Flowchart

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:

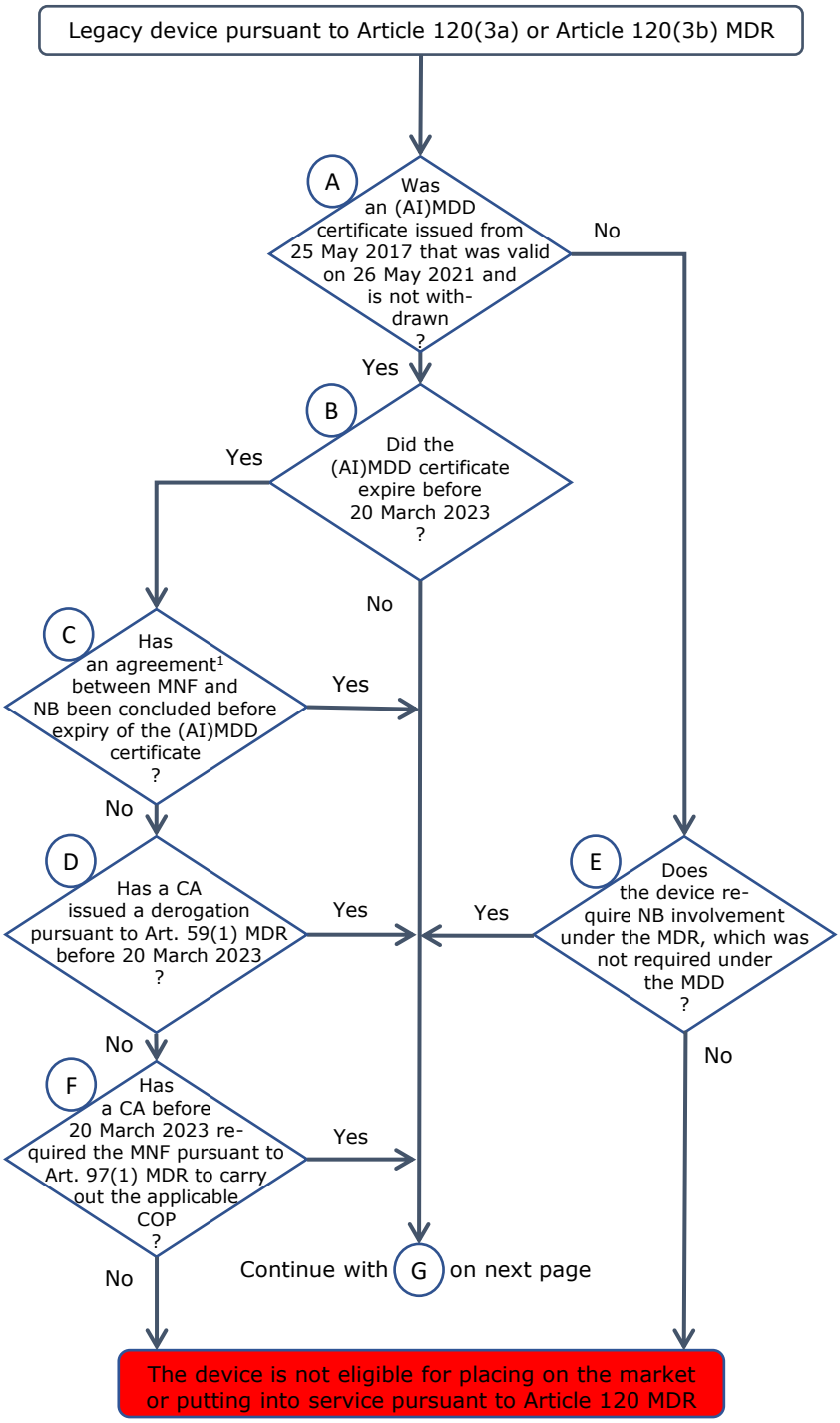
Part 1: 'Legacy devices' referred to in Article 120(3a) MDR, i.e. devices covered by a certificate issued by a notified body in accordance with Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) prior to 26 May 2021; and
'legacy devices' referred to in Article 120(3b) MDR, i.e. devices for which 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:

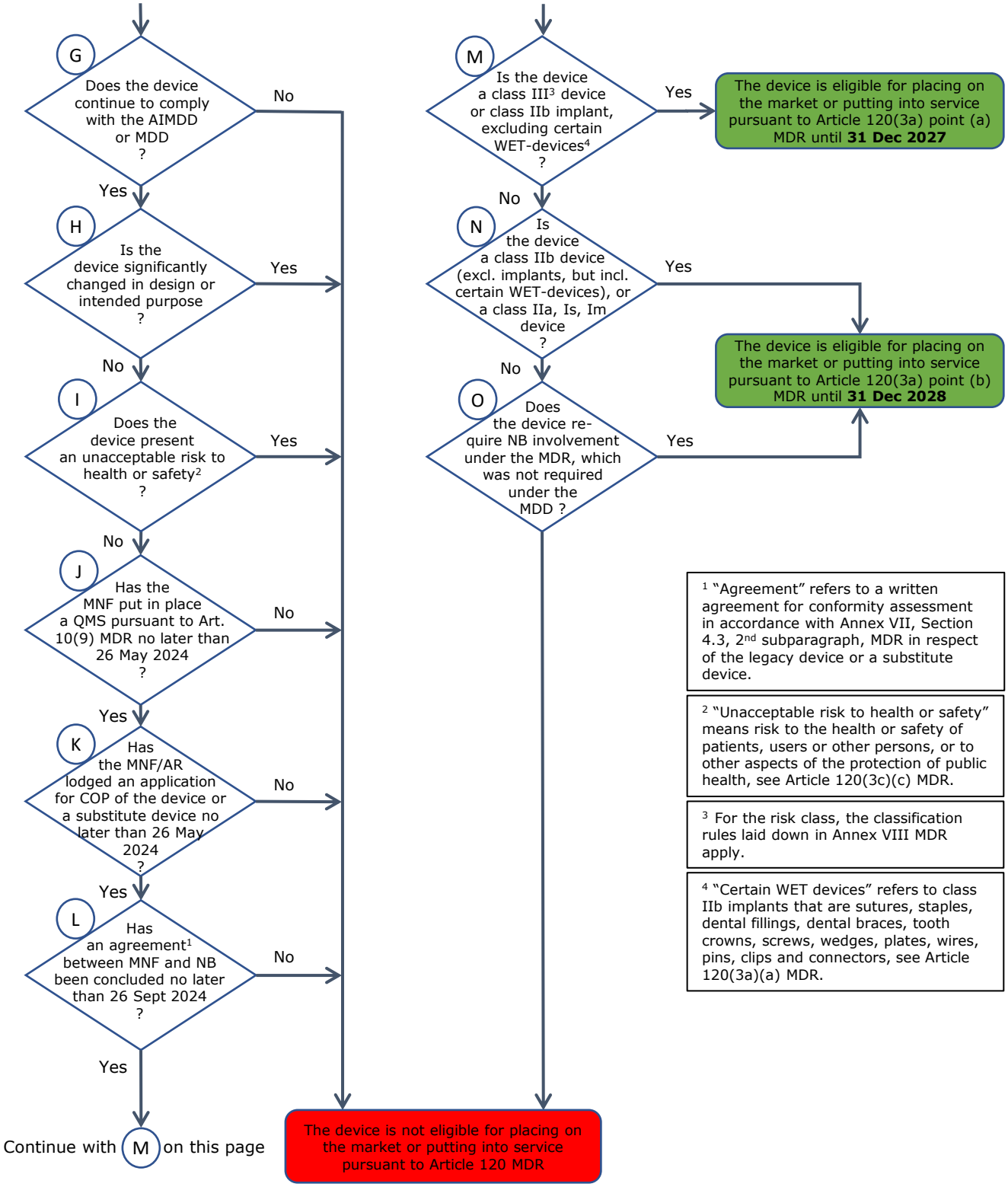
AIMDD:	Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical
MDD:	Council Directive 93/42/EEC concerning medical devices
MDR:	Regulation (EU) 2017/745 on medical devices
AR:	Authorised representative, see Article 2(32) MDR
CA:	Competent 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

Part 1



[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.

Part 1 (ctd.)



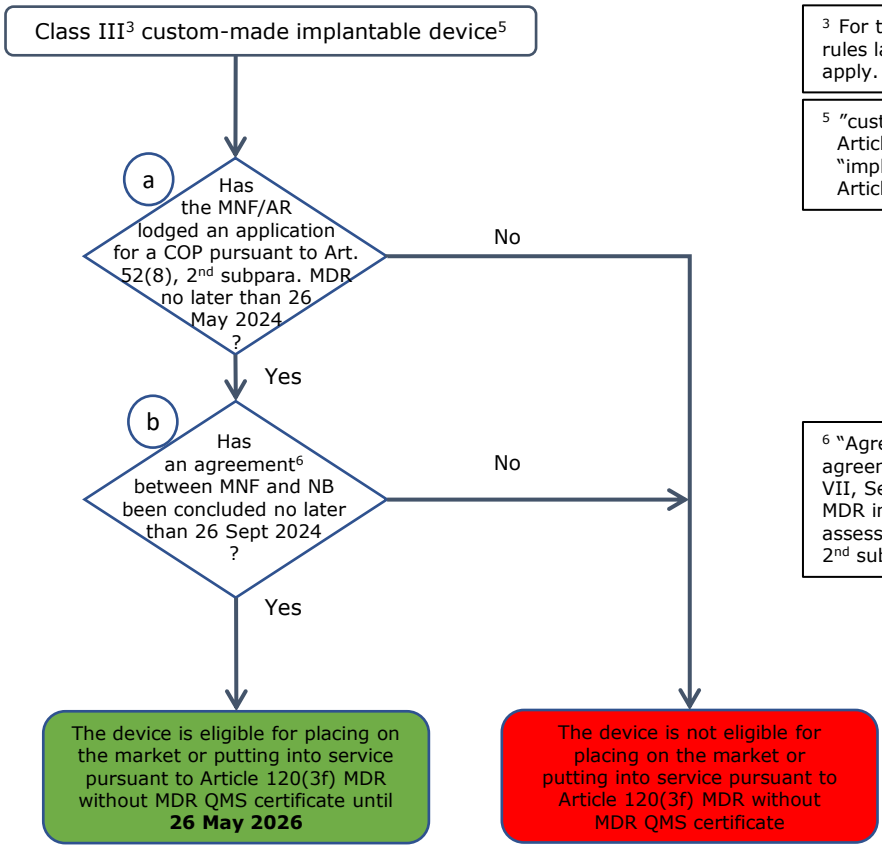
[1] "Agreement" refers to a written agreement for conformity assessment in accordance with Annex VII, Section 4.3, 2nd subparagraph, MDR in respect of the legacy device or a substitute device.

[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



[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.