Your partner in progress

Placing a device on the GB market

Conformity Assessment EU legislations

Directives

Conformity Assessment MDD/AIMDD/IVDD

Class Is Class Im Class IIa Class IIb Class IIb implantable WET	• Upload Article 120 extension confirmation with MHRA • UKRP appointed if required • Conditions under EU 2023/607 are met • PMS requirements as per SI 2024/1368

Products can be placed on the market until **30 June 2028**

Class IIb implantable non-WET Class III AIMD	• Upload Article 120 extension confirmation with MHRA • UKRP appointed if required • Conditions under EU 2023/607 are met • PMS requirements as per SI 2024/1368

Products can be placed on the market until **31 Dec 2027**

List A List B Self-test	• Upload Article 110 extension confirmation with MHRA • Conditions under EU 2024/1860 are met • UKRP appointed if required • PMS requirements as per SI 2024/1368

Products can be placed on the market up until **31 Dec 2027** (for classified General IVDs up until **31 Dec 2029***) or until they expire whichever is sooner

* Class D – **Dec 2027**
Class C – **Dec 2028**
Class B/A sterile – **Dec 2029**

Regulations

Conformity Assessment EU MDR/IVDR

All classifications	• UKRP appointed if required • PMS requirements as per SI 2024/1368

Products can be placed on the market until **30 June 2030**

Conformity Assessment UK legislation

Conformity Assessment UK MDR 2002

All classifications	• UKRP appointed if required • PMS requirements as per SI 2024/1368

Products can be placed on the market until:
- **30 June 2028** for Medical Devices
- **30 June 2030** for IVDs

NOTE: Class I self-certified devices are excluded in this overview. The timelines above are subject to the new legislation coming into force in 2026

CE mark

Registration with MHRA

UKCA mark

PLACE DEVICE ON THE GB MARKET

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