Your partner in progress

# Placing a device on the GB market



## Conformity Assessment EU legislations

### Directives

#### Conformity assessment MDD/AIMDD/IVDD

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

Products can be placed on the market until 30 June 2028

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

Products can be placed on the market until 31 Dec 2027

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

Products can be placed on the market indefinitely*

## Conformity Assessment UK legislation

### Conformity Assessment UK MDR 2002

| | |
|---|---|
| All classifications | • UKRP appointed if required<br>• 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**

CE mark

**Registration with MHRA**

UKCA mark

**PLACE DEVICE ON THE GB MARKET**

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

*subject to parliamentary approval
**subject to change under the transitional arrangements in the Pre-Market SI

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