

Placing a device on the GB market



Conformity Assessment EU legislations

Directives

Conformity assessment EU MDD/AIMDD/IVDD

- | | |
|---------------------------|---|
| Class Is | <ul style="list-style-type: none">• Upload Article 120 extension confirmation with MHRA• UKRP appointed if required• Conditions under 2023/607 are met• PMS requirements as per SI 2024 No.1368 statutory instrument |
| Class Im | |
| Class IIa | |
| Class IIb | |
| Class IIb implantable WET | |

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

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|-------------------------------|---|
| Class IIb implantable non-WET | <ul style="list-style-type: none">• Upload Article 120 extension confirmation with MHRA• UKRP appointed if required• Conditions under 2023/607 are met• PMS requirements as per SI 2024 No.1368 statutory instrument |
| Class III | |
| AIMD | |

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

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|-----------|---|
| List A | <ul style="list-style-type: none">• UKRP appointed if required• PMS requirements as per SI 2024 No.1368 statutory instrument |
| List B | |
| Self-test | |

Products can be placed on the market until **26 May 2025** or until they expire, whichever is sooner

Regulations

Conformity Assessment MDR/IVDR

- | | |
|---------------------|---|
| All classifications | <ul style="list-style-type: none">• UKRP appointed if required• PMS requirements as per SI 2024 No.1368 statutory instrument |
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Products can be placed on the market until **30 June 2030**

Conformity Assessment UK legislation

Conformity Assessment UK MDR 2002

- | | |
|---------------------|--|
| All classifications | <ul style="list-style-type: none">• UKRP appointed and identified if required• PMS requirements as per SI 2024 No.1368 statutory instrument |
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Products can be placed on the market until:

- **30 June 2028** for Medical Devices
- **30 June 2030** for IVDs



CE mark

Registration with MHRA

PLACE DEVICE ON THE GB MARKET



UKCA mark

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