Overview of UK regulations for medical devices

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Introduction

Following the end of the Brexit transition period, the EU Medical Devices Regulation (MDR), EU 2017/745, and In Vitro Diagnostic Medical Devices Regulation (IVDR), EU 2017/746, were not transposed into law in Great Britain. In this context, it is important to be aware of the distinction between Great Britain – England, Scotland and Wales – and the United Kingdom (UK), which comprises Great Britain and Northern Ireland. The MDR and IVDR will not be implemented in England, Scotland and Wales. Northern Ireland has a special status as EU rules will continue to apply there.

The UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended) implement the Directives for active implantable medical devices, medical devices and in vitro diagnostic medical devices (IVDs) in the UK. These regulations continue to have effect in Great Britain. These regulations have undergone several amendments since they came into effect in 2002. Amendments were incorporated to implement into UK law changes that were made in the European Directives. In addition, further amendments were added to make the regulations effective in the UK following Brexit by cutting the links with European Institutions. However, an official, consolidated text incorporating all the amendments has not yet been made available publicly.

The UK Medicines and Healthcare products Regulatory Agency (MHRA) have started the process to update the UK regulations (see below) and indicated that they will continue to recognize European CE marking until 30 June 2023. The UK Trade Association for healthcare industries have asked for a postponement of this date but there is currently no indication that there will be a delay.

Registration of devices

Manufacturers placing products on the UK market are required to register with the MHRA. MHRA has published guidance on registration requirements. An on-line system for registering devices has been set up (MHRA DORS). Registration requires information to be provided on the manufacturer, the device(s) and UK Responsible Person (see below).

Manufacturers of Class I medical devices, IVDs and custom-made devices and that are either based in the UK or whose Authorized Representatives are based in Northern Ireland were required to register their devices with the MHRA prior to 1 January 2021. That requirement continues.

Deadlines for registration certain classes of medical devices that have now passed were:

- 1 May 2021 for active implantable medical devices, Class III medical devices, Class IIb implantable medical devices and IVD List A devices;
- 1 September 2021 for Class IIb non-implantable medical devices, Class IIa medical devices, IVD List B devices, self-test IVDs.

For Class I medical devices and general IVDs from manufacturers or Authorized Representatives that are not based in the UK, the registration deadline is 1 January 2022.

UK responsible person

Manufacturers based outside the UK that are placing products on the market in Great Britain, need to appoint a person with a registered place of business in the UK as their UK responsible person. Most manufacturers based outside the UK that are placing products on the market in Northern Ireland will also need to appoint a UK responsible person. The exceptions are manufacturers based outside the UK that:

- have an EU Authorised Representative is based in Northern Ireland, or
- only intend to place a Class I medical device, custom-made medical device or general IVD on the Northern Ireland market and the device(s) has(ve) been registered with an EU Competent Authority.

MHRA will only accept device registrations from manufacturers based outside the UK with UK Responsible Persons or from EU Authorized Representatives based in Northern Ireland.

The UK responsible person acts on behalf of a manufacturer based outside the UK to carry out specific tasks that the manufacturer has to fulfil. The UK responsible person:

- registers devices with MHRA;
- ensures that a declaration of conformity has been drawn up and keeps it available for inspection by MHRA;
- ensures that the technical documentation has been drawn up and keeps a copy of this documentation available for inspection by MHRA;
- if applicable, ensures that appropriate conformity assessment has been carried out and keeps a copy of any conformity assessment certificate available for inspection by MHRA;
- provides MHRA on request with:
    - information or documentation, to demonstrate conformity of a device; or,
    - samples of devices or access to devices;
- cooperates with MHRA on actions to eliminate or mitigate risks posed by devices;
- informs the manufacturer about reports or complaints about suspected incidents associated with the devices for which they have been appointed.

If the manufacturer acts contrary to their obligations under the UK regulations, the UK responsible person has to terminate their relationship with the manufacturer and inform the MHRA and any UK approved body (see below) that the relationship has been terminated.

UK CA mark

The UK Conformity Assessment (UKCA) mark is being introduced for certain goods being placed on the market in Great Britain for which European CE marking applied. The UKCA mark will apply to medical devices, including IVDs, in Great Britain. The UKCA mark is not recognised in other jurisdictions, including in the European Union (EU) or European Economic Area (EEA).

Manufacturers of medical devices can use the UKCA mark voluntarily until 30 June 2023. From 1 July 2023, a UKCA mark will be required to place a device on the Great Britain market. Manufacturers of Class I device and general IVDs can self-certify against the UKCA mark. Higher-risk medical devices and IVDs will require a UKCA certificate from a UK Approved Body to affix the UKCA mark.

If the UKCA mark has been affixed, manufacturers based outside the UK need to include the name and address of the UK Responsible Person in either the label on the product or the instructions for use. UK Responsible Person details do not need to be included on label for CE marked devices placed on the market in the UK.

UK approved bodies

MHRA can designate organizations to conduct conformity assessments against requirements of the UK regulations to support the UK CA mark. UK organizations that were designated as European notified bodies under the European Directives for medical devices have had their designations rolled over to UK approved bodies without having to undergo a new designation process.

A UK database has been set up to list the UK approved bodies and the approved bodies for medical devices are listed. It is important to be aware of scope for which the body is approved, as not all the approved bodies have a scope covering all medical devices. The scope of each approved body is also listed in the database.

UK designated standards

The UK Medical Devices Regulations have a role for standards to support the regulatory requirements. This role parallels the status of harmonized European standards in demonstrating conformity. Devices in conformity with relevant harmonised standards cited in the Official Journal of the European Union, or applicable parts of standards, are presumed to be in conformity with the regulatory requirements covered by those standards. Additionally, the presumption of conformity has also been accepted for system or process requirements, including those requirements relating to quality management systems and risk management. With the UK leaving the EU, the link with the publication of the list of harmonised standards published in the Official Journal has been cut. As a result, the UK has published its own list of standards that support UK regulation. These have been termed 'designated standards'.

Three lists of designated standards for medical devices have been published on the UK Government website. These lists of standards apply to:

- Medical devices;
- Active implantable medical devices;
- In vitro diagnostic Medical devices.

The initial lists of UK designated standards reproduced the lists of harmonized standards in the Official Journal of the European Union for the respective Directives for medical devices. To date, these lists have not been updated. Therefore, the lists of UK designated standards do not include:

- the additional standards harmonized in Europe that were added by three Commission Implementing Decisions for harmonized standards adopted in April 2021 and published in the Official Journal; or,
- the first standards to be harmonized under the European MDR and IVDR.

The process by which the lists of designated standards will be maintained has not yet been made available publicly. The designation of standards is applicable to a wide range of products and not only medical devices, and so the process is being developed and finalised in discussions between the British Standards Institution and the relevant government departments.

Harmonised European standards under the Directives for medical devices include a European Foreword and an Annex that describe the relationship between the requirements of the standard and the regulatory requirements in the Directives that are applicable to the scope of that standard. The European annex to the standard is described as an Annex Z. The Annex Z can be designated ZA, ZB, ZC or ZZ, depending on the number of Directives that are applicable to the standard and the European standards organization that has adopted the standard.

As the UK Regulations currently mirror the requirements in the EU Directives for medical devices, these Annex Zs for the Directives currently also link the requirements of the standard with the requirements of the UK Regulations. However, this linkage does not apply to standards with an Annex Z showing the relationship with the new European MDR or IVDR.

Two recently published standards, BS EN ISO 13485:2016/A11:2021[1] and BS EN ISO 15223-1:2021[2], have included European Annex Zs to the European Regulations but not the Directives. A UK national Annex, designated Annex NZ, has been added to each of these standards showing the relationship between the standard and the UK regulations.

[1] Medical devices - Quality management systems - Requirements for regulatory purposes
[2] Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

Northern Ireland

The Northern Ireland Protocol is a key part of the agreement on the UK withdrawal from the European Union. The effect of the Northern Ireland Protocol is that products on the Northern Ireland market, including medical devices, are required to comply with EU Regulations and Directives as well as with UK law. Separate requirements regarding CE marking will apply in Northern Ireland. Where CE marking requires the involvement of a notified body, certification has to be done by an EU-based notified body. Under the Northern Ireland Protocol, any product moving from or through Great Britain to Northern Ireland is considered an import into the EU. As a result, a retailer or wholesaler can be considered an importer for Northern Ireland as opposed to a distributor of products. . If conformity assessment against the EU Regulations or Directives is undertaken by a UK Approved Body, then manufacturers also has to apply the 'UKNI' mark along with the CE mark. Products bearing the CE and UKNI marks can be placed on the Northern Ireland market, but cannot be further circulated into the European Union.

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Future changes in UK regulations

The Medicines and Medical Devices Act 2021 is enabling legislation with the stated overarching objective of safeguarding public health. It:

- creates a Commissioner for Patient Safety in relation to human medicines and medical devices;
- provides the authority to amend or supplement the law for human medicines, veterinary medicines and medical devices; and,
- makes provisions for enforcing regulations, and the protecting health and safety, in relation to medical devices;

The Act indicates that any new regulations for medical devices should consider the following factors:

- the safety of medical devices
- the availability of medical devices
- the likelihood of the UK being seen as a favourable place in which to:
  - carry out research relating to medical devices,
  - develop medical devices,
  - manufacture medical devices, or
  - supply medical devices.

The MHRA are looking at ways to update the UK regulations on placing medical devices on the UK market. The MHRA launched a consultation exercise to get input on potential changes to the regulatory regime from patients, medical device researchers, developers, manufacturers and suppliers, clinicians, other healthcare professionals and the wider public. This consultation exercise set out proposals for a future UK-wide regime to regulate medical devices. In Northern Ireland, such a regime could run in parallel with any existing or future EU rules in accordance with the Northern Ireland Protocol. The consultation was published on 16 September 2021 and closed on 25 November 2021.

The MHRA have indicated that they plan to introduce the new regulatory regime at the beginning of July 2023. This aligns with the date from which the UK is due to stop accepting CE marking for medical devices in Great Britain and will require the use of the UKCA mark.

Actions

Manufacturers based outside the UK that are placing medical devices onto the UK market should have appointed a UK responsible person.

Manufacturers or Authorized Representatives for Class I medical devices and general IVDs that are not based in the UK have until 1 January 2022 to register with MHRA. The manufacturer or UK responsible person of other classes of devices should have registered them.

Manufacturers and UK responsible persons should develop plans for implementing the UKCA mark for their devices. In developing their plans, they should consider:

- the need for a UK approved body to perform conformity assessment;
- availability of UK approved bodies with an applicable scope for conformity assessment of their devices;
- the timescales for UK approved bodies to perform their conformity assessment sand provide any necessary certification;
- the development of new regulatory requirements for the UK;
- any transition provisions for the new UK regulatory requirements;
- the stated deadline for the end of acceptance of CE marking in the UK.

Author

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