

EANM suggestions for Amendments

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

Provision	Commission Proposal	EANM Amendment Suggestion (in bold)	In EANM Paper
Revision Recital 13a new		13a. To ensure that patients can benefit from innovative or highly specialised software devices where no suitable CE-marked alternative is available, healthcare professionals should be permitted, under strictly defined conditions, to use devices that do not bear a CE marking.	Section 1. c)
Revision Recital 17a new		17a. Artificial intelligence software incorporated in medical devices may, in certain cases, modify its behaviour or outputs through retraining, adaptation or other changes to the underlying model following conformity assessment. Such modifications may affect the safety, performance or intended purpose of the device and may therefore require additional safeguards to ensure continued compliance with this Regulation. Manufacturers of such devices should establish and maintain predefined change control plans describing the modifications that may be made to the system, the methods for validating those modifications, and the circumstances under which further conformity assessment is required.	Section 2.
Revision Article 1(5) Current MDR	Article 5 is amended as follows: (a) paragraph 5 is amended as follows: (i) the first subparagraph is amended as follows: (1) point (a) is replaced by the following:	Article 5 is amended as follows: (a) paragraph 5 is amended as follows: (i) the first subparagraph is amended as follows: (1) point (a) is replaced by the following:	Sections 1. b) and 1. c)

<p>Article 5(5) and 5(5a) new</p>	<p>‘(a) the devices are not transferred to another legal entity, except to another health institution in the duly justified interest of public health, patient safety or patient health, or to prepare or respond to a public health emergency;’;</p> <p>(2) point (d) is replaced by the following: ‘(d) upon request by a competent authority, the health institution provides information upon request on the use of such devices, which includes the justification referred to in points (a) and (c);’;</p> <p>(3) point (f) is replaced by the following: ‘(f) the health institution draws up documentation that is sufficiently detailed to enable the competent authority to ascertain that the relevant general safety and performance requirements set out in Annex I are met;’;</p> <p>(4) point (g) is deleted;</p> <p>(ii) the second subparagraph is replaced by the following: ‘Member States shall retain the right to restrict the manufacture or the use of any specific type of such devices and shall be permitted access to inspect the activities of the health institutions.’;</p> <p>(iii) The following three subparagraphs are added: ‘For the purposes of the first subparagraph, point (a), in the case of a transfer of the device to another health institution, the transferring and receiving health institutions shall ensure traceability of the device. For the purposes of the first subparagraph, point (c), from the date that the health institution becomes aware that the target patient group's specific needs can be met by a device available on the market, it may continue to manufacture and use its device for a maximum period of 10 years.</p>	<p>‘(a) the devices are not transferred to another legal entity, except to another health institution in the duly justified interest of public health, patient safety or patient health, or to prepare or respond to a public health emergency;’;</p> <p>(1a) point (b) is replaced by the following: (b) manufacture and use of the devices occur under risk-based and proportionate quality management systems,’;</p> <p>(2) point (d) is replaced by the following: ‘(d) upon request by a competent authority, the health institution provides information upon request on the use of such devices, which includes the justification referred to in points (a) and (c);’;</p> <p>(3) point (f) is replaced by the following: ‘(f) the health institution draws up documentation that is sufficiently detailed to enable the competent authority to ascertain that the relevant general safety and performance requirements set out in Annex I are met;’;</p> <p>(4) point (g) is deleted;</p> <p>(5) point (h) is replaced by the following: (h) the health institution reviews experience gained from clinical use of the devices using a risk-based approach and takes all necessary corrective actions.’;</p> <p>(ii) the second subparagraph is replaced by the following: ‘Member States shall retain the right to restrict the manufacture or the use of any specific type of such devices and shall be permitted access to inspect the activities of the health institutions.’;</p> <p>(iii) The following four subparagraphs are added: ‘For the purposes of the first subparagraph, point (a), in the case of a transfer of the device to another</p>	
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<p>Revision Article 1(9)</p> <p>Current MDR Article 10</p>	<p>(9) Article 10 is amended as follows: (a) paragraphs 3 and 7 are deleted; (...)</p>	<p>(...)</p> <p>(9) Article 10 is amended as follows: (a) paragraph 3 is deleted; (aa) the following paragraph 5a is added: '5a. Manufacturers of devices incorporating artificial intelligence software that is capable of modifying its behaviour or outputs through retraining, adaptation or other changes to the underlying model following conformity assessment shall establish, maintain and make available to the notified body a predefined change control plan. That plan shall specify at least: (a) the modifications that may be made to the model following conformity assessment; (b) the performance and safety criteria that shall be met prior to the deployment of any modification and the methods and procedures used to validate such modifications; (c) the circumstances under which a new conformity assessment or notified body review is required.' (ab) paragraph 7 is deleted; (...)</p>	<p>Section 2.</p>
<p>Revision Article 1(47)</p> <p>Current MDR Article 56(2) and (2a) new</p>	<p>2. The validity of certificates shall not be limited in time, unless in exceptional cases where the notified body considers it necessary to limit the period of validity based on duly justified grounds. In those cases, the notified body shall indicate the period of validity on the certificate. If the period of validity of the certificate is limited, on application by the manufacturer, the notified body may, following an assessment performed</p>	<p>2. The validity of certificates shall not be limited in time, except for class IIb implantable and class III devices for which certificates shall be valid for the period they indicate, which shall not exceed five years. On application by the manufacturer, the validity of the certificate may be extended for further periods, each not exceeding five years, based on a re-assessment in accordance with the applicable conformity assessment procedures. Any supplement to a certificate shall</p>	<p>The EANM supports this amendment by the Biomedical Alliance.</p>

	<p>in accordance with Annex VII, Section 4.11, extend the validity of the certificate. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid. 2a. During the validity of the certificate, the notified body shall carry out appropriate surveillance activities, including periodic reviews taking into consideration developments of the state of the art. Those reviews shall be proportionate to the risk class of the device.</p>	<p>remain valid as long as the certificate which it supplements is valid. For other class I and class II devices, the duration of certificates may be limited in exceptional cases where the notified body considers it necessary to limit the period of validity based on duly justified grounds. In those cases, the notified body shall indicate the period of validity on the certificate. If the period of validity of the certificate is limited, on application by the manufacturer, the notified body may, following an assessment performed in accordance with Annex VII, Section 4.11, extend the validity of the certificate. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid. 2a. During the validity of the certificate, the notified body shall carry out appropriate surveillance activities, including periodic reviews taking into consideration developments of the state of the art, Post-Market Surveillance and vigilance data, and relevant data from clinical registries and other real-world evidence sources. Those reviews shall be documented and proportionate to the risk class of the device.</p>	
<p>Revision Article 1(52) Current MDR Article 61(15) new</p>	<p>(52) Article 61 is amended as follows: (...)</p>	<p>(52) Article 61 is amended as follows: (...) (i) the following paragraph 15 is added: ‘15. The Commission shall, in consultation with relevant stakeholders, issue guidance on the application of this Article, including on the type and level of clinical evidence that may be considered sufficient to demonstrate conformity with the safety and performance requirements in different clinical and technological contexts, in</p>	<p>Section 1. e)</p>

		order to ensure a harmonized application of this Regulation.'	
Revision Article 1(84) Current MDR Article 103(5a) new	(84) Article 103 is amended as follows: (...)	(84) Article 103 is amended as follows: (...) (aa) the following paragraph 5a is added: '(5a.) The MDCG shall be supported by a stakeholder advisory group composed of representatives of healthcare professionals, patient organisations, health institutions and other relevant stakeholders, which shall provide advice on the implementation and future development of this Regulation.' (...)	Section 5.