GMED LNE GROUP Newsletter

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UKCA MARKING: KEY STEPS TO CONSIDER

The United Kingdom left the European Union single market on 31st December 2020. As a consequence, the United Kingdom Conformity Assessed (UKCA) mark is being phased in from January 1st, 2021 to replace the CE mark in Great Britain (England, Wales, and Scotland), although for most goods the CE mark will remain acceptable for a transition period ending on 31st December 2022. For medical devices (MD) and in vitro diagnostic medical devices (IVDMD) the transition period ends on June 30th, 2023. It will not be used for products placed on the Northern Ireland market, which require CE marking or UKNI marking. There is no reciprocal transition for the European Union and products currently requiring a CE marking for sale in the European Union will continue to need a CE mark.

A GENERAL REQUIREMENTS

The UKCA marking applies to most goods previously subject to the CE marking. Any products that currently need approval by a Notified Body will have to be certified by a UK Approved Body (UKAB). Notified Body and Approved Body certificates operate under separate accreditations and legal jurisdictions. Hence different certificate numbers will apply in addition to any product marking associated with the Body. If a UKAB has been involved in the conformity route then the UKAB number (4 digits) must follow the UKCA mark on the product. UK-based bodies will keep the same 4-digit identification number that they used as Notified Bodies as these numbers are no longer used in the EU database 'NANDO'.

There are a number of different types of organisations that assist with regulating products on the UK Market:

- Conformity Assessment Bodies (CABs)
- Recognised Third Party Organisations (RTPO's)
- User Inspectorates (UI's)
- Technical Assessment Bodies (TAB's)

Such UK based Bodies that were previously recognised have automatically acquired status as UK Approved CABs, RTPO, UI or TAB's.

The UK Market Conformity Assessment Bodies (UKMCAB) database has been launched on GOV.UK. It serves as the UK's database of CABs and the UK equivalent of the European Union's NANDO database. UKMCAB is the definitive source of UK CABs with corresponding designation scopes. In other words, UKCAB's who can certify goods for both the GB and NI markets.

How do UKABs get onto the UKMCAB database?

For quality management systems certification and product certification, the United Kingdom Accreditation Service (UKAS) provides audit services against ISO/IEC 17021-1 and ISO/IEC 17065. Notification is then prepared for the relevant competent authority who list the UKAB on the database. Depending on the scheme, there may be further audits by the competent authority. For example, medical devices require additional audits by the Medicines and Healthcare products Regulatory Agency (MHRA).

The technical requirements ('essential requirements') manufacturers must meet and the conformity assessment processes and standards that can be used to demonstrate conformity are largely the same as they were for the CE marking. For medical devices, the UK Medical Device Regulations 2002 are based on the EU medical device directives, and not the newer EU regulations.

The circumstances in which manufacturers can use self-declaration of conformity for UKCA marking are the same as for CE marking i.e. If you were able to self-declare conformity for the CE marking, you will be able to do the same for the UKCA marking.

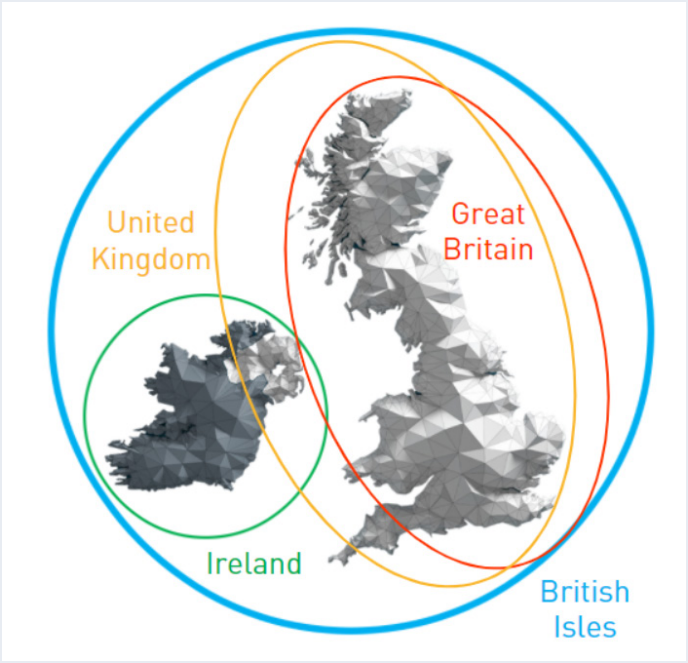
B IMPACT EXAMPLES

If you are an organisation bringing goods from outside the UK and placing them on the market in Great Britain, you will now be an 'importer' and carry more compliance responsibilities.
Importers will need to make sure:

- The manufacturer has drawn up the correct technical documentation and complied with their labelling requirements;
- Products are labelled with your company's details, including your company's name and a contact address (in this case of the UKCA, until December 31st, 2022, you can provide these details on the accompanying documentation rather than on the product itself);
- The correct conformity assessment procedures have been carried out, and products have the correct conformity markings;
- A copy of the declaration of conformity is maintained for 10 years (more for MD and IVDMD);
- Products conform with the relevant essential requirements.

A separate Declaration of Conformity is needed for both CE marking and UKCA, so manufacturers need to be aware that additional paperwork is required. The UK Declaration of Conformity must reference the UK Regulations and the UK Designated Standard versions of British standards, where they exist.

Northern Ireland will remain subject to CE marking under European regulations. Any CE marked product can be sold in Northern Ireland. Products for sale in both Great Britain and the European Union that carry both CE marking and UKCA marking do not need the additional UKNI mark.



Authorised representatives and responsible persons based in the European Union will no longer be recognised in Great Britain from January 1st, 2023. Manufacturers will require an importer or UK Authorised Representative / Responsible Person (UKRP) based in the UK for products being placed on the GB market. They must be identified on the label/packaging.

The UKRP or authorised representative has been defined as a person established in any part of the United Kingdom who acts on behalf of a manufacturer established outside the United Kingdom in relation to specified tasks with regard to the manufacturer's obligations under these regulations.

Conclusion

UK regulations are likely to evolve over the next few years and will require both UK Approved Bodies and manufacturers to consider new requirements not yet established. The engagement of manufacturers ahead of the deadlines proposed by the UK authorities seems to be a necessity.

Concerning medical devices, the MHRA has plans for a new regime for regulating medical devices in the UK and the reforms contemplated by the MHRA are wide ranging. On 16th September 2021, the MHRA published its open consultation on the future regulation of medical devices in the United Kingdom. The consultation sets out the possible areas of reform, many of which will align with the European Regulations and international standards. Alongside the consultation, the MHRA announced its intention to address regulations applying to software and artificial intelligence (AI) as a medical device in the form of an extensive work program.

LNE-GMED UK will support the MHRA and other stakeholders to help shape the future of UK legislation.

Going the extra mile

SOLUTIONS BROUGHT BY LNE GROUP

The LNE group is expanding its certification activities in the UK by setting up a new subsidiary.

LNE-GMED UK will be the future certification body for medical devices, construction products, measuring instruments and products emitting noise outside buildings.

To support manufacturers, for whom the UK is a significant market, LNE, through its subsidiary GMED, is working to obtain UK Approved Body status through a new entity called LNE-GMED UK, based near London. The creation of LNE-GMED UK strengthens LNE's and GMED's position as an international certification body.

This will mean that manufacturers will be able to simultaneously apply to LNE group for both UKCA marking and CE marking, should they require it.

FOR MORE INFORMATION

→ CONTACT US

STATUS OF DESIGNATION & ACCREDITATION

LNE-GMED UK Ltd built its Quality Management System to meet the requirements of ISO 17021-1 and ISO 17065. Its application to UKAS has been processed for the following scope of accreditation:

- ISO 13485 Medical Devices;
- Measuring Instruments;
- Non-Automatic Weighing Instruments (NAWI);
- Construction Products Regulation (CPR);
- Noise emission in the environment by equipment for use outdoors.

LNE-GMED UK's teams are also working with the MHRA in parallel with the above and finalizing an application for designation as a UK Approved Body for UKCA marking services for Medical Devices, Active Implantable Medical Devices and In Vitro Diagnostic Medical Devices.

LNE-GMED UK will accept applications for certification upon accreditation and designation.

Now is the time to speak to LNE-GMED UK about how your product's conformity processes will be affected. Manufacturers may need to take additional action if the product needs third-party conformity assessment, such as Approved Body review of Technical Documentation, Type Examination, or factory production control audits. Manufacturers should start preparations accordingly, to account for possible delays and allow enough time to address and rectify any potential issues during the conformity assessment process.

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