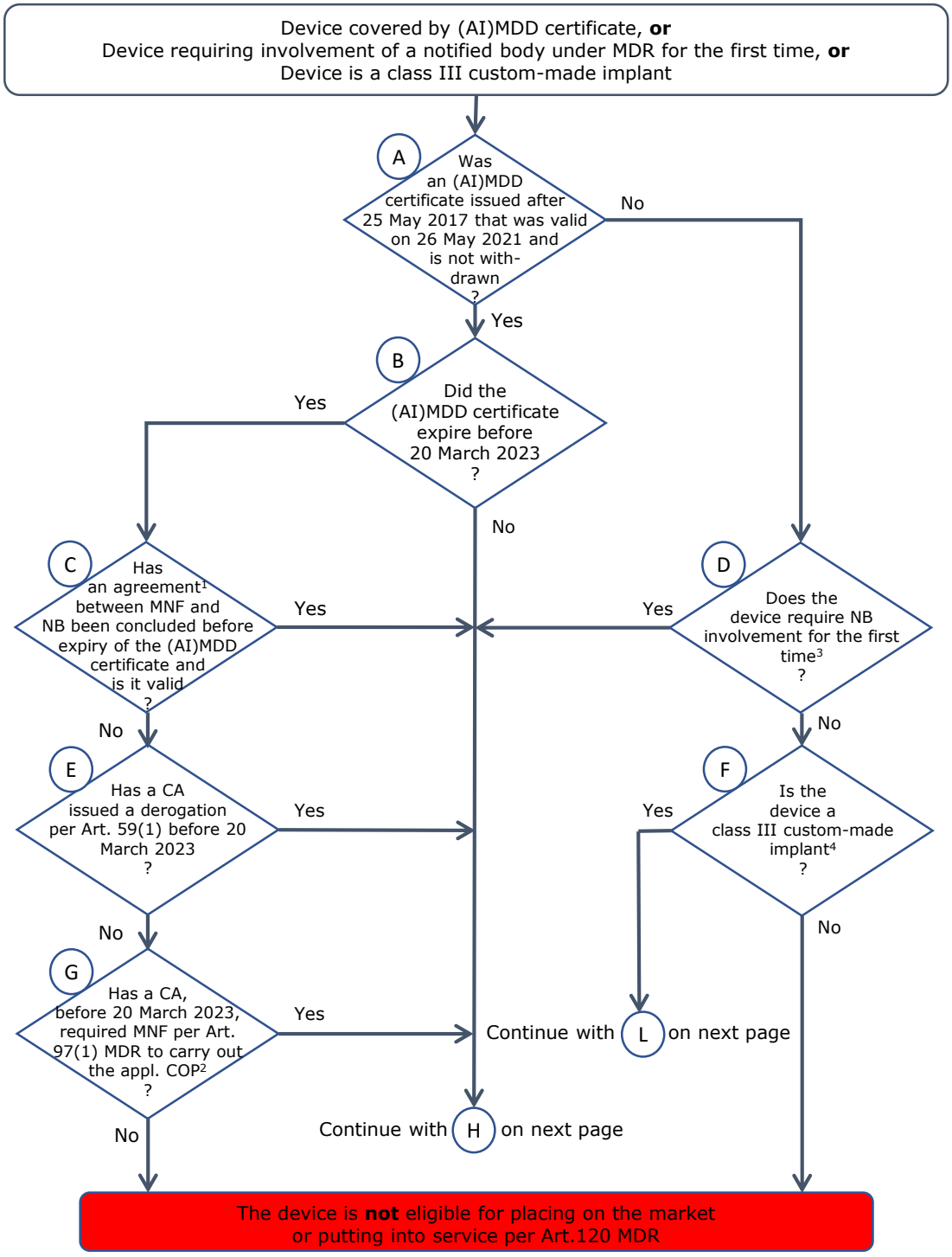
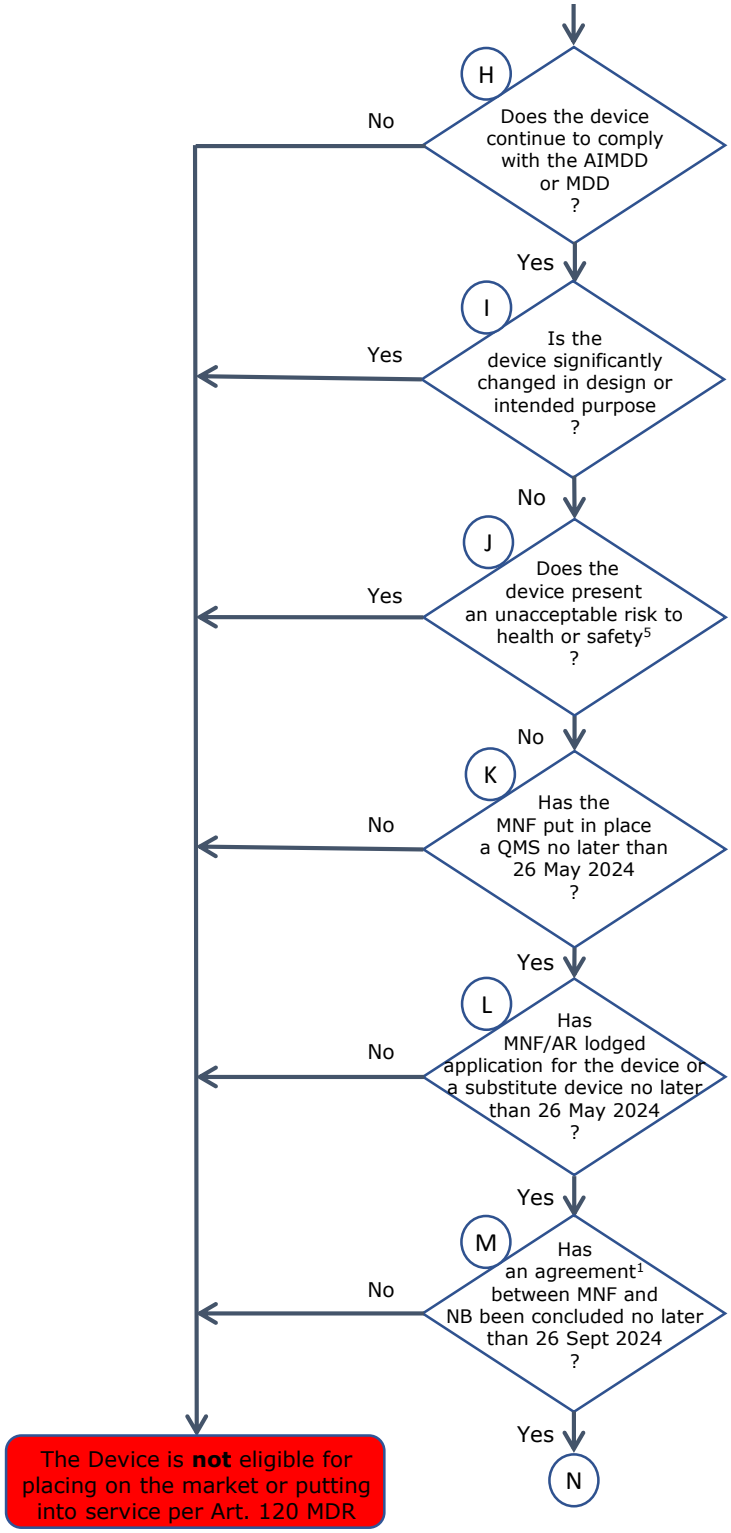
Annex to the Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices

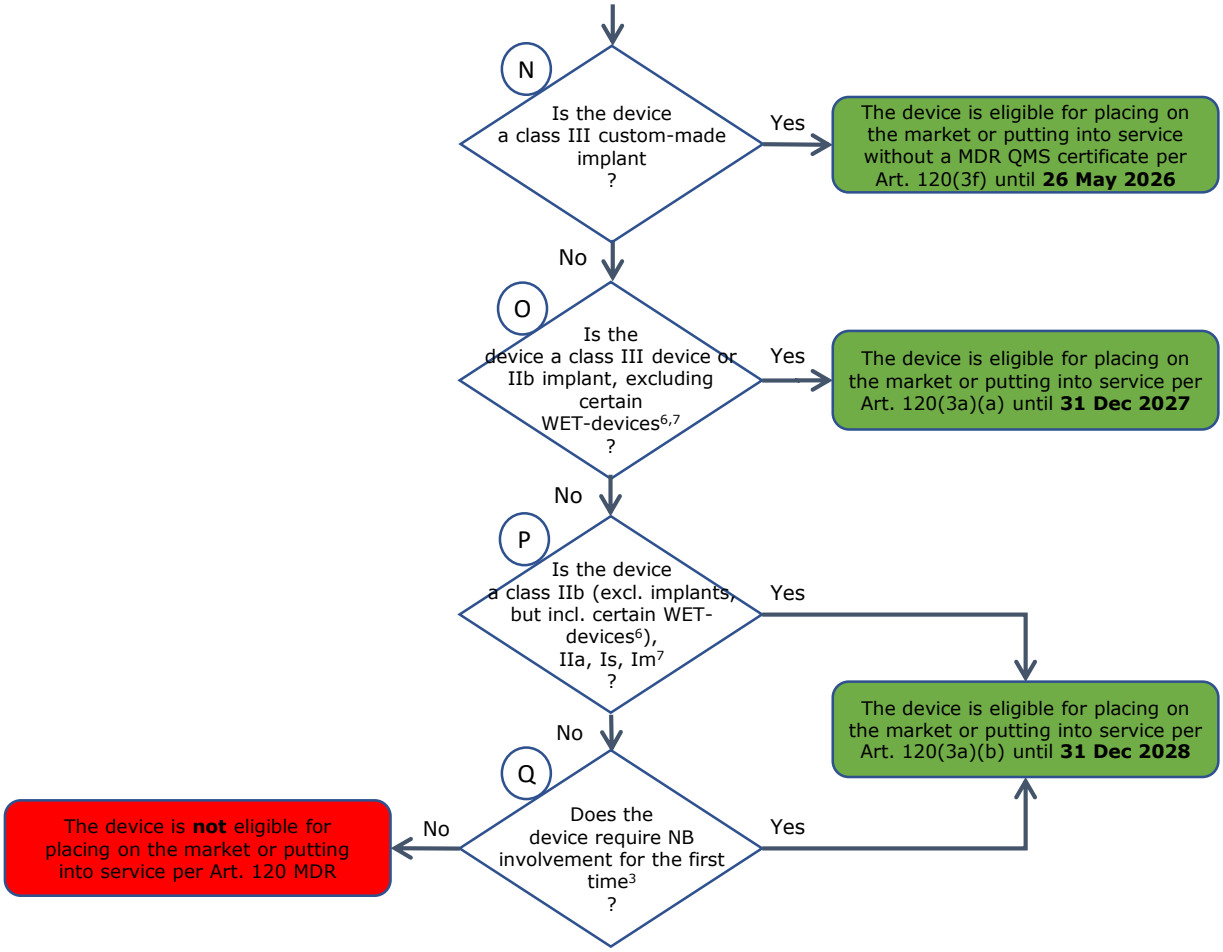
Flowchart: Conditions and deadlines for placing 'legacy devices' on the market or putting them into service in accordance with Article 120 MDR, as amended by Regulation 2023/607



Conditions and deadlines for placing 'legacy devices' on the market or putting them into service in accordance with Article 120 MDR, as amended by Regulation 2023/607



Conditions and deadlines for placing 'legacy devices' on the market or putting them into service in accordance with Article 120 MDR, as amended by Regulation 2023/607



Used Abbreviations:

MDR:	Medical Devices Regulation (EU) 2017/745
AR:	Authorized Representative per MDR Art. 2(32)
MNF:	Manufacturer per MDR Art. 2(30)
CA:	Competent Authority per MDR Art. 101
Device:	Devices as defined in MDR Art. 1(4)
QMS:	Quality Management System in accordance with MDR Art. 10(9)

Explanatory Notes / References:

1) "Agreement" shall mean:
   Contract per MDR Annex VII, Section 4.3, 2nd subparagraph, in respect of the legacy device or a substitute device

2) "appl. COP" shall mean:
   Applicable conformity assessment procedure per MDR Art. 52

3) "Device which requires NB involvement for the first time" shall mean:
   Device for which the conformity assessment procedure pursuant to Directive 93/42/EEC 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 MDR requires the involvement of a notified body.
   See Article 120(3b) MDR.

4) Refer to the defined terms "custom-made" and "implant" per MDR Article 2(3) and 2(5):
   The risk classification rules laid down in Annex VIII MDR apply.

5) "Unacceptable risk to health or safety" shall include:
   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.

6) "Certain WET-devices" shall mean:
   MDR Class IIb implants considered well-established technology, specifically:
   sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors. See Article 120(3a)(a) MDR.

7) The risk classification rules laid down in Annex VIII MDR apply.