Flowchart
(Rev. 1)

Conditions and deadlines for placing ‘legacy devices’ and class III custom-made implantable devices on the market or putting them into service in accordance with Article 120 MDR, as amended by Regulation 2023/607

Introduction
The flowchart is intended to assist manufacturers and other relevant actors in deciding whether or not a device is covered by the extended transitional period provided for in Article 120 of Regulation (EU) 2017/745 on medical devices (MDR), as amended by Regulation 2023/607. The flowchart should help to determine the eligibility, conditions and deadlines for the placing on the market or putting into service of certain devices in accordance with Article 120 MDR. The user of the flowchart is advised to consult the text of the MDR, which takes precedence over the flowchart, and the Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607.

The flowchart is divided into two parts:

Part 1: ‘Legacy devices’ referred to in Article 120(3a) MDR, i.e. devices covered by a certificate issued by a notified body in accordance with Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) prior to 26 May 2021; and
‘legacy devices’ referred to in Article 120(3b) MDR, i.e. devices for which the conformity assessment procedure pursuant to Directive 93/42/EEC (MDD) did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to the MDR requires the involvement of a notified body.

Part 2: Class III custom-made implantable devices referred to in Article 120(3f) MDR).

Used Abbreviations:
MDR: Regulation (EU) 2017/745 on medical devices
AR: Authorised representative, see Article 2(32) MDR
CA: Competent authority of an EU Member State
MNF: Manufacturer, see Article 2(30) MDR
NB: Notified body, see Article 2(42) MDR
QMS: Quality management system in accordance with Article 10(9) MDR
COP: Conformity assessment procedure in accordance with Article 52 MDR
WET: Well-established technology

Disclaimer: This document has not been formally endorsed by the European Commission and is without prejudice to any interpretation of the relevant provisions by the Court of Justice of the European Union or national courts. The information in the flowchart is of a general nature and not intended to address specific circumstances of any particular case; the document does not intend to provide professional or legal advice. The information is not necessarily comprehensive nor complete.
Part 1

Legacy device pursuant to Article 120(3a) or Article 120(3b) MDR

A Was an (AI)MDD certificate issued from 25 May 2017 that was valid on 26 May 2021 and is not withdrawn?

No

Yes

B Did the (AI)MDD certificate expire before 20 March 2023?

No

Yes

C Has an agreement\(^1\) between MNF and NB been concluded before expiry of the (AI)MDD certificate?

No

Yes

D Has a CA issued a derogation pursuant to Art. 59(1) MDR before 20 March 2023?

No

Yes

E Does the device require NB involvement under the MDR, which was not required under the MDD?

No

Yes

The device is not eligible for placing on the market or putting into service pursuant to Article 120 MDR.

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\(^1\) "Agreement" refers to a written agreement for conformity assessment in accordance with Annex VII, Section 4.3, 2\(^{nd}\) subparagraph, MDR in respect of the legacy device or a substitute device.
Part 1 (ctd.)

Does the device continue to comply with the AIMDD or MDD?

Is the device significantly changed in design or intended purpose?

Does the device present an unacceptable risk to health or safety?

Has the MNF put in place a QMS pursuant to Art. 10(9) MDR no later than 26 May 2024?

Is the device a class III device or class IIb implant, excluding certain WET-devices?

Does the device require NB involvement under the MDR, which was not required under the MDD?

The device is eligible for placing on the market or putting into service pursuant to Article 120(3a) point (a) MDR until 31 Dec 2027

The device is eligible for placing on the market or putting into service pursuant to Article 120(3a) point (b) or Article 120(3b) MDR until 31 Dec 2028

1 "Agreement" refers to a written agreement for conformity assessment in accordance with Annex VII, Section 4.3, 2nd subparagraph, MDR in respect of the legacy device or a substitute device.

2 "Unacceptable risk to health or safety" means risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, see Article 120(3c)(c) MDR.

3 For the risk class, the classification rules laid down in Annex VIII MDR apply.

4 "Certain WET devices" refers to class IIb implants that are sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, see Article 120(3a)(a) MDR.
Part 2

Class III custom-made implantable device

a Has the MNF/AR lodged an application for a COP pursuant to Art. 52(8), 2nd subpara. MDR no later than 26 May 2024?

b Has an agreement between MNF and NB been concluded no later than 26 Sept 2024?

The device is eligible for placing on the market or putting into service pursuant to Article 120(3f) MDR without MDR QMS certificate until 26 May 2026

The device is not eligible for placing on the market or putting into service pursuant to Article 120(3f) MDR without MDR QMS certificate

3 For the risk class, the classification rules laid down in Annex VIII MDR apply.

5 "custom-made device" is defined in Article 2(3) MDR and "implantable device" is defined in Article 2(5) MDR.

6 "Agreement” refers to a written agreement in accordance with Annex VII, Section 4.3, 2nd subparagraph, MDR in respect of the conformity assessment referred to in Article 52(8) 2nd subparagraph MDR.

Revision History

<table>
<thead>
<tr>
<th>Revision</th>
<th>Date</th>
<th>Change Description</th>
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<tbody>
<tr>
<td></td>
<td>23 August 2023</td>
<td>Initial issue</td>
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<tr>
<td>1</td>
<td>30 August 2023</td>
<td>Page 3, second green box: addition of a reference to Article 120(3b) MDR</td>
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