Medicines & Healthcare products Regulatory Agency

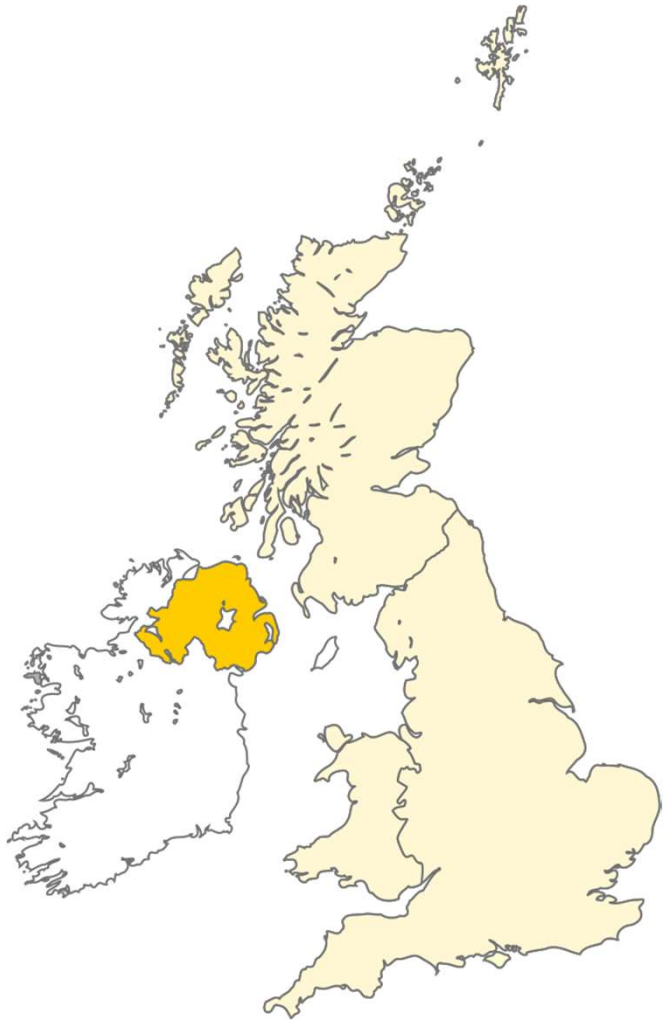
Overview of UK Medical Device Regulation



CPRD NIBSC MHRA

Standstill Position

- The transition period between the UK and the EU ended on 1 January 2021
- 2.5 year ‘standstill period’
- Different regulation in Great Britain (England, Wales, Scotland) and Northern Ireland due to the Northern Ireland Protocol
- Northern Ireland will have access to the EU Single Market and it will continue to align with EU rules for medical devices



Standstill Position

Great Britain

- EU MDR/IVDR not implemented
- Recognition of the CE marking until 30 June 2023
- UKCA marking required after 30 June 2023
- Approved Bodies can now conduct assessments for the UKCA mark

Northern Ireland

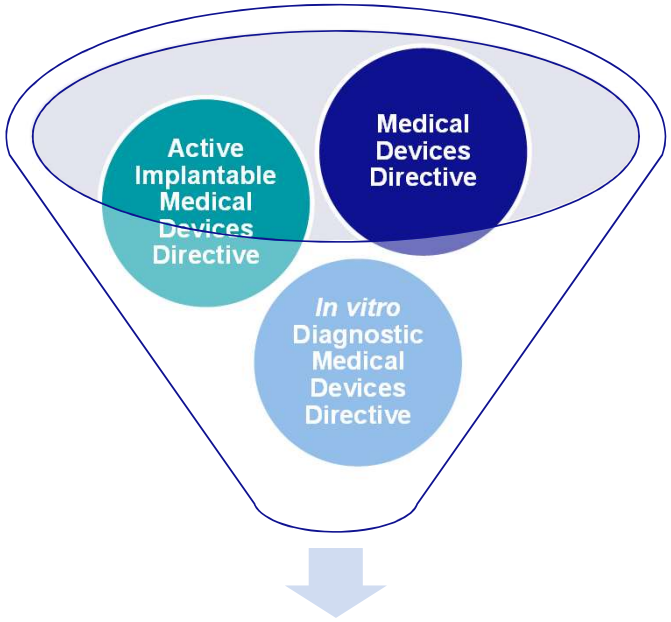
- EU MDR/IVDR implemented with EU timeline
- Devices must be CE or CE UKNI marked
- CE UKNI applied where UK Notified Body used for conformity assessment

UK Legislation

- Medical devices are regulated in the UK under the **UK Medical Devices Regulations 2002** (UK MDR 2002)

- The UK MDR 2002 is based on existing EU legislation which has been transposed into UK law

- **The Medicines and Medical Devices Act (2021)**:
  - allows us to update the UK MDR 2002
  - consolidates enforcement provisions
  - provides for a device information system
  - allows for enhanced data sharing



Future Regulation of Medical Devices in Great Britain

Attractive world-class regulatory system which prioritises patient safety

Early 2021	Late 2021-Early 2023	July 2023
• MMD Act in force • Informal consultation with stakeholders	• Formal public consultation • Agree position and finalise secondary legislation	• Stop recognition of CE marking in GB • New medical device regulatory framework in force

We will take into consideration international standards and global harmonisation in the development of our future system