SmartHealth Healthcare Regulatory Affairs

Update surrounding the transition from the Medical Devices Directive (MDD) to the Medical Devices Regulation (MDR) for CE Marking

Definition

A medical device is an instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for medical purposes:

– diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,

– diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,

– investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,

– providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, And

– which does not achieve its principal intended action by pharmacological, immunological or metabolic means.

The following products shall also be deemed to be medical devices:

– devices for the control or support of conception.

– products specifically intended for the cleaning, disinfection or sterilisation of devices

– accessories for medical devices, and products listed in Annex XVI (contact lenses, liposuction)

Introduction to the CE Mark:

Medical devices within the EU are currently regulated by the following Directives:

• Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (hereafter referred to as AIMDD)

• Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (hereafter referred to as MDD)

• Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (hereafter referred to as IVDD)

In order to lawfully place on the EU market medical devices under the scope of the Directives or the new Regulations, as well as personal protective equipment under the scope of the PPER, these products must be CE-marked with the EC or EU declaration of conformity signed and issued by the manufacturer.

Ultimately, achieving a CE mark is giving you access to the European Union, which comprises 27 countries and over 500 million people.

10 steps to achieving a CE Mark

1. Determine Intended Purpose
2. Determine Classification
3. Determine Conformity Assessment Route
4. Comply with Conformity Requirements i.e Quality Management System (QMS) and Technical Documentation
5. Appoint a Person Responsible for Regulatory Compliance
6. Undertake Assessment by a Notified Body
7. Prepare and sign Declaration of Conformity
8. Obtain Quality Management System (QMS) and CE certificate
9. Place CE marking on Device
10. Undertake Post Market Surveillance & Ongoing Assessments

There are 4 Classification categories for Medical Devices: I, IIa, IIb, III, as show below in Figure 1.

Class I has three "subclasses" (Is, Im, Ir) symbolising sterile, measuring and re-usable equipment respectively.

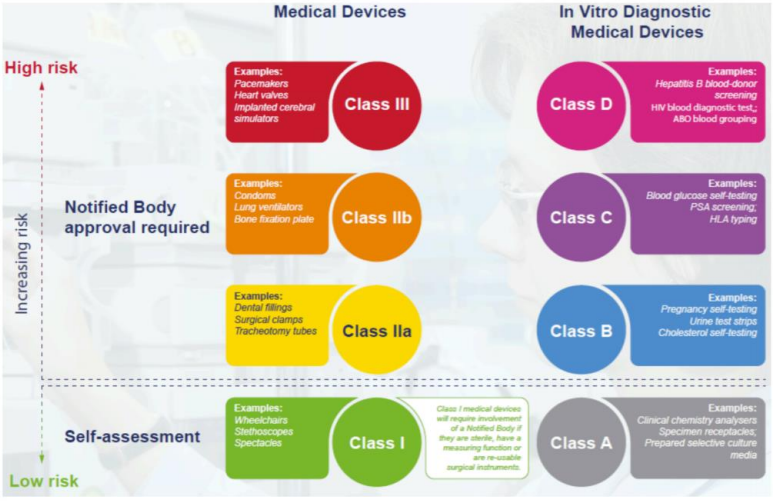

Figure 1: Overview of Medical Device and In Vitro Diagnostic Medical Devices Classifications. Source: MHRA

Intended Purpose

An intended purpose is determined by what the manufacturer states in the device's labelling, instructions for use and any promotional materials. Examples of promotional materials include:

- Adverts
- App store description and category
- The landing page
- The manufacturer's social media channels

Tips:

- Care should be taken with the description of what the software is intended to be used for. Simple changes to the description make the difference between a product being considered a medical device or not.
- A number of apps have a disclaimer saying "for information only" or "for research use only" or other statements that try and reduce the responsibilities of the manufacturer. However, if an app qualifies as a medical device and is placed on the market for a medical purpose will still need to comply with the relevant directive.
- General disclaimers (for example 'this product is not a medical device') are not acceptable if medical claims are made or implied elsewhere in the product labelling or associated promotional literature.
- Anecdotal quotes and testimonials are considered to be implied claims by the manufacturer if they are repeated in product literature.

• Use of a product for a medical purpose does not make it a medical device

A medical device should be used as intended by the manufacturer and described in the instructions for use. If a device is used in any other way, this is considered 'off label' use. Off-label use of a device could entail serious risks. When it is deemed necessary to use an existing medical device for a purpose or in a way that is different from that intended by the manufacturer, risks and benefits to the patient must be carefully assessed. The assessment may typically include steps or factors such as:

- a documented risk assessment on the use of the device
- consideration of ethical and legal implications
- implementation of suitable precautions to minimise the risk
- reviewing the risk assessment at suitable periods
- obtaining approval from the national competent authorities when required.

MDR (Medical Device Regulation)

The MDR was Published in 2017 and was initially scheduled to come into force on 26th May 2020 to replace the MDD (Medical Device Directive) 93/42/EEC.
Please find here the link to the MDR: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02017R0745-20170505&from=EN

Transition from MDD to MDR

Here are 9 noteworthy changes arising from the MDR regarding Medical Devices in comparison to the previous MDD:

1. Additional rules and up classification
2. More emphasis on Software and Risk
3. Essential Requirement -> General Safety and Performance Requirements
4. No grand fathering of devices
5. Substantial equivalence route mostly closed
6. Will require own generated clinical evidence
7. Every medical device manufacturer to have Person Responsible for Regulatory Compliance
8. Will require updated and upgraded technical files
9. Upgraded labels and EUDAMED (European Database on Medical Devices) requirements

Impact of Brexit on MDR

There will be a Transition Period until at least 31 December 2020. During the transition period, EU rules and regulations (MDD & MDR) continue to apply to the UK. Medical devices with a UK notified body (UK CE mark), UK legal representative or manufacturer can continue to be distributed across the EU and UK. At the end of the transition period the UK will revert to the status of third country.

After the Transition Period, manufacturers located in the UK will require an Authorised Rep in EU-27. Manufacturers with UK Notified Bodies should recognise that UK-based Notified Bodies will no longer

be recognised by the EU. Therefore, manufacturers must transfer their files to a Notified Body located within the EU-27. Similarly, manufacturers with EU authorised representatives based in UK will no longer be recognised so should be transferred to a UE-27 authorised representative. Manufacturers exporting to UK require a UK Representative and the CE mark remains recognised.

Impact of COVID-19 on MDR

The European Commission announced that on the 17th April they approved a proposal to postpone the date of application for the Medical Device Regulation (MDR) for one year (until 26 May 2021).

This measure aims to avoid shortages of medical devices during the ongoing COVID-19 pandemic due to the limited capacity of national competent authorities or notified bodies to implement the Regulation.

Useful Links

List of notified bodies for the AIMDD:
https://ec.europa.eu/growth/toolsdatabases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=8

List of notified bodies for the MDD:
https://ec.europa.eu/growth/toolsdatabases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=13

List of notified bodies for the IVDD:
https://ec.europa.eu/growth/toolsdatabases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=20

List of notified bodies for the MDR:
https://ec.europa.eu/growth/toolsdatabases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=34

List of notified bodies for the IVDR:
https://ec.europa.eu/growth/toolsdatabases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=35

European Commission's Latest Highlights and Guidance Reports:
https://ec.europa.eu/growth/sectors/medical-devices_en

MHRA'S CE Mark classifications and routes explained further:
https://www.gov.uk/guidance/medical-devices-conformity-assessment-and-the-ce-mark

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