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MDCG Position Paper on the application of Article 97 MDR to legacy devices for which the MDD or AIMDD certificate expires before the issuance of a MDR certificate

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Application of Article 97 MDR to legacy devices for which the MDD or AIMDD certificate expires before the issuance of a MDR certificate

I. Objective

In accordance with Article 5 of Regulation (EU) 2017/745 on medical devices (MDR), a device may be placed on the market only if it complies with the requirements of the MDR. Pursuant to Article 52 MDR, manufacturers shall undertake an assessment of the conformity of the device in accordance with the applicable conformity assessment procedures set out in the MDR, prior to placing a device on the market. As part of the provisions on market surveillance set out in chapter VII, section 3, the MDR lays down procedures how competent authorities deal with devices that do not comply with MDR requirements.

In accordance with Article 94 MDR, competent authorities (CA) of the Member States shall carry out an evaluation if they have reason to believe that a device

- may present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health, or
- otherwise does not comply with the requirements of the MDR.

Where, after having performed this evaluation pursuant to Article 94 MDR, the CA finds that the device does not comply with certain MDR requirements but does not present an unacceptable risk to health and safety of patients, users or other persons, or to other aspects of the protection of public health, Article 97 MDR is applicable.

This document aims to achieve a common understanding of and a uniform approach to the application of Article 97 of Regulation (EU) 2017/745 on medical devices (MDR) in situations where a device is not in conformity with the MDR because its certificate issued under Directive 93/42/EEC (MDD) or Directive 90/385/EEC (AIMDD) has expired or expires before issuance of the necessary certificate(s) in accordance with the MDR. The use of Article 97 MDR in those situations is meant to be a temporary solution. It will contribute to avoiding disruption of supply of devices on the EU market needed for health systems and patients. This document should not be regarded as a commonly agreed solution for addressing the expected bottleneck of expiring certificates by 26 May 2024.

This document describes how CAs intend to apply Article 97 MDR in a legally sound, coherent and consistent manner to deal with devices that, after 26 May 2021 (i.e. MDR's date of application), fall within the scope of Article 120(3) MDR and for which the MDD or AIMDD certificate has expired or expires before issuance of the necessary certificate(s) in accordance with the MDR.

If certification of devices under the MDR has not been finalised before expiry of the Directive's certificate, and where the device does not present an unacceptable risk to health and safety, Article 97 MDR enables CAs to require the relevant manufacturer, or its authorised representative, to bring the non-compliance to an end within a reasonable and clearly defined period. This will ensure that the conformity of the devices concerned is established as soon as possible under the conditions set by the CA, while limiting as much as possible the impact on the supply of safe and effective devices to patients and healthcare providers.

The mechanism described in this document provides for a legally sound, coherent, consistent and controlled period of the non-compliance of devices, which are impacted by the limited capacity of notified bodies and for which no unacceptable safety concerns are identified.

The documentation to be submitted by the manufacturer, or its authorised representative, is specified in the checklists in the annex to this document.

II. Scope

This document applies to devices that, after the MDR's respective date of application, have fallen within the scope of Article 120(3) MDR and are or were considered to be 'legacy devices' within the meaning of [MDCG 2021-25](#).

It only applies to devices that are 'in transition' from the MDD or AIMDD to the MDR or, respectively, for which, despite reasonable efforts undertaken by the manufacturer to obtain certification under the MDR, the relevant conformity assessment procedure involving a notified body has not been concluded in time.

It does not apply to devices for which the certificate issued under the MDD or AIMDD has been suspended or withdrawn by the notified body; in other words, the Directive's certificate must have been valid at the date of its expiry.

It does not apply either to devices that have undergone a significant change in design or intended purpose within the meaning of Article 120(3) MDR as further explained in [MDCG 2020-3](#).

III. Non-conformity, but no unacceptable risk to health and safety

Manufacturers, or their authorised representatives, should proactively inform the CA of the Member State in which they have their registered place of business about the forthcoming or incurred non-compliance with the relevant MDR requirements. The non-compliance should consist of the expiry of the MDD or AIMDD certificate and the risk or fact that, at the moment of the expiry of the certificate, the device will not be or was not covered by a certificate issued by a notified body under the MDR.

For the purpose of an evaluation by the CA as to whether the (non-compliant) device presents an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health (Article 94 MDR), the manufacturer should submit a report containing relevant data gathered through its post-market surveillance system (PMS), in particular data concerning incidents, serious incidents and/or field safety corrective actions.

The evaluation by the CA should be based on available vigilance or market surveillance data or other information received. In addition to the data submitted by the manufacturer, the CA should also check the vigilance and market surveillance data to which it has access. In the context of its evaluation, the CA should also take into account information from the relevant notified body submitted by the manufacturer, such as recent audit reports in particular with regard to information about potential safety-related shortcomings identified during the last surveillance audit and their resolution.

Based on the information at its disposal, the CA should conclude whether or not the device presents an unacceptable risk to health or safety.

If the CA comes to the conclusion that the non-compliant device does not present an unacceptable risk to health and safety, Article 97(1) MDR will be applicable; the CA should use it under the conditions specified in this document.

The manufacturer is obliged to apply the MDR requirements applicable to ‘legacy devices’, in particular in relation to PMS, vigilance and market surveillance, see also [MDCG 2021-25](#). Moreover, the manufacturer should demonstrate that it has adapted its quality management system (QMS) to the MDR requirements.

At any moment, based on new information that has come to its attention, the CA will be able to assess any potential emerging risk to health and safety in relation to the device concerned. Where the CA finds that, on the basis of such new information, the device presents an unacceptable risk to health and safety, it should terminate the application of Article 97 MDR and apply Article 95 MDR.

IV. Expected end of non-compliance within reasonable period of time

The application of Article 97(1) MDR aims to allow the manufacturer to bring the non-compliance to an end within a reasonable period of time.

Therefore, for these provisions to apply, the manufacturer should already have undertaken reasonable efforts to transition its device to the MDR. That means in particular that the manufacturer’s application for conformity assessment under the MDR should have been accepted by a notified body and a written agreement signed by notified body and manufacturer in line with section 4.3 of Annex VII MDR.

In duly justified cases, the CA may waive this condition, in particular where the following conditions are all met: (i) the manufacturer is a SME, (ii) MDD or AIMDD certificate of that SME manufacturer had been issued by a notified body not (yet) designated under the MDR, (iii) the SME manufacturer can demonstrate that it has undertaken reasonable efforts to apply to a considerable number of relevant notified bodies and that their application has not been accepted due to limited notified body capacity.

The CA should define the reasonable period by when the manufacturer should bring the device into compliance; this period should be proportionate to the non-compliance in accordance with Article 97(1) MDR.

The reasonable period should be set by the CA on a case-by-case basis, having regard to the estimated time to finalise the conformity assessment in accordance with the MDR and to make the certified device ready for its placing on the market in compliance with the relevant MDR’s requirements (e.g. label, instructions for use, etc.). In general, the period should not exceed 12 months, but could be extended in duly justified cases. If the MDR certificate is issued before the end of the period set by the CA and the device is brought into compliance with the relevant MDR requirements, the period granted by the CA in accordance with Article 97(1) MDR should cease ahead of the set deadline and the manufacturer should no longer be allowed to place non-compliant devices on the market.

If the manufacturer does not bring the non-compliance to an end within the period set by the CA, the CA should take appropriate measures in accordance with Article 97(2) MDR.

The manufacturer should commit to immediately inform the CA about any circumstances that could lead to a delay as regards the end of the non-compliance, namely in respect of the conformity assessment procedure. Furthermore, the manufacturer should submit a commitment by the notified body to immediately report to the CA any major shortcoming identified during the conformity assessment procedure which gives reason to believe that the device may present an unacceptable risk to health and safety.

V. Competent authority

The CA of the Member State where the manufacturer, or its authorised representative, has its registered place of business should be the authority that deals with the above described case of non-conformity.

If the CA, after having performed the evaluation according to Article 94 MDR, comes to the conclusion that the conditions to apply Article 97(1) MDR are met, it should issue a written communication to the manufacturer, or its authorised representative, requiring the manufacturer to bring the device concerned into compliance within the defined period of time. Such communication may set out conditions regarding the manufacturer's duty and its plan of action to correct the identified non-compliance. This will have the effect that the device can be placed and made available on the EU market provided that the conditions imposed by the CA are met. The CA's written communication could be used by the manufacturer or other economic operators in their contacts with CAs of other Member States or customs authorities as evidence that they place and make available on the EU market a non-compliant device, for which the CA has defined a reasonable period of time within which the manufacturer has to bring the device into compliance with the MDR. The written communication should be based on a standard form to be agreed between CAs and clearly identify the device concerned and specify the end-date by when the manufacturer should bring the device in compliance with the MDR.

To ensure a high level of transparency and to support a uniform approach, the CA should inform the CAs of the other Member States regarding the devices for which they have applied Article 97(1) MDR pursuant to this document by appropriate means. By the same means, the CA should inform the CAs of the other Member States also about any significant change related to the measure adopted pursuant to Article 97(1) MDR (e.g. extension of the deadline, unforeseen termination). In addition, CAs should consider whether information regarding devices, for which Article 97 MDR has been applied pursuant to the document, could be made publicly available.

The application of Article 97 MDR by the CA vis-à-vis the manufacturer or its authorised representative does not prevent the CA of another Member State to take duly justified measures for its national market addressed to other relevant economic operator(s) regarding the device(s) for which the leading CA applied Article 97 MDR.

Application of Article 97 MDR does not exempt the device or any relevant economic operator from being subject to any other market surveillance activities, such as those mentioned in Article 93 MDR.

VI. Presentation of the device, information to other parties, certificates of free sale

The device should not be subject to any change as regards its labelling, including CE marking.

The manufacturer should inform its distributors and, if applicable, importers about the non-compliance and the measures undertaken to end the con-compliance (Article 10(12) MDR). If deemed appropriate having regard to the type of the device and its intended users, the CA may request the manufacturer to inform also the users.

Having regard to the fact that the device may be placed on the EU market, certificates of free sale may be issued in accordance with national provisions with a validity that should not exceed the period by when the manufacturer should bring the device in compliance with the MDR.

VII. Relationship with Article 59 MDR

Where a CA has applied Article 97 MDR with the effect that the device may be placed on the market despite its non-compliance, no additional derogation pursuant to Article 59 MDR is necessary.

Annex
Checklist for the application of Article 97 MDR

Criteria		Document(s) to be provided	Responsible			
			MF/ AR	MDD/ AIMDD NB	MDR NB	CA
Criteria and documents for the application of Article 97(1) MDR	Device is or was a 'legacy device' within the meaning of MDCG 2021-25 covered by a certificate issued by a notified body in accordance with MDD or AIMDD (not suspended nor withdrawn)	➤ Certificate issued by a notified body in accordance with MDD or AIMDD ➤ Declaration of conformity issued in accordance with MDD or AIMDD	X			
	<i>Optional: registration of the device in accordance with national requirements</i>	<i>Proof of registration</i>	X			X
	Forthcoming or incurred non-compliance	Short description from which date and for which reason the device is not or will not be in compliance with MDR	X			
	No significant change in design or intended purpose since 26 May 2021 and until the end of non-compliance	Confirmation and commitment by manufacturer <i>upon request by CA: documentation regarding manufacturer's assessment of changes including their potential significance</i>	X			
	No unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health	Vigilance, market surveillance or other information, in particular: ➤ report by manufacturer containing relevant data gathered through its post-market surveillance (PMS) system, in particular data concerning incidents, serious incidents and/or field safety corrective actions ➤ recent notified body's audit report, in particular with regard to information about potential safety-related shortcomings identified by notified body during last surveillance audit and confirmation regarding satisfactory resolution ➤ check of vigilance and market surveillance data to which CA has access	X	X		X
	Device 'in transition' to MDR	➤ Confirmation letter by notified body that application for MDR certification has been accepted and contract with manufacturer signed (in accordance with MDR Annex VII 4.3), including expected timeline of conformity assessment procedure			X	

		➤ Commitment by notified body to inform CA about major safety-related shortcomings identified during conformity assessment ➤ Commitment by manufacturer to inform CA about any delays [In duly justified cases, the CA may waive the submission of the documentation referred to in the first two bullet points where the manufacturer is a SME and can demonstrate that it has undertaken reasonable efforts to apply to a considerable number of relevant notified bodies and that their application has not been accepted due to limited notified body capacity. In that case documentation to be submitted: rejection letters from notified bodies or other correspondence between manufacturer and notified bodies demonstrating frustrated efforts to submit application to notified bodies.]	X		X	
	Adaptation of manufacturer's QMS to MDR requirements	MDR QMS certificate or confirmation by manufacturer with supporting documents including valid ISO 13485 certificate	X			
	Continuous application of MDR requirements in relation to PMS, vigilance and market surveillance including commitment by manufacturer to proactively inform the CA about any safety related corrective or preventive actions	Confirmation by manufacturer	X			
Decision by CA and follow-up by manufacturer	Acceptance of manufacturer's commitment and its plan of action to correct the non-compliance	Written communication addressed to manufacturer or authorised representative				X
	Information of distributors and, if applicable, importers about non-compliance and measures to end non-compliance	Copy of letter to distributors/importers (to be provided within x weeks of CA's written communication informing about the acceptance manufacturer's commitment and its plan of action to correct the non-compliance)	X			
	<i>Optional: information of users about non-compliance and measures to end non-compliance</i>	<i>Copy of letter to users (to be provided within x weeks of CA's acceptance/no objection letter)</i>	X			