positive or negative (no indication if not)</i></p>	<p>What is your recommendation?</p> <p><i>Change needed, if any. Recommended action to be taken, if any</i></p>
1.	<p>Recital 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.</p>	<p>The approach is internally inconsistent. Prioritising legal certainty and the free movement of goods necessarily precludes leaving decisions on regulatory status to national authorities other than the competent authority of the Member State where the manufacturer is established.</p>		<p>Pharma Deutschland suggests an amendment to recital 11 as follows:</p> <p>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 competent authority of the Member State, in which the manufacturer has its registered place of business or, where appropriate, with the Commission acting through implementing acts.</p>
2.	<p>Recital 15: While it should remain the responsibility of each Member State to determine the language in which information should be supplied to the users within their territory, Member States should consider accepting such information in other languages of the Union that are commonly understood in the medical field, especially regarding devices intended for professional users, in order to reduce costs for translations.</p>	<p>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.</p> <p>Healthcare professionals in the European Union can reasonably be expected to understand English, as they</p>		<p>Pharma Deutschland suggests an amendment to recital 15 as follows:</p> <p>While it should remain the responsibility of each Member State to determine the language in which information should be supplied to the lay lay users within their territory, Member States should consider accepting such information in other languages of the Union that are commonly understood in the medical field, especially regarding devices intended for professional users, in order to reduce costs for translations. Where a device is made available exclusively to professional users, the information shall be provided in English.</p>

	<p align="center">European Commission legal proposal Dated December 2025</p> <p>Commission proposed amendments within the MDR/IVDR text, showing:</p> <ul style="list-style-type: none"> Deleted text in strikethrough (example: text) New text in bold (example: text) 	<p>Impact & Gap analysis</p> <p><i>What is positive, what are issues (missing, unclear...)? Add a brief rationale</i></p>	<p>Redlines: Critical negative or positive? Colour code R or G</p> <p><i>Indicate where the amendment is critically positive or negative (no indication if not)</i></p>	<p>What is your recommendation?</p> <p><i>Change needed, if any. Recommended action to be taken, if any</i></p>
		<p>undergo extensive professional education and training. English is a commonly understood working language among healthcare professionals across the EU.</p>		
3.	<p>CHAPTER I SCOPE AND DEFINITIONS</p>			
4.	<p align="center">Article 2 Definitions</p> <p>(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.</p>	<p>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.</p>		<p>Pharma Deutschland proposes maintaining the current provision of Article 2(7), which is based on alternative conditions:</p> <p align="center">Article 2 Definitions</p> <p>(7) 'generic device group' means a set of devices having the same or similar intended purposes or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics.</p>
5.	<p>(72) 'well-established technology device' means a device that belongs to a generic device group, which fulfils the following criteria:</p> <p>a) it has simple, common and stable design;</p>	<p>Pharma Deutschland welcomes the proposal to include a definition of WET device in the MDR while deleting the current list of products. From our</p>		<p>Pharma Deutschland proposes a minor amendment to the proposed Article 2(72):</p> <p align="center">Article 2 Definitions</p>

	<p align="center">European Commission legal proposal Dated December 2025</p> <p>Commission proposed amendments within the MDR/IVDR text, showing:</p> <ul style="list-style-type: none"> Deleted text in strikethrough (example: text) New text in bold (example: text) 	<p>Impact & Gap analysis</p> <p><i>What is positive, what are issues (missing, unclear...)? Add a brief rationale</i></p>	<p>Redlines: Critical negative or positive? Colour code R or G</p> <p><i>Indicate where the amendment is critically positive or negative (no indication if not)</i></p>	<p>What is your recommendation?</p> <p><i>Change needed, if any. Recommended action to be taken, if any</i></p>
	<p>b) it has not been associated with safety issues in the past;</p> <p>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;</p> <p>d) it has a long history on the Union market;’;</p>	<p>perspective, it is proportionate and appropriate to extend the MDR’s regulatory simplifications to all devices that demonstrably qualify as WET 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.</p> <p>However, the term “safety issues” is not defined in the MDR, which may lead to divergent interpretations by notified bodies.</p>		<p>(72) ‘well-established technology device’ means a device that belongs to a generic device group, which fulfils the following criteria:</p> <p>a) it has simple, common and stable design;</p> <p>b) it has a well-known safety history not been associated with safety issues in the past;</p> <p>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;</p> <p>d) it has a long history on the Union market;’;</p>
<p>6.</p>	<p align="center">Article 4 Regulatory status of products</p> <p>1. Without prejudice to Article 2(2) of Directive 2001/83/EC, upon a duly substantiated request of a Member State, the Commission shall, after consulting the Medical Device Coordination Group established under Article 103 of this Regulation (‘MDCG’), by</p>	<p>The current version of Article 4 includes a legally binding procedure for the determination of the regulatory status of a product. Such a procedure has been missing under the former Directive 93/42/EEC on medical</p>	<p>Critically negative</p>	<p>Pharma Deutschland proposes the complete deletion of the proposed Article 4 and a rewording of the proposed Article 4a.</p> <p>As an alternative, Pharma Deutschland suggests retaining the current wording of Article 4.</p>

	<p align="center">European Commission legal proposal Dated December 2025</p> <p>Commission proposed amendments within the MDR/IVDR text, showing:</p> <ul style="list-style-type: none"> Deleted text in strikethrough (example: text) New text in bold (example: text) 	<p>Impact & Gap analysis</p> <p><i>What is positive, what are issues (missing, unclear...)? Add a brief rationale</i></p>	<p>Redlines: Critical negative or positive? Colour code R or G</p> <p><i>Indicate where the amendment is critically positive or negative (no indication if not)</i></p>	<p>What is your recommendation?</p> <p><i>Change needed, if any. Recommended action to be taken, if any</i></p>
	<p>means of implementing acts, determine The competent authorities of the Member States shall coordinate their activities when determining whether or not a specific product, or category, or group of products, falls within the definitions 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. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3) of this Regulation.</p> <p>2. The Commission may also, on its own initiative, after consulting the MDCG, decide, by means of implementing acts, on the issues referred to in paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3). 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</p>	<p>devices and therefore it is an appreciated improvement. As no procedure according to the current Article 4 has been conducted yet, it remains unclear, why the European Commission suggests an amendment.</p> <p>The reform proposal appears to seek to legally entrench the so-called Helsinki procedure, a decision-making mechanism characterized by limited transparency and an insufficient scientific basis.</p> <p>The formally structured procedure proposed in the revision of Articles 4 and 4a is highly questionable, as a decision on the regulatory status of a product initiated by a single competent authority becomes decisive unless another authority of a Member State raise a substantiated objection. Even the mandatory</p>		<p>The following assumptions are necessary to ensure legal certainty for manufacturers, to enable their willingness to place devices on the market, and to guarantee the availability of devices on the Union market:</p> <ul style="list-style-type: none"> Apart from a decision of the Commission adopted by means of an implementing act, only the competent authority of the Member State in which the manufacturer has its registered place of business should be empowered to determine the regulatory status of a product of that manufacturer. The free movement of CE-marked medical devices must be safeguarded, as guaranteed by Article 24. National authorities responsible for market surveillance in Member States where a CE-marked device is merely distributed should be empowered to carry out market surveillance activities in accordance with Article 93 ff. Any concerns regarding the correct regulatory status of a CE-marked device should be referred to the Commission by means of a duly substantiated request or to the Member State in which the manufacturer has its registered place of business after opinion of an expert panel. Expert panels should demonstrate proven and up-to-date clinical, scientific, technical or regulatory expertise in the field of medical devices, as well as

	<p align="center">European Commission legal proposal Dated December 2025</p> <p>Commission proposed amendments within the MDR/IVDR text, showing:</p> <ul style="list-style-type: none"> Deleted text in strikethrough (example: text) New text in bold (example: text) 	<p>Impact & Gap analysis</p> <p><i>What is positive, what are issues (missing, unclear...)? Add a brief rationale</i></p>	<p>Redlines: Critical negative or positive? Colour code R or G</p> <p><i>Indicate where the amendment is critically positive or negative (no indication if not)</i></p>	<p>What is your recommendation?</p> <p><i>Change needed, if any. Recommended action to be taken, if any</i></p>
	<p>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).</p> <p>3. The Commission shall ensure that Member States share expertise in the fields of medical devices, in vitro diagnostic medical devices, medicinal products, human tissues and cells, cosmetics, biocides, food and, if necessary, other products, in order to determine the appropriate regulatory status of a product, or category or group of products. Where a competent authority of a Member State, after having performed an evaluation in accordance with Article 94, considers that a product that is CE marked in accordance with Article 20, does not fall within the scope of this Regulation, it shall consult the competent authorities of the other Member States regarding its envisaged measure determining the regulatory status of the product in question.</p> <p>4. When deliberating on the possible regulatory status as a device of products involving medicinal products, human tissues and cells, biocides or food products, the</p>	<p>involvement according to Article 4(2) of other European bodies (e.g. EMA, ECHA or EFSA) does not remedy the structural deficit resulting from the lack of systematic involvement of independent scientific, technical and industry expertise, which may lead to isolated and inconsistent outcomes.</p> <p>Particularly critical in this context is the new provision in Article 4(3) MDR, which allows Member States to adopt measures affecting the regulatory status of products that already bear the CE marking. This significantly relativizes the principle of free movement of goods enshrined in Article 24 MDR and undermines legal certainty and legitimate expectations. In the absence of clearly defined substantive criteria, procedural</p>		<p>impartiality, objectivity and transparency. For the determination of the regulatory status of products, it must be ensured that the expert panel has access to all relevant information necessary to fulfil its tasks. This includes, in particular, information provided by the manufacturer, who possesses the most comprehensive knowledge of the products concerned.</p> <ul style="list-style-type: none"> The expert panel should also assess whether a previous determination of a product, and the underlying reasoning of such a determination by authorities or administrative or civil courts, remains applicable under the current and amended Union legislation.

	<p align="center">European Commission legal proposal Dated December 2025</p> <p>Commission proposed amendments within the MDR/IVDR text, showing:</p> <ul style="list-style-type: none"> Deleted text in strikethrough (example: text) New text in bold (example: text) 	<p>Impact & Gap analysis</p> <p><i>What is positive, what are issues (missing, unclear...)? Add a brief rationale</i></p>	<p>Redlines: Critical negative or positive? Colour code R or G</p> <p><i>Indicate where the amendment is critically positive or negative (no indication if not)</i></p>	<p align="center">What is your recommendation?</p> <p><i>Change needed, if any. Recommended action to be taken, if any</i></p>
	<p>Commission shall ensure an appropriate level of consultation of the European Medicines Agency (EMA), the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA), as relevant. 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.</p> <p>5. The results of the coordination activities of the competent authorities in accordance with this Article and the opinions of the expert panel delivered in accordance with paragraph 4 of this Article and Article 4a(2) shall be made publicly available, without disclosing any confidential information as referred to in Article 109.</p> <p>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).</p>	<p>safeguards and effective mechanisms for the protection of vested rights, there is a substantial risk that individual national decisions may de facto undermine EU-wide market access.</p> <p>Moreover, the specific wording of the new provision raises fundamental questions regarding the role and legal effect of the expert panels referred to in Article 106 MDR. While their opinions are to be “given the utmost consideration” by the competent authorities, they are not legally binding. Consequently, the final decision on regulatory status remains discretionary. The risk of divergent assessments under identical EU-wide conditions is therefore not fully eliminated, particularly since there is no obligation to apply the</p>		

	<p align="center">European Commission legal proposal Dated December 2025</p> <p>Commission proposed amendments within the MDR/IVDR text, showing:</p> <ul style="list-style-type: none"> Deleted text in strikethrough (example: text) New text in bold (example: text) 	<p>Impact & Gap analysis</p> <p><i>What is positive, what are issues (missing, unclear...)? Add a brief rationale</i></p>	<p>Redlines: Critical negative or positive? <i>Colour code</i> R or G</p> <p><i>Indicate where the amendment is critically positive or negative (no indication if not)</i></p>	<p>What is your recommendation?</p> <p><i>Change needed, if any. Recommended action to be taken, if any</i></p>
		<p>procedures set out in Articles 4 and 4a MDR. As a result, the intended strengthening of legal certainty is unlikely to be achieved in practice. In addition, unresolved issues remain regarding technical coverage and the long-term availability of sufficient expertise, especially for complex demarcation and classification questions.</p> <p>Furthermore, it remains entirely unclear how decisions published by the authorities according to Article 4(5) can be legally challenged or subjected to effective judicial or democratic review by the affected economic operators. In the absence of clearly defined legal effects, procedural rights, and review mechanisms grounded in the rule of law, such a mechanism warrants strong criticism.</p>		

	<p align="center">European Commission legal proposal Dated December 2025</p> <p>Commission proposed amendments within the MDR/IVDR text, showing:</p> <ul style="list-style-type: none"> Deleted text in strikethrough (example: text) New text in bold (example: text) 	<p>Impact & Gap analysis</p> <p><i>What is positive, what are issues (missing, unclear...)? Add a brief rationale</i></p>	<p>Redlines: Critical negative or positive? Colour code R or G</p> <p><i>Indicate where the amendment is critically positive or negative (no indication if not)</i></p>	<p>What is your recommendation?</p> <p><i>Change needed, if any. Recommended action to be taken, if any</i></p>
		<p>Article 4(6) MDR grants the European Commission the power to specify, by means of implementing acts, the procedure, including binding deadlines, for the coordination and demarcation mechanisms referred to in Articles 4(1) to (4) and Article 4a. While this allocation of powers would be welcome in principle, the general procedural framework already reflects key elements of the Helsinki procedure, which has been subject to justified criticism. Moreover, there is a risk that, despite formal legal restructuring, the demarcation process will continue in practice to be marked by delays, isolated positions and divergent national approaches.</p>		

	<p align="center">European Commission legal proposal Dated December 2025</p> <p>Commission proposed amendments within the MDR/IVDR text, showing:</p> <ul style="list-style-type: none"> Deleted text in strikethrough (example: text) New text in bold (example: text) 	<p>Impact & Gap analysis</p> <p><i>What is positive, what are issues (missing, unclear...)? Add a brief rationale</i></p>	<p>Redlines: Critical negative or positive? Colour code R or G</p> <p><i>Indicate where the amendment is critically positive or negative (no indication if not)</i></p>	<p>What is your recommendation?</p> <p><i>Change needed, if any. Recommended action to be taken, if any</i></p>
7.	<p align="center">Article 4a</p> <p align="center">Opinion on and determination of the regulatory status of a product</p> <p>1. A competent authority, a notified body, a manufacturer, a developer of a product or the Commission may submit a substantiated request for an opinion from an expert panel referred to in Article 106 on the question whether a specific product, or category or group of products, falls within the definitions of ‘medical device’ or ‘accessory for a medical device’, or whether a product falls within the scope of Annex XVI or is an accessory for a product listed in that Annex. Where, in such a request, the requester considers that the product in question is a device, the request shall also specify the proposed classification of the device in accordance with Article 51 and Annex VIII.</p> <p>2. The expert panel shall provide its opinion without undue delay. The requester shall give utmost consideration to the opinion of the expert panel.</p> <p>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</p>	<p>The analysis of the proposed Article 4 also applies for the proposed Article 4a.</p> <p>Furthermore, although the decision-making process appears to be more closely aligned with democratic principles, the mandatory involvement of industry experts remains absent. Such expertise could provide essential technical and scientific input to the assessment. The possible involvement of the newly established expert panels cannot adequately compensate for this structural deficit.</p> <p>At least the procedure concludes with the adoption of a formal legal act.</p>	<p>Critically negative</p>	<p>Pharma Deutschland proposes the following amendments to the proposed new Article 4a:</p> <p align="center">Article 4a</p> <p align="center">Opinion on and determination of the regulatory status of a product</p> <p>1. A competent authority, a notified body, a manufacturer, a developer of a product or the Commission may submit a substantiated request for an opinion from an expert panel referred to in Article 106 on the question whether a specific product, or category or group of products, falls within the definitions of ‘medical device’ or ‘accessory for a medical device’, or whether a product falls within the scope of Annex XVI or is an accessory for a product listed in that Annex. Where, in such a request, the requester considers that the product in question is a device, the request shall also specify the proposed classification of the device in accordance with Article 51 and Annex VIII.</p> <p>2. Where a competent authority of a Member State, after having performed an evaluation in accordance with Article 94, considers that a product that is CE marked in accordance with Article 20, does not fall within the scope of this Regulation, it shall consult the competent authority of the Member State where the manufacturer has its registered place of business</p>

	<p align="center">European Commission legal proposal Dated December 2025</p> <p>Commission proposed amendments within the MDR/IVDR text, showing:</p> <ul style="list-style-type: none"> Deleted text in strikethrough (example: text) New text in bold (example: text) 	<p>Impact & Gap analysis</p> <p><i>What is positive, what are issues (missing, unclear...)? Add a brief rationale</i></p>	<p>Redlines: Critical negative or positive? Colour code R or G</p> <p><i>Indicate where the amendment is critically positive or negative (no indication if not)</i></p>	<p>What is your recommendation?</p> <p><i>Change needed, if any. Recommended action to be taken, if any</i></p>
	<p>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.</p> <p>The Commission shall decide on the substantiated request of the Member State or on its own initiative, by means of implementing acts, which shall be adopted in accordance with the examination procedure referred to in Article 114(3).</p> <p>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.</p> <p>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.</p>			<p>and the manufacturer other Member States regarding its envisaged measure determining the justification on the regulatory status of the product in question, before submitting a substantiated request for an opinion of an expert panel as referred to in paragraph 1.</p> <p>3. The Member States expert panel shall ensure an appropriate level of consultation of the relevant competent authorities of the Member States in the fields of in vitro diagnostic medical devices, medicinal products, substances of human origin (SoHO), biocides, food products, cosmetics or other products subject to Union legislation, where the determination of whether a product has the regulatory status of a device involves aspects concerning the borderline with any of those types of products. If that is the case, Member States the expert panel shall also ensure an appropriate level of consultation of the relevant advisory or regulatory bodies established in the relevant Union legislation, such as the European Medicines Agency (EMA), the SoHO Coordination Board, the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA). The expert panel shall consult the notified body, the manufacturer, the developer of the concerned product.</p> <p>4. The expert panel shall provide its opinion within 30 days without undue delay. The requester shall give utmost consideration to accept the opinion of the expert panel.</p> <p>5. Any opinion of an expert panel in relation to the determination of the regulatory status, shall be made</p>

	<p style="text-align: center;">European Commission legal proposal Dated December 2025</p> <p>Commission proposed amendments within the MDR/IVDR text, showing:</p> <ul style="list-style-type: none"> Deleted text in strikethrough (example: text) New text in bold (example: text) 	<p>Impact & Gap analysis</p> <p><i>What is positive, what are issues (missing, unclear...)? Add a brief rationale</i></p>	<p>Redlines: Critical negative or positive? Colour code R or G</p> <p><i>Indicate where the amendment is critically positive or negative (no indication if not)</i></p>	<p>What is your recommendation?</p> <p><i>Change needed, if any. Recommended action to be taken, if any</i></p>
				<p>publicly available, without disclosing any confidential information as referred to in Article 109.</p> <p>6. Having regard to the expert panel opinion referred to in paragraph 4 2 or in Article 4(4), a Member State requester as referred in paragraph 1 may submit a substantiated request to the Commission to determine whether a specific product, or category or group of products, falls within the definitions of ‘medical device’ or ‘accessory for a medical device’, or whether a product falls within the scope of Annex XVI or is an accessory for a product listed in that Annex.</p> <p>The Commission shall decide on the substantiated request of the requester Member State or on its own initiative, by means of implementing acts, which shall be adopted in accordance with the examination procedure referred to in Article 114(3).</p> <p>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.</p> <p>6. 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, provided that such determination remains valid in light of the current regulatory</p>

	<p align="center">European Commission legal proposal Dated December 2025</p> <p>Commission proposed amendments within the MDR/IVDR text, showing:</p> <ul style="list-style-type: none"> Deleted text in strikethrough (example: text) New text in bold (example: text) 	<p>Impact & Gap analysis</p> <p><i>What is positive, what are issues (missing, unclear...)? Add a brief rationale</i></p>	<p>Redlines: Critical negative or positive? Colour code R or G</p> <p><i>Indicate where the amendment is critically positive or negative (no indication if not)</i></p>	<p>What is your recommendation?</p> <p><i>Change needed, if any. Recommended action to be taken, if any</i></p>
				<p>framework, or where a procedure for the determination of the regulatory status is ongoing within the framework of another Union legislation.</p>
<p align="center">8.</p>	<p align="center">CHAPTER II MAKING AVAILABLE ON THE MARKET AND PUTTING INTO SERVICE OF DEVICES, OBLIGATIONS OF ECONOMIC OPERATORS, REPROCESSING, CE-MARKING, FREE MOVEMENT</p>			
<p align="center">9.</p>	<p align="center">Article 10 General obligations of manufacturers</p> <p>[...]</p> <p>11. Manufacturers shall ensure that the device is accompanied by the information set out in Section 23 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient. The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient.</p> <p>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,</p>	<p>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.</p> <p>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</p>		<p>Pharma Deutschland proposes amending the proposed Article 10(11) as follows:</p> <p align="center">Article 10 General obligations of manufacturers</p> <p>Manufacturers shall ensure that the device is accompanied by the information set out in Section 23 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient. The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient. When determining the official language of the Union in which the information set out in Section 23 of Annex I or other information to be provided by the manufacturer shall be made available, Member States shall consider accepting another official language of the Union in which the</p>

	<p align="center">European Commission legal proposal Dated December 2025</p> <p>Commission proposed amendments within the MDR/IVDR text, showing:</p> <ul style="list-style-type: none"> Deleted text in strikethrough (example: text) New text in bold (example: text) 	<p>Impact & Gap analysis</p> <p><i>What is positive, what are issues (missing, unclear...)? Add a brief rationale</i></p>	<p>Redlines: Critical negative or positive? Colour code R or G</p> <p><i>Indicate where the amendment is critically positive or negative (no indication if not)</i></p>	<p>What is your recommendation?</p> <p><i>Change needed, if any. Recommended action to be taken, if any</i></p>
	<p>experience, education or training of the average intended user(s).</p> <p>[...]</p> <p>15. Where manufacturers have their devices designed or and manufactured by another legal or natural person, the information on the identity of that person shall be part of the information to be submitted in accordance with Article 29(4). In those cases, the manufacturer shall ensure that the relevant parts of the technical documentation are drawn up, kept up to date and, upon request, made available to the competent authorities in accordance with paragraphs 4 and 8 of this Article by the legal or natural person that has designed and manufactured the device. In addition, the manufacturer shall draw up, keep up to date and, upon request, make available to the competent authorities the remaining parts of the technical documentation, in particular those referred to in Section 2 of Annex II and in Annex III.</p>	<p>healthcare professionals across the EU.</p> <p>The proposed replacement of alternative conditions by cumulative ones in Art. 10(15) has the effect that cases in which devices are only designed or manufactured by another legal or natural person are no longer covered by this provision. However, precisely in cases where the device is manufactured by another legal or natural person, it is essential to have information about that person as well as the maintenance of the relevant parts of the technical documentation.</p>		<p>information is made available, taking into consideration the technical knowledge, experience, education or training of the average intended user(s).</p> <p>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.</p> <p>Pharma Deutschland proposes maintaining the first sentence of the current provision of Article 10(15), which is based on alternative conditions:</p> <p align="center">Article 10 General obligations of manufacturers</p> <p>15. Where manufacturers have their devices designed or manufactured by another legal or natural person, the information on the identity of that person shall be part of the information to be submitted in accordance with Article 29(4). In those cases, the manufacturer shall ensure that the relevant parts of the technical documentation are drawn up, kept up to date and, upon request, made available to the competent authorities in accordance with paragraphs 4 and 8 of this Article by the legal or natural person that has designed and manufactured the device. In addition, the manufacturer shall draw up,</p>

	<p align="center">European Commission legal proposal Dated December 2025</p> <p>Commission proposed amendments within the MDR/IVDR text, showing:</p> <ul style="list-style-type: none"> Deleted text in strikethrough (example: text) New text in bold (example: text) 	<p>Impact & Gap analysis</p> <p><i>What is positive, what are issues (missing, unclear...)? Add a brief rationale</i></p>	<p>Redlines: Critical negative or positive? Colour code R or G</p> <p><i>Indicate where the amendment is critically positive or negative (no indication if not)</i></p>	<p>What is your recommendation?</p> <p><i>Change needed, if any. Recommended action to be taken, if any</i></p>
				<p>keep up to date and, upon request, make available to the competent authorities the remaining parts of the technical documentation, in particular those referred to in Section 2 of Annex II and in Annex III.</p>
<p>10.</p>	<p align="center">Article 15 Person responsible for regulatory compliance</p> <p>1. Manufacturers shall have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices. The requisite expertise shall be demonstrated by either of the following qualifications: (a) a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices; (b) four years of professional experience in regulatory affairs or in quality management systems relating to medical devices. Without prejudice to national provisions regarding professional qualifications, manufacturers of custom-</p>	<p>The functions assigned to the PRRC require a certain level of qualification. The requirement set out in the current Art. 15(1)(a) for a diploma, certificate or other evidence of formal qualification appears to be superfluous. Nevertheless, the PRRC must possess a basic understanding of regulatory and quality management matters, which is indispensable for the proper fulfilment of their responsibilities. Therefore, the requirement laid down in the current version of Art. 15(1)(b) should not be deleted. The same applies to the current version of Art. 15(6)(b). The removal of the obligation for SMEs relying on an external PRRC to ensure that this</p>		<p>Pharma Deutschland proposes maintaining the first sentence of the current provision of Article 15(1)(b) and Article 15(6)(b):</p> <p align="center">Article 15 Person responsible for regulatory compliance</p> <p>1. Manufacturers shall have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices. The requisite expertise shall be demonstrated by either of the following qualifications: (a) a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices; (b) four years of professional experience in regulatory affairs or in quality management systems relating to medical devices.</p>

	<p align="center">European Commission legal proposal Dated December 2025</p> <p>Commission proposed amendments within the MDR/IVDR text, showing:</p> <ul style="list-style-type: none"> Deleted text in strikethrough (example: text) New text in bold (example: text) 	<p>Impact & Gap analysis</p> <p><i>What is positive, what are issues (missing, unclear...)? Add a brief rationale</i></p>	<p>Redlines: Critical negative or positive? Colour code R or G</p> <p><i>Indicate where the amendment is critically positive or negative (no indication if not)</i></p>	<p>What is your recommendation?</p> <p><i>Change needed, if any. Recommended action to be taken, if any</i></p>
	<p>made devices may demonstrate the requisite expertise referred to in the first subparagraph by having at least two years of professional experience within a relevant field of manufacturing.</p> <p>2. Micro and small enterprises within the meaning of Commission Recommendation 2003/361/EC shall not be required to have the person responsible for regulatory compliance within their organisation but shall have such person permanently and continuously at their disposal.</p> <p>3. The person responsible for regulatory compliance shall at least be responsible for ensuring that:</p> <p>(a) the conformity of the devices is appropriately checked, in accordance with the quality management system under which the devices are manufactured, before a device is released;</p> <p>(b) the technical documentation and the EU declaration of conformity are drawn up and kept up-to-date;</p> <p>(c) the post-market surveillance obligations are complied with in accordance with Article 10(10) 83;</p> <p>(d) the reporting obligations referred to in Articles 87 to 91 are fulfilled;</p> <p>(e) in the case of investigational devices, the statement referred to in Section 4.1 of Chapter II of Annex XV is issued.</p> <p>4. If a number of persons are jointly responsible for regulatory compliance in accordance with paragraphs</p>	<p>person is available “permanently and continuously”, replacing it with a general availability requirement, is welcomed. This change better reflects the operational realities of SMEs while maintaining an adequate level of regulatory oversight.</p>		<p>Without prejudice to national provisions regarding professional qualifications, manufacturers of custom-made devices may demonstrate the requisite expertise referred to in the first subparagraph by having at least two years of professional experience within a relevant field of manufacturing.</p> <p>[...]</p> <p>6. Authorised representatives shall have permanently and continuously at their disposal at least one person responsible for regulatory compliance who possesses the requisite expertise regarding the regulatory requirements for medical devices in the Union. The requisite expertise shall be demonstrated by either of the following qualifications:</p> <p>(a) a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices;</p> <p>(b) four years of professional experience in regulatory affairs or in quality management systems relating to medical devices.</p>

	<p align="center">European Commission legal proposal Dated December 2025</p> <p>Commission proposed amendments within the MDR/IVDR text, showing:</p> <ul style="list-style-type: none"> Deleted text in strikethrough (example: text) New text in bold (example: text) 	<p>Impact & Gap analysis</p> <p><i>What is positive, what are issues (missing, unclear...)? Add a brief rationale</i></p>	<p>Redlines: Critical negative or positive? Colour code R or G</p> <p><i>Indicate where the amendment is critically positive or negative (no indication if not)</i></p>	<p>What is your recommendation?</p> <p><i>Change needed, if any. Recommended action to be taken, if any</i></p>
	<p>1, 2 and 3, their respective areas of responsibility shall be stipulated in writing.</p> <p>5. The person responsible for regulatory compliance shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his or her duties, regardless of whether or not they are employees of the organisation.</p> <p>6. Authorised representatives shall have permanently and continuously at their disposal at least one person responsible for regulatory compliance who possesses the requisite expertise regarding the regulatory requirements for medical devices in the Union. The requisite expertise shall be demonstrated by either of the following qualifications:</p> <p>(a) a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices;</p> <p>(b) four years of professional experience in regulatory affairs or in quality management systems relating to medical devices.</p>			

	<p align="center">European Commission legal proposal Dated December 2025</p> <p>Commission proposed amendments within the MDR/IVDR text, showing:</p> <ul style="list-style-type: none"> Deleted text in strikethrough (example: text) New text in bold (example: text) 	<p>Impact & Gap analysis</p> <p><i>What is positive, what are issues (missing, unclear...)? Add a brief rationale</i></p>	<p>Redlines: Critical negative or positive? Colour code R or G</p> <p><i>Indicate where the amendment is critically positive or negative (no indication if not)</i></p>	<p>What is your recommendation?</p> <p><i>Change needed, if any. Recommended action to be taken, if any</i></p>
11.	<p align="center">CHAPTER IV NOTIFIED BODIES</p>			
12.	<p align="center">Article 50 List of standard Access to notified bodies and fees</p> <p>1. Notified bodies shall establish lists of their standard fees for the conformity assessment activities that they carry out and shall make those lists publicly available. They shall notify the lists to the Commission, which shall make references to them available to the public on a dedicated website.</p> <p>2. Notified bodies shall apply at least a 50 % fee reduction for manufacturers that are micro enterprises within the meaning of Recommendation 2003/361/EC and at least a 25% fee reduction for small enterprises within the meaning of that Recommendation. They shall apply at least a 50% fee reduction for manufacturers that apply for conformity assessment of an orphan device referred to in Article 52a(3). Notified bodies shall provide manufacturers that are micro or small enterprises within the meaning of Recommendation 2003/361/EC the possibility to defer the payment of</p>	<p>Fee reductions for micro and small manufacturers as well as for orphan devices are essential. The empowerment of the Commission to determine the level and structure of notified body fees is also welcomed. However, medium-sized enterprises are likewise significantly affected by the high fees charged by notified bodies. It would therefore be advisable to extend fee reduction mechanisms to medium-sized enterprises as well.</p> <p>In this context, the proposed Article 50(4) is of particular importance. Manufacturers benefiting from fee reductions must not be placed at a competitive disadvantage compared to other manufacturers.</p>		<p>Pharma Deutschland proposes the following amendment to the proposed Article 50(2):</p> <p align="center">Article 50 Access to notified bodies and fees</p> <p>[...]</p> <p>2. Notified bodies shall apply at least a 50 % fee reduction for manufacturers that are micro enterprises within the meaning of Recommendation 2003/361/EC and at least a 25% fee reduction for small and medium-sized enterprises within the meaning of that Recommendation. They shall apply at least a 50% fee reduction for manufacturers that apply for conformity assessment of an orphan device referred to in Article 52a(3). Notified bodies shall provide manufacturers that are micro or small enterprises within the meaning of Recommendation 2003/361/EC the possibility to defer the payment of fees until the relevant conformity assessment activity is finalised.</p> <p>[...]</p>

	<p align="center">European Commission legal proposal Dated December 2025</p> <p>Commission proposed amendments within the MDR/IVDR text, showing:</p> <ul style="list-style-type: none"> Deleted text in strikethrough (example: text) New text in bold (example: text) 	<p>Impact & Gap analysis</p> <p><i>What is positive, what are issues (missing, unclear...)? Add a brief rationale</i></p>	<p>Redlines: Critical negative or positive? Colour code R or G</p> <p><i>Indicate where the amendment is critically positive or negative (no indication if not)</i></p>	<p>What is your recommendation?</p> <p><i>Change needed, if any. Recommended action to be taken, if any</i></p>
	<p>fees until the relevant conformity assessment activity is finalised.</p> <p>3. The Commission, in consultation with the MDCG, may adopt implementing acts to specify the structure and level of the fees referred to in paragraph 1, taking into account the need to:</p> <p>(a) establish and maintain high standards of quality and safety of devices;</p> <p>(b) ensure the availability of devices;</p> <p>(c) protect the interests of micro, small or medium-sized enterprises within the meaning of Recommendation 2003/361/EC;</p> <p>(d) support innovation and competitiveness.</p> <p>4. Notified bodies shall ensure that manufacturers, which are micro, small or medium-sized enterprises within the meaning of Recommendation 2003/361/EC, have access to their conformity assessment activities in a manner that is not less favourable than the manner in which access is provided to other manufacturers.</p> <p>5. Notified bodies shall deal with any request for conformity assessment activities from a manufacturer and, within 15 days of receipt of the request, inform the manufacturer accordingly.</p> <p>6. When duly justified in the interest of public health or patient health or safety, the authority responsible for notified bodies may instruct a</p>			

	<p align="center">European Commission legal proposal Dated December 2025</p> <p>Commission proposed amendments within the MDR/IVDR text, showing:</p> <ul style="list-style-type: none"> Deleted text in strikethrough (example: text) New text in bold (example: text) 	<p>Impact & Gap analysis</p> <p><i>What is positive, what are issues (missing, unclear...)? Add a brief rationale</i></p>	<p>Redlines: Critical negative or positive? Colour code R or G</p> <p><i>Indicate where the amendment is critically positive or negative (no indication if not)</i></p>	<p>What is your recommendation?</p> <p><i>Change needed, if any. Recommended action to be taken, if any</i></p>
	<p>notified body to accept a manufacturer's request for conformity assessment activities falling within that notified body's scope of designation.</p>			
<p>13.</p>	<p align="center">CHAPTER V CLASSIFICATION AND CONFORMITY ASSESSMENT</p>			
<p>14.</p>	<p align="center">Article 51 Classification of devices</p> <p>1. Devices shall be divided into classes I, IIa, IIb and III, taking into account the intended purpose of the devices and their inherent risks. Classification shall be carried out in accordance with Annex VIII.</p> <p>2. Any dispute between the manufacturer and the notified body concerned, arising from the application of Annex VIII, shall be referred for a decision to the competent authority of the Member State in which the manufacturer has its registered place of business. In cases where the manufacturer has no registered place of business in the Union and has not yet designated an authorized representative, the matter shall be referred to the competent authority of the Member State in which the authorized representative referred to in the</p>	<p>The proposal allows for questions concerning classification to be referred to an expert panel. These expert panels should be more closely involved, as they have the necessary qualifications, as set out in Article 106. Experience has shown that the MDCG is not the appropriate forum for addressing classification and borderline issues. Instead, the Commission should consult the expert panels when deciding on the classification of devices. Commission should rather consult the expert panels when</p>	<p>Critically negative</p>	<p>Pharma Deutschland proposes amending the proposed Article 51 as follows:</p> <p align="center">Article 51 Classification of devices</p> <p>1. Devices shall be divided into classes I, IIa, IIb and III, taking into account the intended purpose of the devices and their inherent risks. Classification shall be carried out in accordance with Annex VIII.</p> <p>2. The competent authorities shall coordinate their activities when determining the classification of a device, or a category or group of devices. The results of the coordination activities of the competent authorities, including the results of any decision or measure adopted by a competent authority in accordance with Articles 51a or 51b and any opinion issued by an expert panel in</p>

	<p align="center">European Commission legal proposal Dated December 2025</p> <p>Commission proposed amendments within the MDR/IVDR text, showing:</p> <ul style="list-style-type: none"> Deleted text in strikethrough (example: text) New text in bold (example: text) 	<p>Impact & Gap analysis</p> <p><i>What is positive, what are issues (missing, unclear...)? Add a brief rationale</i></p>	<p>Redlines: Critical negative or positive? Colour code R or G</p> <p><i>Indicate where the amendment is critically positive or negative (no indication if not)</i></p>	<p>What is your recommendation?</p> <p><i>Change needed, if any. Recommended action to be taken, if any</i></p>
	<p>last indent of point (b) of the second paragraph of Section 2.2 of Annex IX has its registered place of business. Where the notified body concerned is established in a Member State other than that of the manufacturer, the competent authority shall adopt its decision after consultation with the competent authority of the Member State that designated the notified body. The competent authority of the Member State in which the manufacturer has its registered place of business shall notify the MDCG and the Commission of its decision. The decision shall be made available upon request. The competent authorities shall coordinate their activities when determining the classification of a device, or a category or group of devices. The results of the coordination activities of the competent authorities, including the results of any decision or measure adopted by a competent authority in accordance with Articles 51a or 51b and any opinion issued by an expert panel in relation to classification, shall be made publicly available, without disclosing any confidential information as referred to in Article 109.</p> <p>3. At the request of a Member State the Commission shall after consulting the MDCG, decide, by means of implementing acts, on the following:</p>	<p>deciding about classification of devices.</p>		<p>relation to classification, shall be made publicly available, without disclosing any confidential information as referred to in Article 109.</p> <p>2. A requester as referred in Article 51b paragraph 1 may submit a substantiated request At the request of a Member State to the Commission to decide shall after consulting an expert panel the MDCG, decide, by means of implementing acts, on the following:</p> <p>(a) application of Annex VIII to a given device, or category or group of devices, with a view to determining the classification of such devices;</p> <p>(b) that a device, or category or group of devices, shall for reasons of public health based on new scientific evidence, or based on any information which becomes available in the course of the vigilance and market surveillance activities be reclassified, by way of derogation from Annex VIII, taking into consideration the principle of proportionality and classification of devices at international level.</p> <p>4. The Commission may also, on its own initiative and after consulting an expert panel the MDCG, decide, by means of implementing acts, on the issues referred to in points (a) and (b) of paragraph 3.</p> <p>5. In order to ensure the uniform application of the rules set out in Annex VIII, and taking account of the relevant scientific opinions of the relevant scientific committees or expert panels, the Commission is empowered to adopt</p>

	<p align="center">European Commission legal proposal Dated December 2025</p> <p>Commission proposed amendments within the MDR/IVDR text, showing:</p> <ul style="list-style-type: none"> Deleted text in strikethrough (example: text) New text in bold (example: text) 	<p>Impact & Gap analysis</p> <p><i>What is positive, what are issues (missing, unclear...)? Add a brief rationale</i></p>	<p>Redlines: Critical negative or positive? Colour code R or G</p> <p><i>Indicate where the amendment is critically positive or negative (no indication if not)</i></p>	<p>What is your recommendation?</p> <p><i>Change needed, if any. Recommended action to be taken, if any</i></p>
	<p>(a) application of Annex VIII to a given device, or category or group of devices, with a view to determining the classification of such devices;</p> <p>(b) that a device, or category or group of devices, shall for reasons of public health based on new scientific evidence, or based on any information which becomes available in the course of the vigilance and market surveillance activities be reclassified, by way of derogation from Annex VIII, taking into consideration the principle of proportionality and classification of devices at international level.</p> <p>4. The Commission may also, on its own initiative and after consulting the MDCG, decide, by means of implementing acts, on the issues referred to in points (a) and (b) of paragraph 3.</p> <p>5. In order to ensure the uniform application of the rules set out in Annex VIII, and taking account of the relevant scientific opinions of the relevant scientific committees or expert panels, the Commission may is empowered to adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application.</p> <p>6. The implementing acts referred to in paragraphs 3, 4 and 5 of this Article shall be adopted in accordance with the examination procedure referred to in Article 114(3).</p> <p>7. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend</p>			<p>implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application.</p> <p>6. The implementing acts referred to in paragraphs 3, 4 and 5 of this Article shall be adopted in accordance with the examination procedure referred to in Article 114(3).</p> <p>7. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend Annex VIII in order to adapt it to technical or scientific progress or to take into account developments regarding classification of devices at international level.</p>

	<p align="center">European Commission legal proposal Dated December 2025</p> <p>Commission proposed amendments within the MDR/IVDR text, showing:</p> <ul style="list-style-type: none"> Deleted text in strikethrough (example: text) New text in bold (example: text) 	<p>Impact & Gap analysis</p> <p><i>What is positive, what are issues (missing, unclear...)? Add a brief rationale</i></p>	<p>Redlines: Critical negative or positive? Colour code R or G</p> <p><i>Indicate where the amendment is critically positive or negative (no indication if not)</i></p>	<p>What is your recommendation?</p> <p><i>Change needed, if any. Recommended action to be taken, if any</i></p>
	<p>Annex VIII in order to adapt it to technical or scientific progress or to take into account developments regarding classification of devices at international level.</p>			
15.	<p align="center">Article 51a Classification in the event of a dispute between manufacturer and notified body</p> <p>1. A manufacturer or a notified body may refer any dispute between them arising from the application of Annex VIII to the competent authority of the Member State in which the manufacturer has its registered place of business. In cases where the manufacturer has no registered place of business in the Union and has not yet designated an authorized representative, the matter shall be referred to the competent authority of the Member State in which the authorized representative referred to in Section 2.2, second paragraph, point (b), last indent, of Annex IX has its registered place of business.</p> <p>2. Within 30 days of receipt of the referral referred to in paragraph 1, the competent authority shall consult the other Member States regarding its draft classification decision.</p>	<p>The proposed Article 51a MDR introduces a formalised procedure for resolving classification disputes between manufacturers and notified bodies. The procedure is clearly structured, subject to binding deadlines, and provides for EU-wide consultation and, in cases of disagreement, the involvement of an expert panel. The involvement of expert panels should not be reduced for cases of substantiated disagreement. Furthermore, the binding effect of expert opinions remains limited, as the competent national authority is merely obliged to “give utmost consideration” to them. Ultimately, decision-making</p>	<p>Critically negative</p>	<p>Pharma Deutschland proposes the following amendments to the proposed Article 51a:</p> <p align="center">Article 51a Classification in the event of a dispute between manufacturer and notified body</p> <p>1. A manufacturer or a notified body may refer any dispute between them arising from the application of Annex VIII to the competent authority of the Member State in which the manufacturer has its registered place of business. In cases where the manufacturer has no registered place of business in the Union and has not yet designated an authorized representative, the matter shall be referred to the competent authority of the Member State in which the authorized representative referred to in Section 2.2, second paragraph, point (b), last indent, of Annex IX has its registered place of business.</p> <p>2. Within 30 days of receipt of the referral referred to in paragraph 1, the competent authority shall consult the other Member States an expert panel regarding its draft classification decision.</p>

	<p align="center">European Commission legal proposal Dated December 2025</p> <p>Commission proposed amendments within the MDR/IVDR text, showing:</p> <ul style="list-style-type: none"> Deleted text in strikethrough (example: text) New text in bold (example: text) 	<p>Impact & Gap analysis</p> <p><i>What is positive, what are issues (missing, unclear...)? Add a brief rationale</i></p>	<p>Redlines: Critical negative or positive? Colour code R or G</p> <p><i>Indicate where the amendment is critically positive or negative (no indication if not)</i></p>	<p>What is your recommendation?</p> <p><i>Change needed, if any. Recommended action to be taken, if any</i></p>
	<p>3. Where, within 30 days of receipt of the consultation referred to in the paragraph 2, no substantiated disagreement has been raised by a Member State, the competent authority shall adopt its decision within 90 days of receipt of the referral referred to in paragraph 1.</p> <p>4. Where, within 30 days of receipt of the consultation referred to in paragraph 2, a substantiated disagreement has been raised by a Member State regarding the draft classification decision, the matter shall be referred to an expert panel as referred to in Article 106. That expert panel shall deliver an opinion on the classification of the device within 30 days. The competent authority may ask the expert panel for clarifications on its opinion.</p> <p>5. Within 30 days of receipt of the expert panel opinion, or any requested clarification, referred to in paragraph 4, the competent authority shall adopt its decision, giving utmost consideration to the expert panel opinion. It shall notify the other Member States and the Commission of its decision without undue delay.</p> <p>6. The Commission may, by means of implementing acts, lay down further details of the procedure for the application of this Article and of Article 51b. Those implementing acts shall be adopted in</p>	<p>authority remains with the Member States, meaning that divergent outcomes cannot be excluded even under identical circumstances. This do not provide legal certainty for manufacturers.</p>		<p>3.-That expert panel shall consult the notified body and the manufacturer of the concerned product.Where, within 30 days of receipt of the consultation referred to in the paragraph 2, no substantiated disagreement has been raised by a Member State, the competent authority shall adopt its decision within 90 days of receipt of the referral referred to in paragraph 1.</p> <p>4. Where, within 30 days of receipt of the consultation referred to in paragraph 2, a substantiated disagreement has been raised by a Member State regarding the draft classification decision, the matter shall be referred to an expert panel as referred to in Article 106. That expert panel shall deliver an opinion on the classification of the device within 30 days. The competent authority may ask the expert panel for clarifications on its opinion.</p> <p>5. Within 30 days of receipt of the expert panel opinion, or any requested clarification, referred to in paragraph 4, The competent authority shall adopt its decision, giving utmost consideration to accept the expert panel opinion. It shall notify the other Member States and the Commission of its decision without undue delay.</p> <p>6. Any opinion of an expert panel in relation to classification, shall be made publicly available, without disclosing any confidential information as referred to in Article 109. The Commission may, by means of implementing acts, lay down further details of the procedure for the application of this Article and of</p>

	<p align="center">European Commission legal proposal Dated December 2025</p> <p>Commission proposed amendments within the MDR/IVDR text, showing:</p> <ul style="list-style-type: none"> Deleted text in strikethrough (example: text) New text in bold (example: text) 	<p>Impact & Gap analysis</p> <p><i>What is positive, what are issues (missing, unclear...)? Add a brief rationale</i></p>	<p>Redlines: Critical negative or positive? Colour code R or G</p> <p><i>Indicate where the amendment is critically positive or negative (no indication if not)</i></p>	<p>What is your recommendation?</p> <p><i>Change needed, if any. Recommended action to be taken, if any</i></p>
	<p>accordance with the examination procedure referred to in Article 114(3).</p>			<p>Article 51b. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).</p>
<p>16.</p>	<p align="center">Article 51b Challenges to the classification of CE marked devices</p> <p>1. Where a competent authority, after having performed an evaluation in accordance with Article 94, considers that a device that is CE marked in accordance with Article 20, is not classified in accordance with Annex VIII, it shall consult the other Member States regarding its envisaged measure on the classification of the device.</p> <p>2. Where, within 30 days of receipt of the consultation referred to in paragraph 1, no substantiated disagreement is raised by a Member State, the competent authority may adopt the measure on the classification of the device in question and shall notify the other Member States and the Commission of its decision giving the reasons for the decision.</p> <p>3. Where, within 30 days of receipt of the consultation referred to in paragraph 1, a substantiated disagreement is raised by a Member State</p>	<p>The proposed Article 51b MDR introduces a distinct procedure for challenging the classification of products that already bear the CE marking. While this addresses an enforcement gap that has so far been insufficiently regulated, it also gives rise to new legal uncertainties. As the procedure applies exclusively to products already placed on the market and does not provide for transitional arrangements, grandfathering provisions or limitations on retroactive effect, the regulatory status of a product remains vulnerable even after market access has been granted. This may entail considerable economic risks, particularly for small and</p>	<p>Critically negative</p>	<p>Pharma Deutschland proposes the rewording of the proposed Article 51b as follows:</p> <p align="center">Article 51b Challenges to the classification of CE marked devices</p> <p>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 classification of a specific product in accordance with Annex VIII.</p> <p>2. Where a competent authority of a Member State, after having performed an evaluation in accordance with Article 94, considers that a device that is CE marked in accordance with Article 20, is not classified in accordance with Annex VIII, it shall consult the competent authority of the Member State where the manufacturer has its registered place of business and the manufacturer other Member States regarding its envisaged measure justification on the classification of the device, before submitting a substantiated</p>

	<p align="center">European Commission legal proposal Dated December 2025</p> <p>Commission proposed amendments within the MDR/IVDR text, showing:</p> <ul style="list-style-type: none"> Deleted text in strikethrough (example: text) New text in bold (example: text) 	<p>Impact & Gap analysis</p> <p><i>What is positive, what are issues (missing, unclear...)? Add a brief rationale</i></p>	<p>Redlines: Critical negative or positive? Colour code R or G</p> <p><i>Indicate where the amendment is critically positive or negative (no indication if not)</i></p>	<p>What is your recommendation?</p> <p><i>Change needed, if any. Recommended action to be taken, if any</i></p>
	<p>regarding the envisaged measure on the classification, the matter shall be referred to an expert panel referred to in Article 106, which shall deliver an opinion on the classification of the device within 30 days. The competent authority may ask the expert panel for clarifications on its opinion.</p> <p>4. The competent authority shall give utmost consideration to the expert panel opinion. Where the competent authority adopts a measure on the classification, it shall notify the other Member States and the Commission of its measure without undue delay.</p>	<p>medium-sized enterprises, and conflicts with the principle of free movement of goods laid down in Article 24 MDR.</p>		<p>request for an opinion of an expert panel as referred to in paragraph 1.</p> <p>3. The expert panel shall consult the competent authority, the notified body, the manufacturer and the developer of the concerned product.</p> <p>4. The expert panel shall provide its opinion within 90 days. The requester shall accept the opinion of the expert panel.</p> <p>5. Having regard to the expert panel opinion referred to in paragraph 4 a requester as referred in paragraph 1 may submit a substantiated request to the Commission to determine whether a specific product is classified in accordance with Annex VIII. The Commission shall decide on the substantiated request of the requester or on its own initiative, by means of implementing acts, which shall be adopted in accordance with the examination procedure referred to in Article 114(3). The Commission may ask the expert panel for clarifications or refer the opinion back to the expert panel for further consideration, including in cases where a Member State's substantiated request raises new questions of a scientific or technical nature.</p>

17.	<p style="text-align: center;">Article 60 Certificate of free sale</p> <p>[...] 1b. The competent authority shall make the certificates of free sale issued in accordance with paragraphs 1 and 1a publicly available in Eudamed. [...]</p>	<p>The addition of this new paragraph creates an obligation to publish certificates of free sale in Eudamed. 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.</p> <p>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.</p> <p>Manufacturers have a legitimate interest in not disclosing sensitive information on their commercial relationships with non-EU trade partners.</p>		Pharma Deutschland suggests deleting Article 60(1b).
18.	CHAPTER VIII COOPERATION BETWEEN MEMBER STATES, MEDICAL DEVICE COORDINATION GROUP, EXPERT LABORATORIES, EXPERT PANELS AND DEVICE REGISTERS			
19.	<p style="text-align: center;">Article 106 Expert panels Provision of scientific, technical and clinical opinions and advice</p> <p>[...]</p>	<p>In order to provide scientific, clinical, technical or regulatory opinions, the expert panel must have access to all information necessary to fulfil its mandate.</p>		<p>Pharma Deutschland suggests amending the proposed Article 106(4) as follows:</p> <p style="text-align: right;">Article 106 Expert panels</p>

	<p>4. Expert panels shall take into account relevant information provided by stakeholders including patients' organisations and healthcare professionals' associations when preparing their scientific opinion.</p> <p>[...]</p>	<p>In particular, this includes information supplied by the manufacturer, as the entity with the most comprehensive knowledge of the product concerned.</p>		<p>[...]</p> <p>4. Expert panels shall take into account relevant information provided by stakeholders including patients' organisations, and healthcare professionals' associations and industry associations.</p> <p>[...]</p>
20.	<p style="text-align: center;">Article 106b Support by the EMA</p> <p>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:</p> <p>(a) regulatory status of products and classification of devices in accordance with Articles 4, 4a, 51, 51a and 51b of this Regulation and Articles 3, 3a, 47, 47a and 47b of Regulation (EU) 2017/746;</p> <p>(b) derogations from the applicable conformity assessment procedures in accordance with Articles 59 and 59a of this Regulation and Articles 54 and 54a of Regulation (EU) 2017/746;</p> <p>(c) clinical evaluation, clinical investigations, performance evaluation and performance studies in accordance with Chapter VI of this Regulation and Chapter VI of Regulation (EU) 2017/746, including support to the coordinating Member State for the coordinated assessment procedure for clinical investigations and performance studies referred to in Article 78 of</p>	<p>The reform proposal responds to a real enforcement deficit in a system that has, to date, been strictly decentralised. In practice, insufficient coordination between Member States has led to divergent assessments, duplication of work and considerable delays. Against this background, entrusting a Union agency with coordination and support tasks appears understandable. However, it remains questionable whether the EMA is the appropriate agency to assume these tasks.</p> <p>The EMA's technical and human resources are of particular concern. The agency currently has only limited specific expertise in the field of medical devices, especially when compared with its many years of experience in the regulation of medicinal products. Without a substantial expansion of its technical</p>	Critically negative	<p>Pharma Deutschland proposes deleting proposed Article 106b.</p> <p>Given the specific characteristics of the medical device sector, establishing a separate, specialised agency for medical devices may be a more effective long-term solution than transferring these tasks to the EMA. Alternatively, these responsibilities could be assigned to the MDCG.</p>

	<p>this Regulation and Article 74 of Regulation (EU) 2017/746;</p> <p>(d) vigilance and market surveillance in accordance with Chapter VII of this Regulation and Chapter VII of Regulation (EU) 2017/746, including support to the coordinating competent authority for the coordinated procedure referred to in Article 89(9) of this Regulation and Article 84(9) of Regulation (EU) 2017/746.</p> <p>2. The EMA shall provide scientific, technical and administrative support to the Commission for the establishment of Union regulatory sandboxes in accordance with Article 59c of this Regulation and Article 54c of Regulation (EU) 2017/746.</p> <p>3. The EMA shall set up a support scheme for manufacturers of medical devices and in vitro diagnostic medical devices, which are micro, small and medium-sized within the meaning of Recommendation 2003/361/EC, regarding the requirements of this Regulation and Regulation (EU) 2017/746.</p> <p>4. The EMA shall have access to Eudamed and any electronic system referred to in Article 33(2) of Regulation (EU) 2017/745 or Article 30(2) of Regulation (EU) 2017/746 that is not included in Eudamed.</p>	<p>expertise, there is a risk that the EMA will formally assume a central role while being unable in practice to fulfil this role with the necessary depth and quality. This poses a particular risk for substance-based medical devices, combination products and complex demarcation issues.</p> <p>Furthermore, the role of the EMA in the decision-making process remains unclear. The agency is expected to coordinate, support and promote exchange without being granted any decision-making powers of its own. This intermediate position risks leading to a diffusion of responsibility, as national authorities may rely on the EMA while it remains unclear who ultimately bears responsibility for substantive assessments and potential incorrect decisions.</p> <p>Access to EUDAMED and other electronic systems also presents a mixed picture. While it allows for improved coordination and analysis of vigilance and market surveillance data, it simultaneously raises questions regarding data sovereignty, the allocation of</p>		
--	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--	--

		responsibilities and practical integration into existing national workflows.		
21.	CHAPTER X FINAL PROVISIONS			
22.	<p>Article 120 Transitional provisions</p> <p>[...]</p> <p>14. By way of derogation from Article 5 and from paragraphs 3 to 3e of this Article, a device as referred to in paragraph 3a or 3b of this Article that meets the criteria for an orphan device as referred to in Article 52a(3) may be placed on the market or put into service after the dates referred to in paragraphs 3a and 3b of this Article if the following conditions are met:</p> <p>(a) an expert panel referred to in Article 106 has issued an opinion confirming the fulfilment of the criteria for an orphan device as referred to in Article 52a(3);</p> <p>(b) there are no significant changes in the design and intended purpose of the device;</p> <p>(c) the device 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.</p> <p>The requirements of this Regulation, with the exception of Chapters IV, V and VI, shall apply to a device referred to in the first subparagraph.</p> <p>By way of derogation from Article 86(1), manufacturers of class IIa devices, class IIb devices and class III devices placed on the market</p>	<p>The provision on grandfathering should not be limited to orphan devices that were CE marked under the former Directives and for which an expert panel has confirmed compliance with the criteria for an “orphan device”. All devices classified as class I, IIa and IIb that were CE marked under the former Directives should be allowed to continue to be placed on the market beyond the transitional periods, provided that they have not been associated with safety issues in the past and have a long history of safe use on the Union market.</p>		

	<p>or put into service in accordance with this paragraph shall update the PSUR at least annually. On an annual basis, the manufacturer shall submit the PSUR and, where applicable, an update of the summary of safety and clinical performance to the competent authority of the Member State in which it is established.</p> <p>The competent authority of the Member State may require the manufacturer to conduct defined post-market surveillance or PMCF activities within a specified period of time to generate additional clinical data to confirm the safety and performance of the device and to evaluate any undesirable side-effects and the acceptability of the benefit-risk-ratio.</p> <p>Devices placed on the market or put into service in accordance with this paragraph, which do not have a valid certificate in accordance with paragraph 2, shall not bear the CE marking. In its EU declaration of conformity, the manufacturer shall make reference to the fact that the device is an orphan device placed on the market or put into service in accordance with this provision.</p> <p>The manufacturer shall inform the intended users about the fact that the device is an orphan device placed on the market or put into service in accordance with this provision, where applicable, in the summary of safety and clinical performance and in the instructions for use or any other accompanying documentation.</p> <p>At least every 10 years, the manufacturer shall request an opinion from an expert panel referred to in Article 106 confirming the fulfilment of the criteria for an orphan device as referred to in Article 52a(3).</p>			
--	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--	--	--

	<p>15. As regards devices for which a conformity assessment procedure is pending on ...[OP please insert the date = six months after the date of entry into force of this Regulation], or for which a certificate is issued by a notified body before that date, the manufacturer and the notified body may agree to continue applying the provisions of this Regulation in the form applicable before ...[OP please insert the date = six months after the date of entry into force of this Regulation] until the conformity assessment procedure is finalised or until the certificate is renewed.</p>			
23.	<p>ANNEX I GENERAL SAFETY AND PERFORMANCE REQUIREMENTS</p>			
24.	<p>CHAPTER III REQUIREMENTS REGARDING THE INFORMATION SUPPLIED WITH THE DEVICE</p> <p>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 Regulation (EU) No 207/2012 Commission Implementing Regulation (EU) 2021/2226 or in any subsequent implementing rules adopted pursuant to this Regulation.</p>	<p>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.</p> <p>Providing instructions for use in electronic form offers several significant advantages. First, it</p>		<p>Pharma Deutschland suggests amending Annex I, Chapter III, 23.1(f) as follows:</p> <p>“(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.”</p>

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

25.	<p style="text-align: center;">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</p>			
26.	<p style="text-align: center;">PART B CORE DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE IN ACCORDANCE WITH ARTICLES 28 AND 29</p> <p>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, [...]</p>	<p>The further expansion of the scope of the 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. Against this background, the mere provision of distribution-related information adds no tangible regulatory value and cannot justify the additional administrative burden placed on companies.</p>		<p>Pharma Deutschland suggests the removal of the proposed Annex VI PART B Nr. 4.</p>
27.	<p style="text-align: center;">ANNEX VIII CLASSIFICATION RULES CHAPTER III CLASSIFICATION RULES</p>			
28.	<p>5.2. Rule 6</p> <p>All surgically invasive devices intended for transient use are classified as class IIa unless they:</p> <ul style="list-style-type: none"> - are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact 	<p>Pharma Deutschland welcomes the clarification that reusable surgical instruments should be classified as class I, irrespective of the body part with which they come into contact. However, this clarification should apply to all surgical instruments and not</p>		<p>Pharma Deutschland proposes to delete the term “reusable” in the second bullet point of the proposed Rule 6. This 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).</p> <p>“5.2. Rule 6</p>

	<p>with those parts of the body, in which case they are classified as class III;</p> <ul style="list-style-type: none"> - 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. 	<p>be limited to reusable ones only.</p> <p>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.</p> <p>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.</p>		<p>All surgically invasive devices intended for transient use are classified as class IIa unless they:</p> <ul style="list-style-type: none"> - 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.”
<p>29.</p>	<p>5.3. Rule 7</p> <p>All surgically invasive devices intended for short-term use are classified as class IIa unless they:</p> <ul style="list-style-type: none"> - 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; 	<p>The impact and underlying analysis are the same as those described for Rule 6.</p>		<p>Pharma Deutschland proposes to delete the term “reusable” in the last bullet point of the proposed Rule 7. This 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).</p> <p>5.3. Rule 7</p>

	<ul style="list-style-type: none"> - 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 - 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; - 			<p>All surgically invasive devices intended for short-term use are classified as class IIa unless they:</p> <ul style="list-style-type: none"> - 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 - 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;”
30.	<p>6.3. Rule 11 Software which is intended to provide information which is used to take decisions with generate an output that confers a clinical benefit and is used for diagnosis, or therapeutic purposes treatment, prevention, monitoring, prediction, prognosis, compensation or alleviation of a disease or condition is classified as class I IIa, except if such decisions have an impact that may cause, unless the output is intended for a disease or condition:</p>	<p>The Commission’s proposal to introduce a default class I classification under the revised MDR Rule 11 (Annex VIII, Section 6.3) is welcomed, as it aims to introduce greater proportionality for clinical benefit software. However, a fundamental inconsistency remains within</p>	<p>Critically negative</p>	<p>Pharma Deutschland proposes the amendment to Rule 11 as follows:</p> <p>„6.3 Rule 11 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</p>

	<ul style="list-style-type: none"> - 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 in class III; or - 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 case it is classified as class IIb. - in a non-serious situation, or to drive clinical management in a serious situation or to inform clinical management in a critical or serious situation in which cases it is classified as class IIa. <p>Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb. All other software is classified as class I.</p>	<p>Rule 11. While the opening part of the rule allows for a class I classification, the final indent effectively makes it almost impossible for software to be classified as class I in practice. In particular, the final indent referring to software intended “to inform clinical management in a critical or serious situation” renders the identification of class I software ineffective. In practice, virtually all software outputs relate to situations beyond “non-serious”, thereby triggering a default classification as class IIa.</p> <p>Illustrative examples include:</p> <ul style="list-style-type: none"> – BMI calculators used for obesity risk screening → Class IIa – Dyscalculia exercise applications → Class IIa <p>This approach results in trivial, low-risk software tools being placed in the same risk class as genuinely medium- or high-risk software, such as ECG analysis software. Consequently, such products would be subject to full conformity assessment procedures involving a notified body, leading to disproportionate time and cost</p>	<p>disease or condition is classified as class I, unless the output is intended for a disease or condition:</p> <ul style="list-style-type: none"> - in a critical situation with a risk of causing death or an irreversible deterioration of a person's state of health, in which case it is classified as class III; - in a serious situation with a risk of causing a serious deterioration of a person's state of health or a surgical intervention, or to drive clinical management in a critical situation in which cases it is classified as class IIb; - in a non-serious situation, or to drive clinical management in a serious situation or to inform clinical management in a critical or serious situation in which cases it is classified as class IIa; <p>The classification of software should always take into account the impact and the complexity of the medical context in which the software is involved as well as the level of immediacy to intervene before a reasonably foreseeable harm occurs.”</p>
--	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

		<p>burdens. Low-risk and non-critical products should be made available to patients and users without unnecessary regulatory obstacles.</p> <p>Moreover, the proposal would create international regulatory divergence:</p> <ul style="list-style-type: none"> - FDA: Simple clinical calculators and certain clinical decision support tools are excluded from active regulation, whereas they would fall under Class IIa in the EU. - UK MHRA: Simple clinical calculators are excluded from medical device classification, while they would be Class IIa under the proposed EU approach. <p>As a result, the proposed revision of Rule 11 for software fails to achieve its stated objective of simplification and risks discouraging digital health innovation within the EU market.</p>		
31.	<p>7.8. Rule 21</p> <p>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:</p>	<p>The proposed addition of the wording "on or" 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. This</p>		<p>Pharma Deutschland proposes maintaining the current provision of Rule 21:</p> <p>7.8 Rule 21 Devices that are composed of substances or of combinations of substances that are intended to be</p>

	<ul style="list-style-type: none"> - 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. 	<p>would affect products such as electrode gel, ultrasound gel and ultrasound cream, which are consistently classified as class I devices, according to MDCG 2021-24.</p> <p>These products are low-risk preparations. Reclassifying them from class I (Rule 1) to class IIa (Rule 21) would therefore be disproportionate and not risk-based.</p> <p>Such a reclassification would be difficult to justify from a regulatory perspective and could lead to bottlenecks, as manufacturers of these products may be unwilling or unable to undergo a conformity assessment procedure involving a notified body. The higher classification would entail significant additional time and cost, without any corresponding benefit for patient safety.</p>		<p>introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body are classified as:</p> <ul style="list-style-type: none"> - 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.
--	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------