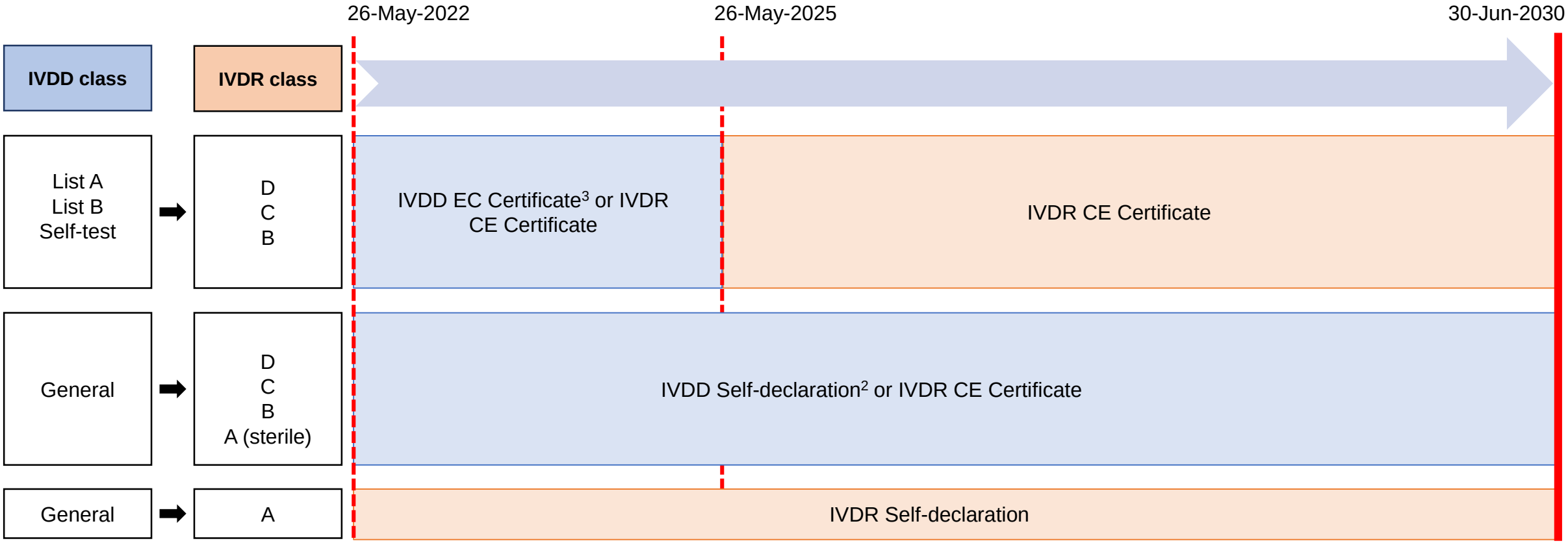
Medicines & Healthcare products Regulatory Agency

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.

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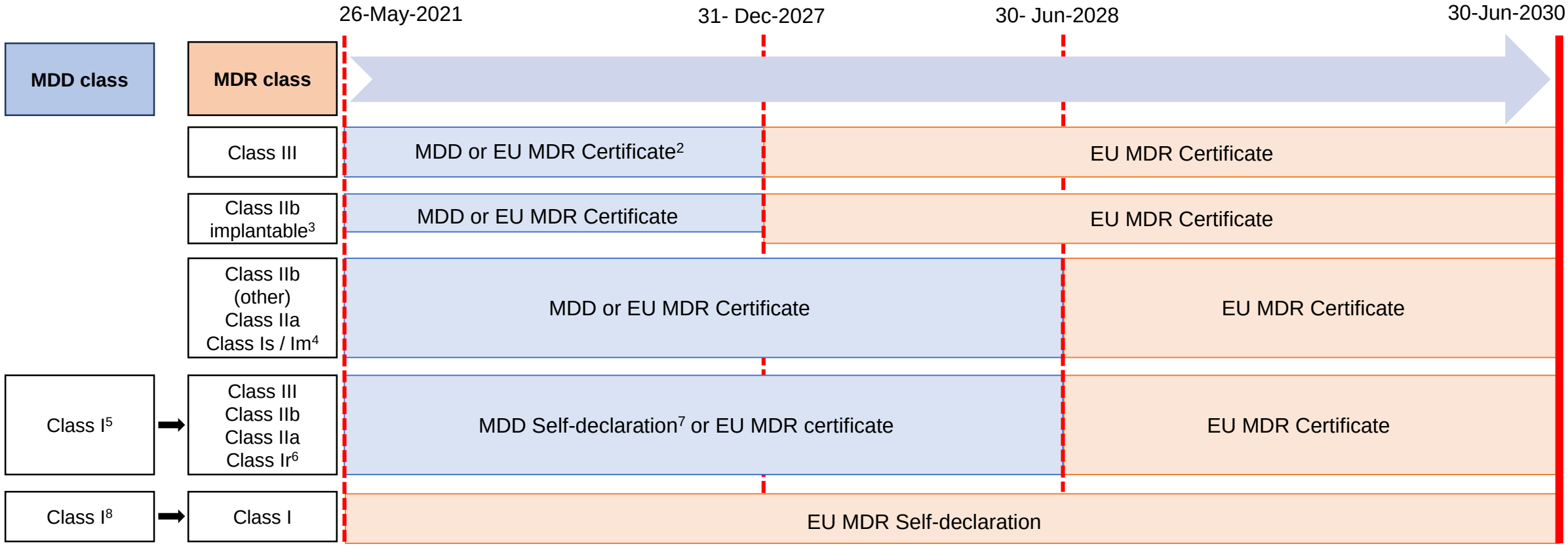
Timelines for placing CE marked medical devices on the Great Britain market[1]



[1]As provided for under The Medical Devices
[2]A valid AIMDD certificate can also be relied
[3]This excludes sutures, staples, dental fillings
[4]Class Im means class I devices with a meas
[5]Class I devices that **did not** require notified assessment under the EU MDR.
[6]Class Ir means class I devices that are reus
[7]Declaration of conformity to MDD requireme
[8]Class I devices that **do not** require notified I
MDD refers to EU medical devices directive (regulation (2017/745).

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ll within Class IIb other.

lvement in their conformity

IDR refers to EU medical devices