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Guidance on What You Need To Do To Place a Medical Device on the Great Britain Market From January 1, 2021

The MHRA has published new guidance titled "Regulating medical devices from January 1, 2021."

From January 1, 2021, the MHRA will take on the responsibilities for the UK medical devices market that are currently undertaken through the EU system.

In the guidance, 'medical device' includes in vitro diagnostic medical devices and active implantable medical devices. The guidance does not cover other CE-marked products. The proposals outlined in the guidance will take effect through legislative changes which are still subject to parliamentary approval and will be introduced later in 2020.

The guidance covers the following matters:

- **Summary of key requirements for placing a device on the Great Britain market:**
    - **CE marking:** Recognised in Great Britain until June 30, 2023
        - If you currently CE mark your medical device on the basis of self-certification, you will be able to continue to do so after January 1, 2021 and place your device on the Great Britain market until June 30, 2023
    - **Certificates issued by EU-recognised Notified Bodies:** Valid until June 30, 2023
        - From January 1, 2021, any mandatory third-party conformity assessment for the CE marking will need to be carried out by an EU-recognised Notified Body
            - This includes both EU-based Notified Bodies and Notified Bodies in countries which are listed on the EU's NANDO Information System
    - **UK Notified Bodies:** Will not be recognised by the EU after the transition period; will not be able to issue CE certificates (other than for the purposes of the "CE UKNI" marking, which will be valid in Northern Ireland); will become UK approved bodies from January 1, 2021
    - **Register with the MHRA:** Requirement for all medical devices placed on the UK market from January 1, 2021
    - **Manufacturers based outside the UK:** To place a medical device on the Great Britain market you will need to appoint a UK Responsible Person
- **Legislation that will apply in Great Britain from January 1, 2021:** The Great Britain route to market and UK Conformity Assessed (UKCA) marking requirements will continue to be based on the requirements derived from current EU legislation
    - **The following directives are given effect in UK law through the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002):**
        - **Directive 90/385/EEC:** Active implantable medical devices
        - **Directive 93/42/EEC:** Medical devices
        - **Directive 98/79/EC:** In vitro diagnostic medical devices
            - The UK MDR 2002 will continue to have effect in Great Britain after the transition period has ended in the form in which they exist on January 1, 2021
- **EU legislation which will not be transposed into law in Great Britain and will not be implemented in Great Britain:**
    - **The EU Medical Devices Regulation (EU MDR):** Will fully apply in EU Member States from May 26, 2021

    - **EU in vitro Diagnostic Medical Devices Regulation (EU IVDR):** Will fully apply in EU Member States from May 26, 2022
- **The role of the MHRA:** Performs marketing surveillance of medical devices on the UK market and will be able to take decisions over the marketing and supply of medical devices in the UK; responsible for the designation and monitoring of UK Conformity Assessment Bodies
- **From January 1, 2021, any medical device, IVD, or custom-made device must be registered with the MHRA before being placed on the Great Britain market:**
    - To be registered with the MHRA, medical devices must conform to the UK MDR 2002, the EU MDR (until June 30, 2023), or the EU IVDR (until 30 June 2023)
    - The manufacturer or their UK Responsible Person must have a registered place of business in the UK
        - **Manufacturers based outside the UK:** Appoint a UK Responsible Person that has a registered place of business in the UK; this UK Responsible Person will then assume the responsibilities of the manufacturer in terms of registering the device with the MHRA
- **Grace periods for compliance with the new registration process:**
    - **Class IIIs and Class IIb implantables, and all active implantable medical devices and IVD List A products:** Must be registered from May 1, 2021
    - **Other Class IIb and all Class IIa devices and IVD List B products and self-test IVDs:** Must be registered from September 1, 2021
    - **Class I devices, custom-made devices, and general IVDs (that do not currently need to be registered):** Must be registered from January 1, 2022
        - It is possible to register devices ahead of the above dates
        - It will be possible for manufacturers to register devices of different classes, that are subject to different grace periods, at the same time
        - Registration for custom-made devices will be in line with the risk class of the device
        - Failure to register from these dates will mean that you will no longer be able to lawfully place your device on the Great Britain market
    - **Manufacturers of Class I devices, custom-made devices, and general IVDs that are currently required to register their devices with the MHRA:** Must continue to register their devices from January 1, 2021 on the same basis as they do now until the new registration requirements start to apply to those devices
    - **Medical device already registered with the MHRA:** Does not need to be re-registered after January 1, 2021
        - Manufacturers (or their UK Responsible Person) will be required to review the information held by the MHRA to ensure it remains in line with the above grace periods
        - **Fee for changes to registrations:** £100 per application
    - **Northern Ireland-based manufacturers that have already registered their medical device with the MHRA for the purposes of Northern Ireland:** The medical device can be placed on the Great Britain market and will not need to undergo any further registration in Great Britain
- **UK Responsible Person:** Required for manufacturers based outside of Great Britain; importers and distributors will not be required to appoint a UK Responsible Person
    - Aim to appoint your UK Responsible Person ASAP
    - An importer or the distributor can act as a UK Responsible Person
    - **Responsibilities of the UK Responsible Person:** Will be set out in the UK MDR 2002

        - Register relevant devices with the MHRA in line with the above grace periods depending on the device class
        - Act on behalf of the outside-UK manufacturer to carry out specified tasks in relation to the manufacturer's obligations
        - Ensure that the declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer
        - Keep available a copy of the technical documentation, a copy of the declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements for inspection by the MHRA
        - In response to a request from the MHRA, provide the MHRA with all the information and documentation necessary to demonstrate the conformity of a device
        - Provide samples of a device to the MHRA or allow the MHRA access to the device where the UK Responsible Person has samples or access or, where they do not have access or samples, forward to the manufacturer any request from the MHRA for samples or access
        - Cooperate with the MHRA on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices.
        - Immediately inform the manufacturer about complaints and reports from healthcare professionals, patients, and users about suspected incidents related to a device for which they have been designated
        - Terminate the legal relationship with the manufacturer if the manufacturer acts contrary to its obligations under the applicable regulations and inform the MHRA and, if applicable, the relevant Notified Body of that termination
    - **Product labelling where the UKCA mark has been affixed:** From January 1, 2021, the name and address of the UK Responsible Person, where applicable, will need to be included
    - **Product labelling for CE-marked devices:** UK Responsible Person details will not need to be included
- **Importers and distributors:**
    - Where the Great Britain importer is not the UK Responsible Person, the importer will be required to inform the relevant UK Responsible Person of their intention to import a device; the UK Responsible Person will be required to provide the MHRA with a list of device importers
        - Other than this, there will be no additional obligations on distributors or suppliers of medical devices as of January 1, 2021
    - Existing obligations around storage, transportation, and checking device labels for the CE marking or the UKCA marking will continue to apply
    - The importer's name and address will not need to be present on the label unless the importer or the distributor are acting as the UK Responsible Person
- **The UKCA mark:** A new UK product marking that will be used for certain goods, including medical devices, being placed on the Great Britain market after the transition period
    - **Available to use:** From January 1, 2021 (on a voluntary basis)
    - **Mandatory:** From July 1, 2023
    - **Not recognised in the EU, EEA, or Northern Ireland markets; products currently requiring a CE marking will still need a CE marking for sale in these markets**
- **UK approved body:** Required where a third-party conformity assessment is required

  - From January 1, 2021, the MHRA will be able to designate UK approved bodies to conduct assessments against the relevant requirements for the purpose of the UKCA mark
  - Existing UK Notified Bodies with designations under the EU MDD, the EU IVDD, or the EU AIMDD will have their designations rolled over automatically, without having to undergo a new designation process
  - For the purposes of the Great Britain market, UK approved bodies will only be able to conduct conformity assessments in relation to the UKCA mark for medical devices; UK approved bodies will not be able to conduct conformity assessments in relation to the CE marking other than for the purposes of the "CE UKNI" marking, which will be valid in Northern Ireland
- **Manufacturers of Class I medical devices and general IVDs:** Able to self-declare their conformity against the EU MDD or the EU IVDD as transposed by the UK MDR 2002, before affixing a UKCA mark and placing the device on the Great Britain market
  - **Class I medical devices that are sterile or have a measuring function:** Still require approval from a UK approved body in order to be affixed with the UKCA mark and placed on the Great Britain market
- **Recognition of existing CE certificates for the Great Britain market:** From January 1, 2021 under the UK MDR 2002, CE-marked devices with a valid declaration of conformity or certificate will be viewed as meeting the UKCA mark requirements until June 30, 2023
  - This will include devices placed on the market that are:
    - CE marked in conformance with the EU MDD, the EU IVDD, or the EU AIMDD
    - CE marked in conformance with the EU MDR or the EU IVDR
  - Any enforcement or market surveillance powers available in respect of the UKCA mark will apply to CE-marked devices placed on the Great Britain market
  - Where certificates have been issued by a UK Notified Body, the Notified Body will be re-designated as a UK approved body and will continue to oversee these devices and their manufacturers to ensure continued compliance with the applicable standards of safety and performance under the UKCA mark
- **Labelling requirements:** Depending on which legislation the medical device has been certified under, as of January 1, 2021, medical devices placed on the Great Britain market will need to have either a UKCA or a CE marking
  - Where relevant, the number of the Notified Body or the approved body will also need to appear on the label
  - **Valid CE marking on your device:** You will not be required to re-label the device with a UKCA mark until July 1, 2023
  - **Dual marking:** Both the CE mark and UKCA mark can be present on the labelling prior to July 1, 2023, and dual marking will continue to be accepted on the Great Britain market after July 1, 2023
  - **Where the UKCA mark has been affixed (including when devices have been dual marked):** From January 1, 2021, the name and address of the UK Responsible Person, where applicable, will need to be included on product labelling
- **Post-market surveillance and vigilance:**
  - Manufacturer is required to submit vigilance reports to the MHRA when certain incidents occur in the UK that involve their device
  - Manufacturer must take appropriate safety action when required
  - Manufacturer must ensure their device meets appropriate standards of safety and performance for as long as it is in use