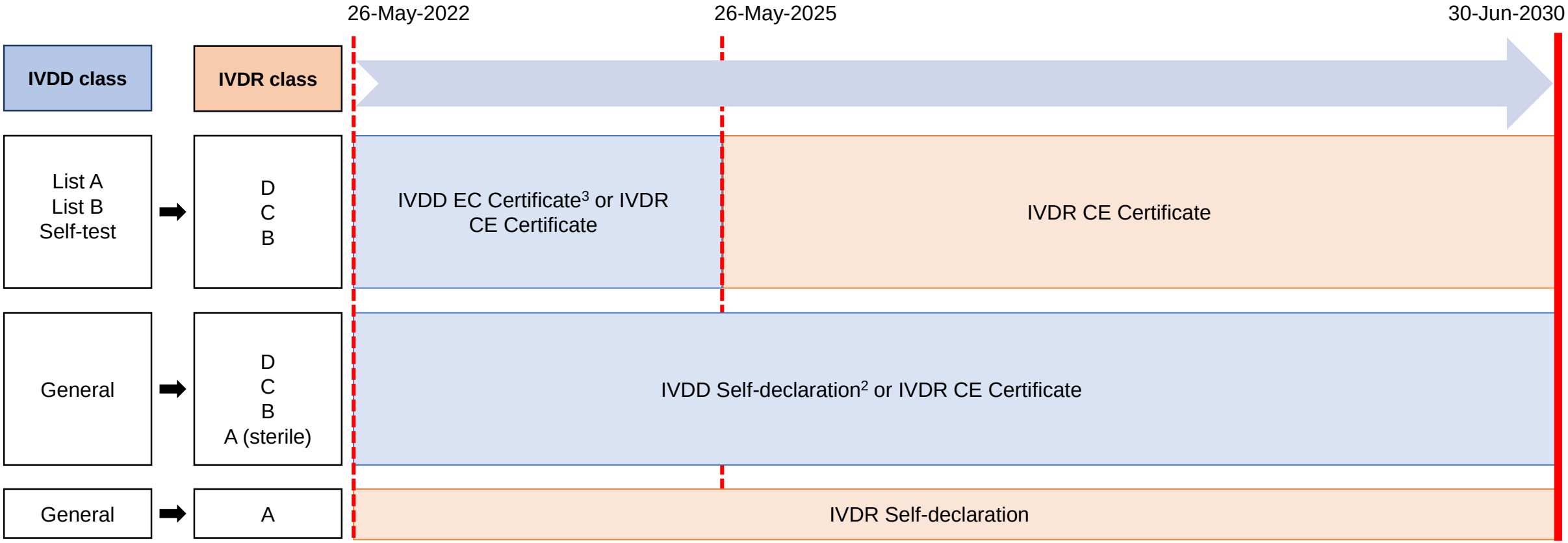
Medicines & Healthcare products Regulatory Agency

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

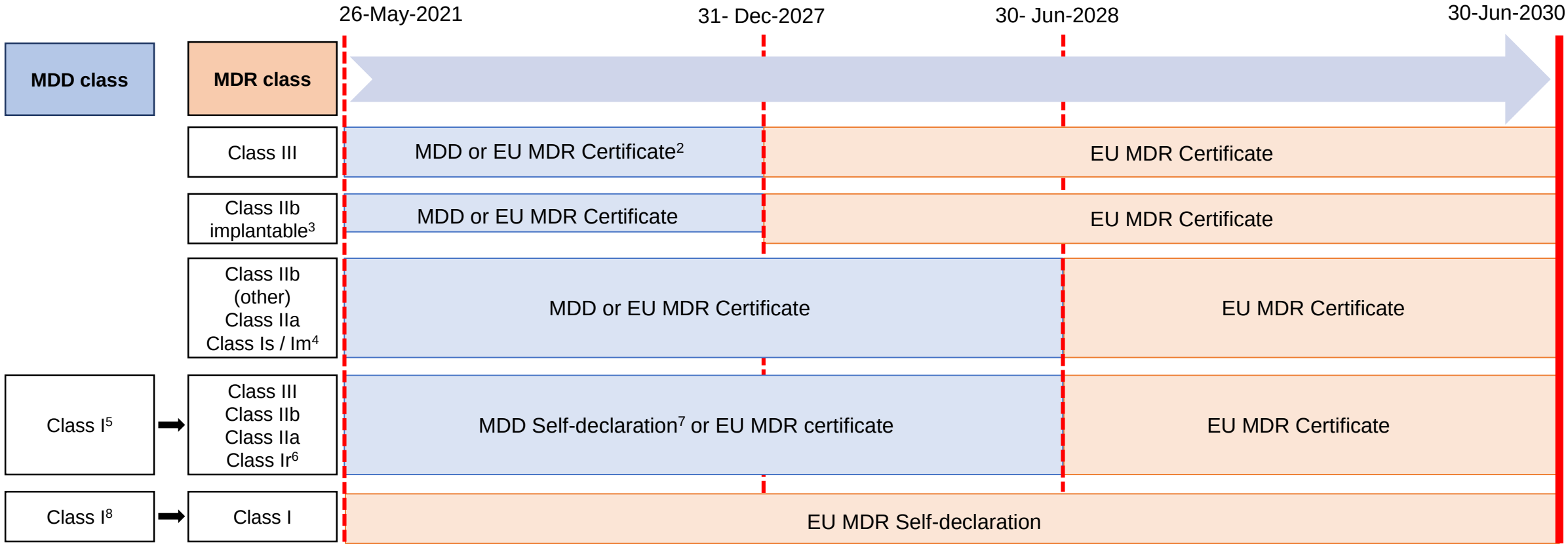


IVDD refers to the EU *in vitro* diagnostic medical devices directive (98/79/EC).
IVDR refers to the EU *in vitro* diagnostic medical devices regulation (2017/746).

[1]As provided for under The Medical Devices (Amendment) (Great Britain) Regulations 2023.
[2]Declaration of conformity to IVDD requirements that must have been made before 26 May 2022.
[3]IVDD EC certificates can be relied on until they expire or until they become void under Article 110 of the IVDR on 27 May 2025, whichever is sooner. The 26 May 2025 therefore represents the latest possible date that an IVD can be placed on the GB market relying on a valid IVDD EC certificate.

Medicines & Healthcare products Regulatory Agency

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).