Revised MHRA timelines for UKCA transition

Release of the new statutory instrument

- **SI 2023 no. 627:**

  The Medical Devices (Amendment) (Great Britain) Regulations 2023

  - Come into force: 30th June 2023 for regulations 1 to 4
  - Remainder comes into force 1st July 2023
  - Amends The Medical Devices Regulations 2002

- **Purpose:**

  - To extend the acceptance of CE marked medical devices on the Great Britain market. This will support the ongoing safe supply of medical devices to Great Britain and ease the transition to the future regulatory regime.

Timelines

Directive conforming general medical devices

- Devices with a valid declaration and CE marking can be placed on the Great Britain market up until the sooner of expiry of certificate or 30th June 2028

Directive conforming IVDs

- IVDs with a valid declaration and CE marking can be placed on the Great Britain market up until the sooner of expiry of certificate or 30th June 2030

Regulation conforming devices (general and IVD)

- A valid EU regulation certificate enables devices to be placed on the market up until the 30th June 2030

- Expired certificates must be deemed valid by the EU

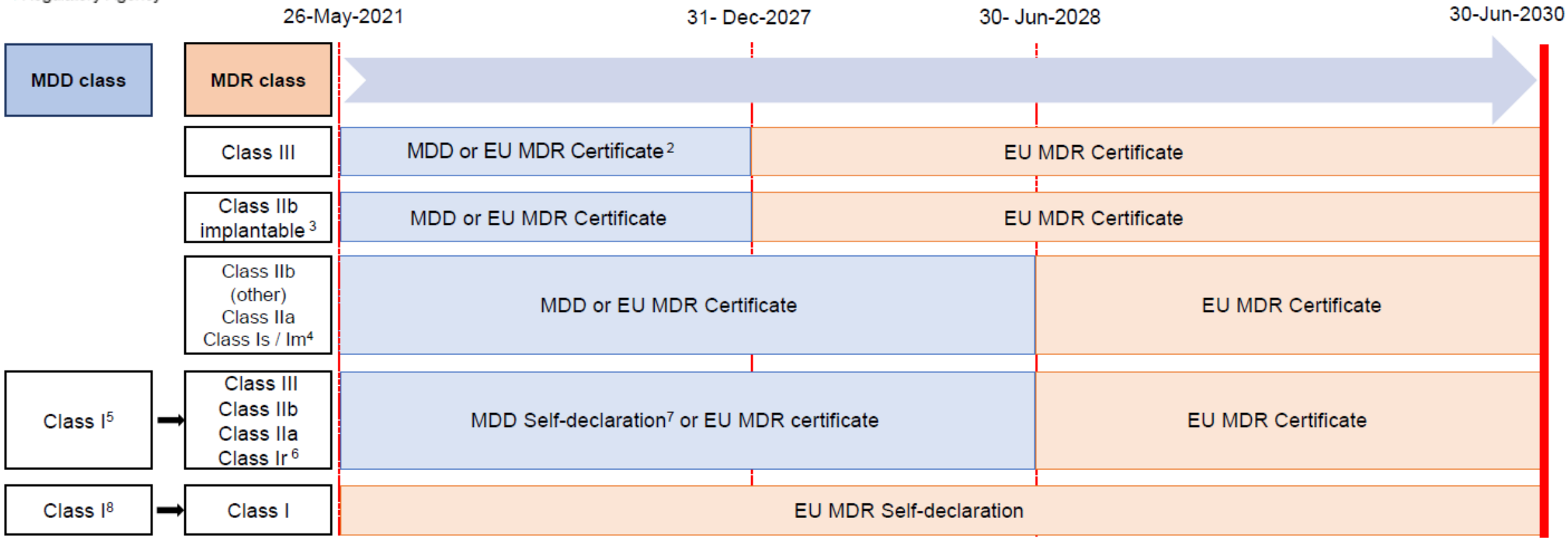
Class I / self certified devices

Class I m or s	▪ If such devices have a valid MDD certificate, then they may be placed on the GB market until 30 June 2028
Class I upclassified by EU MDR	▪ Class I upclassified devices or class I r may be placed on the GB market until 30 June 2028, if the DoC predates 26 May 2021
General IVDs or class I MDs	▪ An EU regulation declaration of conformity enables IVD /medical devices to be placed on the market up until the 30 June 2030

▪ Expired certificates must be deemed valid by the EU

Medicines & Healthcare products Regulatory Agency

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

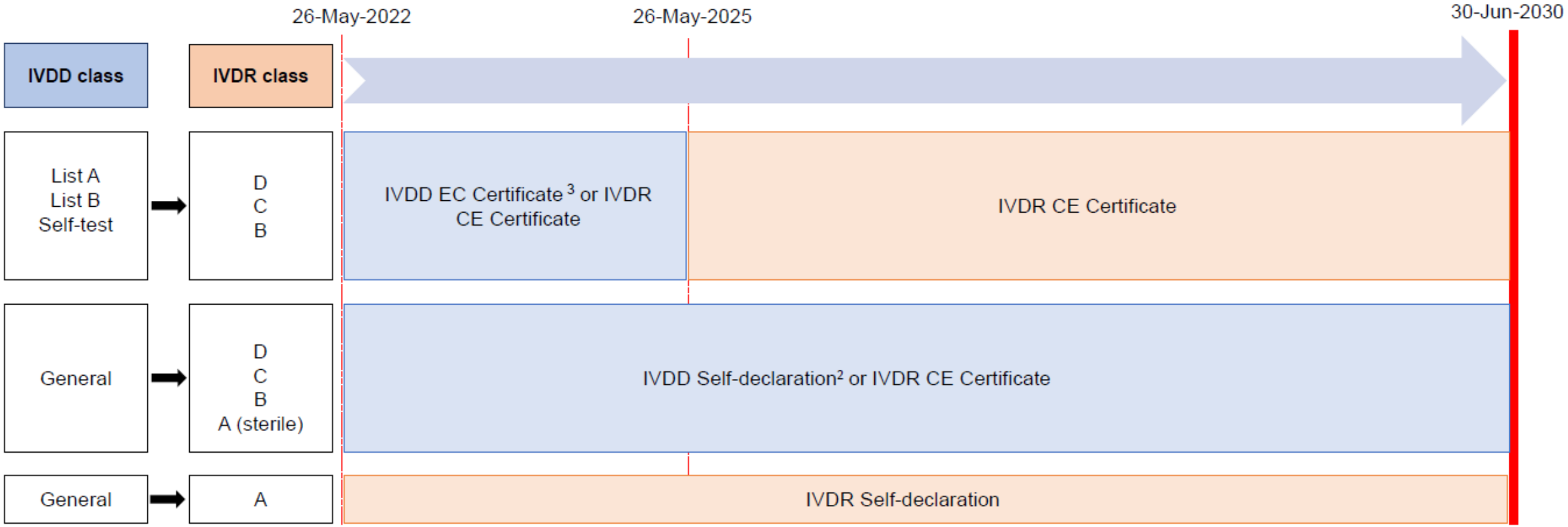


[1] As provided for under The Medical Devices (Amendment) (Great Britain) Regulations 2023
[2] A valid AIMDD certificate can also be relied on for placing medical devices on the GB market in this period.
[3] This excludes sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, 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)

Medicines & Healthcare products Regulatory Agency

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

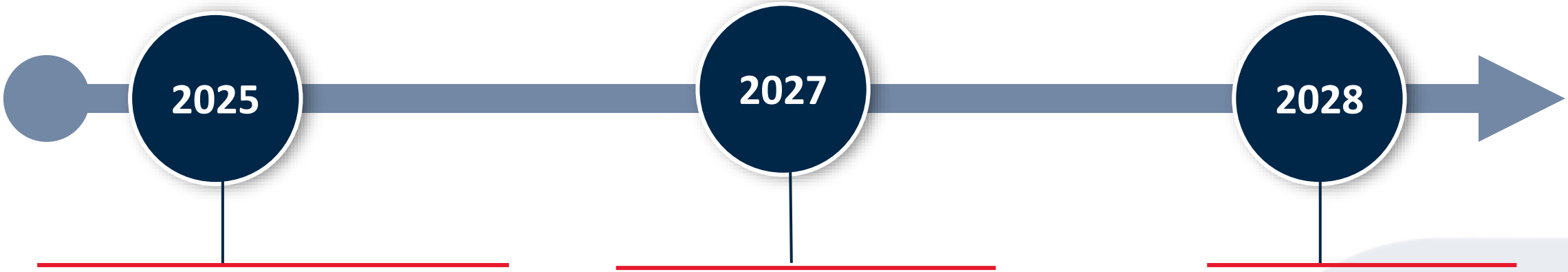


IVDD refers to the EU *in vitro* diagnostic medical devices directive (98/79/EC)
IVDR refers to the EU *in vitro* diagnostic medical devices regulation (2017/746)

[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.

Watch the dates

ONLY EU regulation certificates accepted after:



List A, B and self test IVDs:
26th May 2025

Class III or IIb implantable (excluding well established technologies):
31st Dec. 2027

All other medical devices except self certified:
30 June 2028

Procedure Packs will use the date of the component that has the earliest transition time

Thank you for your attention

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