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Post-Brexit UK legislation for MEDICAL DEVICES

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Post-Brexit UK legislation for Medical Devices

Brexit Timeline - Key Milestones

On 23 January 2020, Royal assent received for the European Union (Withdrawal Agreement) Act. On 31 January 2020, UK Leaves EU; so, Transition Period for Trade negotiations ended on 31 December 2020. During Transition Period, EU treats the UK as if it was a Member State, but UK cannot participate in the EU institutions and governance structures. Northern Ireland (NI) will continue to follow EU rules from 01 Jan 2021 while the rest of UK will not.

MHRA Guidance - UK Medical Device Legislations

- ✓ Great Britain will recognize EU CE marking and EU NB issued CE certificates (both Directives and Regulations) until **30 June 2023.**
- ✓ In parallel, from 01 Jan 2021 a new route to market and product marking (UKCA) will be available for manufacturers wishing to place a device on the Great Britain market.
- ✓ MHRA will continue to perform market surveillance of medical devices on the UK market
- ✓ MHRA is responsible for the designation and monitoring of UK conformity Assessment Bodies for Medical devices.

Placing a device on the Great Britain Market from 01 Jan 2021

1. **Conformity Assessment as per EU legislations (Directives, Regulations):**
   - ✓ Only valid until **30 Jun 2023** with exception of NI traders
   - ✓ EU Declaration of conformity Certificate → **CE mark** for the product → Registration with MHRA → Place device on the Great Britain market
2. **Conformity Assessment as per UKCA Legislation:**
   - ✓ Mandatory from **01 July 2023**
   - ✓ UK Declaration of conformity Certificate → **UKCA mark** for the product → Registration with MHRA → Place device on the Great Britain market.

UKCA Legislation

1. After the transition period, Great Britain will continue to operate under MDD, AIMDD and IVDD as incorporated into UK law **(UK MDR 2002)** and in the form they exist on 01 Jan 2021.
2. **UK MMD Bill** (Medicines and Medical Devices Bill 2019-21) introduces secondary legislation to establish a new stand-alone regulatory framework for Great Britain.
3. MDR and IVDR will not apply in Great Britain (GB) as their dates of application are beyond the end of the transition period and hence are not automatically retained EU law. But they will apply in Northern Ireland (NI) as per the NI protocol.

UK Approved Bodies (UKABs)

To conduct Conformity Assessment against UKCA requirements:

- ✓ Must be based in the UK
- ✓ From 01 Jan2021, UK Notified Bodies (UK NBs) will become UK Approved Bodies (UK ABs); no additional designation process required for UK NBs.
- ✓ UKABs will retain their Notified Bodies number (e.g. BSI UK will be 0086 even under UKCA)
- ✓ EU NANDO to UK MCAB transformation will occur.

UKCA Certificates

To conduct Conformity Assessment against UKCA requirements:

- ✓ **UKCA** Prefix on Certificates
- ✓ Need to refer to the **UK legislation MDR 2002**
- ✓ Any CE certificates issued prior to 01 Jan 2021 by UK based NBs will continue to remain Valid after 01 Jan 2021 for GB market until 30 Jun 2023.
- ✓ Changes to, renewal of certificate after 01 Jan 2021 will need to be processed as UKCA certificates.

UK Conformity Assessedmark - UKCA mark

To conduct Conformity Assessment against UKCA requirements:

- ✓ Applies from 01 Jan 2021
- ✓ Placed on devices when the UKCA requirements have been met
- ✓ Not recognized in EU, EEA or NI
- ✓ Mandatory from 1 July 2023 to place a device on the GB market; but will not apply to NI traders (to be clarified in the future)
- ✓ Manufacturer who has met both CE and UKCA requirements can **dual mark** their devices.
- ✓ Manufacturers of **class I** medical devices and general IVDs will be able to **self-declare** their conformity against **Part II and Part IV of the UK MDR 2002** (in the form in which they exist on 1 January 2021), before affixing a UKCA mark and placing the device on the Great Britain market.

Registration of Devices and timelines

To conduct Conformity Assessment against UKCA requirements:

1. After 01 Jan 2021, devices must be registered with MHRA before being placed on the UK market irrespective of whether UKCA marked or CE marked.

2. 12 months grace period will not apply to manufacturers of **Class I devices** and **general IVDs** that are currently required to register with the MHRA.

3. Need a **UK responsible person (UKRP)**

- -- If the legal manufacturer is based outside UK
- -- Has very similar responsibility as an EU rep under the directives.
- -- Will act on behalf of manufacturer to perform specific tasks including registering devices
- -- Grace period for appointing UKRP- aligned to the grace period for registration of devices.
- -- No symbol is yet published for UKRP
- -- No requirements for PRRC (as per MDR, IVDR)

Grace Period for Registration of Devices

For Custom-made devices, timelines depends based on the their classification

- **30 April 2021 (4 months)**
  - Active implantable medical devices,
    Class III medical devices,
    Class IIb implantable medical devices
    IVD list A
- **30 April 2021 (4 months)**
  - Class IIb non-implantable medical devices
    Class IIa medical devices
    IVD list B
    Self-test IVDs
- **31 Dec 2021 (12 months)**
  - Class I medical devices, General IVDs

Labeling Transition

1. **Conformity For a Non-UK manufacturer placing devices on GB market**
   - If product placed on GB market using CE mark – **not mandatory to re-label** to add UKCA mark or UK Responsible Person information **until the 30 June2023**.
   - Devices that are **dual labelled** with both the CE and UKCA marks will continue to be accepted on the Great Britain market after **1 July2023**.

2. **For UK manufacturer (or non-UK manufacturer with GB based EU Rep) placing devices in EU/EEA**
   - Need CE certificate issued by an EU NB to access EU market
   - Need an EU Rep based in EU/EEA/NI
   - No additional guidance from EU on labeling transition – prepare to implement by 01 Jan 2021.

MHRA Guidance - UK Medical Device Legislations

- ✓ EU MDR and IVDR will apply from 26 May 2021 and 26 May 2022 respectively
- ✓ Even after 01 July 2023, CE mark will continue to be needed for devices placed on the Northern Ireland market and EU rules will need to be met.
- ✓ CE certificates issued prior to 01 Jan 2021 by UK NBs will not be recognized after that date for NI market
- ✓ UK Approved Bodies will be able to conduct conformity assessments for NI market under the Directives (UK MDR 2002)
  - **UK (NI) mark** to accompany, but not replace, the CE mark.
  - Products carrying both the CE mark and UK (NI) mark cannot be placed on the EU market.
  - UKCA marked devices will not be accepted on the Northern Ireland market unless accompanied by the CE or CE UK (NI) mark.
- ✓ Specific Registration and UKRP requirements apply for NI

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