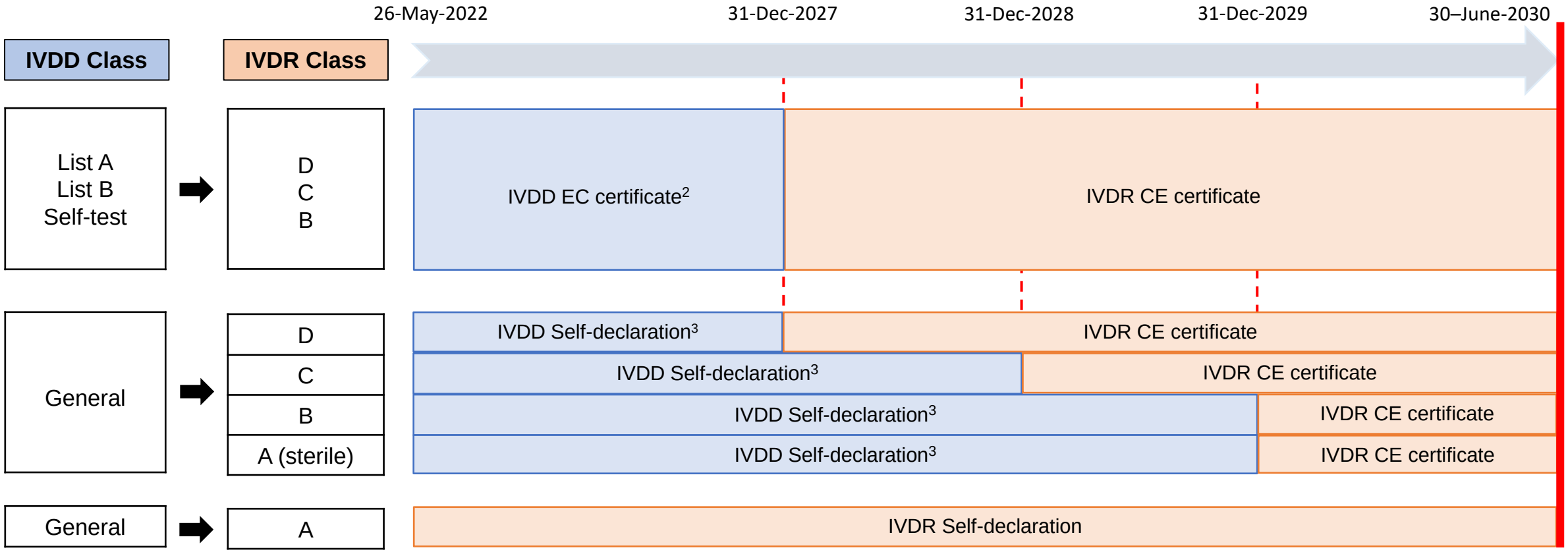
Medicines & Healthcare products Regulatory Agency

Timelines for placing CE marked IVDs on the Great Britain market[1]



IVDD refers to the EU *in vitro* diagnostic medical devices directive (98/79/EC).
IVDR refers to the EU *in vitro* diagnostic medical devices regulation (2017/746).
[1]As provided for under The Medical Devices (Amendment) (Great Britain) Regulations 2023.
[2]IVDD EC certificates still valid on 26 May 2022 and that have not been withdrawn thereafter can be relied on after the end of the period indicated on the certificate until 31 December 2027, except for certificates issued in accordance with IVDD Annex VI which shall become void at the latest on 27 May 2025. In case of devices for which the relevant certificate has expired before 9 July 2024, also the conditions laid in the second subparagraph of Article 110(2), points (a) or (b), IVDR.
[3]Declaration of conformity to IVDD requirements made prior to 26 May 2022 can be relied on until the indicated dates only if the conditions laid down in Article 110(3c) IVDR (as amended by Regulation (EU) 2024/1860 of 13 June 2024) are fulfilled.

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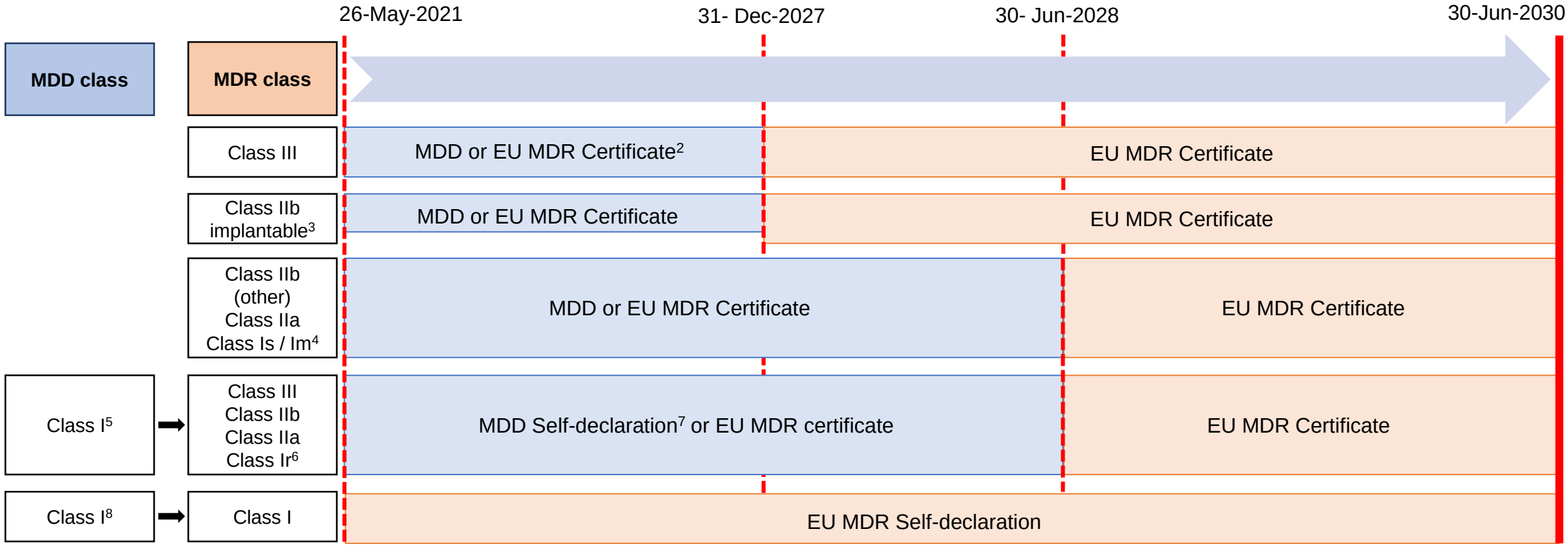
Timelines for placing CE marked medical devices on the Great Britain market[1]



[1]As provided for under The Medical Devices (Amendment) (Great Britain) Regulations 2023.
[2]A valid AIMDD certificate can also be relied on for placing medical devices on the GB market in this period.
[3]This excludes sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors – those fall within Class IIb other.
[4]Class Im means class I devices with a measuring function. Class Is means class I devices that are placed on the market in sterile condition.
[5]Class I devices that **did not** require notified body involvement in their conformity assessment under the MDD and **do require** notified body involvement in their conformity assessment under the EU MDR.
[6]Class Ir means class I devices that are reusable surgical instruments.
[7]Declaration of conformity to MDD requirements must have been made before 26 May 2021.
[8]Class I devices that **do not** require notified body involvement in their conformity assessment under the MDD nor under the EU MDR.
MDD refers to EU medical devices directive (93/42/EEC); **AIMDD** refers to EU active implantable medical devices directive (90/385/EEC); **EU MDR** refers to EU medical devices regulation (2017/745).