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

<table>
<thead>
<tr>
<th>Early 2021</th>
<th>Late 2021-Early 2023</th>
<th>July 2023</th>
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<tbody>
<tr>
<td>• MMD Act in force</td>
<td>• Formal public consultation</td>
<td>• Stop recognition of CE marking in GB</td>
</tr>
<tr>
<td>• Informal consultation with stakeholders</td>
<td>• Agree position and finalise secondary legislation</td>
<td>• New medical device regulatory framework in force</td>
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Attractive world-class regulatory system which prioritises patient safety

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