UK Responsible Person

Non UK Manufacturer

Medical devices and IVD registration with the MHRA

UK Responsible Person

The UK RP will need to have access to the technical documentation in one or another way. It can be a hard copy or e-copy, or a link to the manufacturer's documentation system. **WTUK** prefers to have a contact person at the manufacturer that is available for the UK RP to answer and discuss specific questions regarding the technical documentation and where to find them as well as for vigilance and incidents.

The Letter of Designation and the contract/engagement letter between the manufacturer and **WTUK** are two separate documents. The Letter of Designation includes standard text provided by the MHRA. This letter must be uploaded in the database. Next to this, **WTUK** has written a contract/Engagement letter between the manufacturer and UK RP to identify the responsibilities included in the UK RP service. Hence, the Letter of Designation cannot be replaced by the contract between the manufacturer and UK RP.

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Grace Period

The MHRA guidance states that a manufacturer must appoint a UK RP as soon as possible. The MHRA has provided a grace period for the registration of medical devices and IVDs in order to allow time for compliance with the new registration process. Medical devices and IVDs must be registered with the MHRA as per table 1.

WTUK advises to register devices ahead of these dates, but there will be no legal obligation until the end of the grace period.

Classification

It is compulsory to list the GMDN code during the registration process. Without the GMDN code the registration of the device cannot be completed. If a manufacturer does not have a GMND code,

WTUK can support the manufacturer in identifying the appropriate GMDN code.

The MHRA has not listed an overview of recognized GMDN codes for the public as this would be against the GMDN Agency policies.
During the registration process of a device into the UK database, all GMDN codes can be searched for. This means that the list of GMDN codes in the UK database is always up to date with the GMDN Agency.

Labeling

The labeling and packaging of devices placed on the Great Britain market based on the EU MDD/IVDD or EU MDR/IVDR do not have to change until 30 June 2023. This means that the current labeling and packaging including the CE mark remain valid. The name and address of the UK RP do not need to be on the label and packaging until 30 June 2023.

Devices can have both the CE mark as well as the UKCA mark present on the labeling prior to 1 July 2023, and dual marking will continue to be accepted on the Great Britain market after 1 July 2023.

Information and documentation for registration

There are three levels of information:

1. Manufacturer details

Manufacturer details include the name, address, Phone number, email address and contact person of the organization

2. Device details

Device details include high level details based on the GMND code. Among other things, this includes the risk classification, technical specifications such as sterile or non-sterile device,

single or reusable device and compliance to EU MDD/IVDD MDR/IVDR. Furthermore, the conformity assessment certificate and declaration of conformity must be provided.

3. Product details

Product details include the specific device name (brand/trade/or common name), device model(s), catalogue number(s)/reference(s), contra-indications, and critical warnings. For manufacturers with a large product portfolio, the MHRA has made available a specific template for 'bulk upload' which can be used to upload all information into the database.

Bulk Upload

No, bulk upload is not possible for all GMDN codes combined. The feature 'bulk upload' can only be used for device models per GMDN code. For example; the registration of 1 GMDN code, including 150 different device models, can use the bulk upload for the registration of the 150 device models.

Access database

Once the manufacturer and medical devices are registered with the MHRA, some details will be accessible through the Public Access Database for Medical Device Registration. This database will not show all device and product details, but it will show high level details. This includes the manufacturer name, address, UK Responsible Person, registration date, MHRA Reference Number and all devices registered with the MHRA by GMDN term.

Notified Body

A Notified Body is a EU-recognized body that can undertake a conformity assessment and grant approval for EU market access for devices that comply with the EU MDD/IVDD and EU MDR/IVDR. This allows the manufacturer to bear the CE mark on the labeling and packaging of the device after approval of the Notified Body. A manufacturer can then place the CE marked devices on the Great Britain market until 30 June 2023.

UK Notified Body

A UK Approved Body is a new conformity assessment body that has been designated by the Secretary of State. This means that former known Notified Bodies located in the UK are not automatically becoming a UK Approved Body.

The role and tasks of a UK Approved Body are in essence similar to those of a EU-recognized Notified Body however the UK Approved Body will grant approval for UK market access for

devices that comply with the UK MDR. This allows a manufacturer to bear the UKCA mark on the labeling and packaging of the device after approval of the UK Approved Body.

UKNI marking

UK Notified Bodies can conduct conformity assessments for the purposes of the Northern Ireland market.

In addition to the CE marking, device manufacturers also need to apply the UKNI marking if they choose to use a UK Notified Body for mandatory third-party conformity assessment. Device manufacturers must never apply the UKNI marking on its own - it must always accompany a CE marking. To place goods on the EU market, manufacturers must use the CE marking on its own, without the UKNI marking. Goods bearing the "CE & UKNI" marking will not be accepted on the EU market.

In summary, you need to use the UKNI marking if:

- you are placing certain medical devices on the Northern Ireland market; and
- your goods require mandatory third-party conformity assessment; and
- you use a UK Notified Body to carry out those conformity assessments.

The UKNI marking is sometimes referred to as the UK(NI) mark or the UK(NI) indication, including in Article 7(3) of the Northern Ireland Protocol. These terms refer to the same marking.

Responsibilities of WTUK as Responsible Person

- Register devices with the MHRA
- 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 these Regulations and inform the MHRA and, if applicable, the relevant notified body of that termination.