Medical Device Regulation HSENPSA 002/2023
Supplementary Information

Date of Issue 16 October 2023

1. Background

This information provides an overview of the existing processes and regulations in place at both EU and national level, to further strengthen awareness for the safe use of medical devices within healthcare organisations.

A medical device is a product, piece of equipment or system that is intended by its manufacturer to be used for a medical purpose to treat, diagnose, or manage illness, injuries, or other health issues.
The term 'medical devices' represents a broad range of medical technologies from simple plasters, surgical equipment, and diagnostic equipment to permanent implants. In addition, certain software and information systems which have a diagnostic, predictive or treatment-planning function are often medical devices.

Medical devices act primarily in a physical manner, rather than through pharmacological means (although sometimes their overall action is assisted pharmacologically).

2. Overview of EU regulatory framework for Medical Devices

Medical Devices within the EU are subject to regulation under the Medical Devices Regulation (MDR) (EU) 2017/745[1], which came into effect in Ireland on May 26th 2021. A medical device 'CE marking of conformity' or 'CE marking' is a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in the MDR.

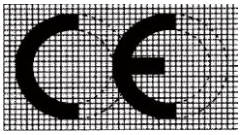
The essential objective of a conformity assessment procedure is to provide assurance to the public, healthcare professionals, health systems and public authorities that products placed on the market meet the general safety and performance requirements of the Regulation, to ensure the health and safety of users and consumers. While CE marks may be found on other products, such as electrical goods and toys, the CE mark on a medical device indicates that it meets the requirements of the medical device regulation.

At national level, medical device regulation is further upheld by the Health Products Regulatory Authority (HPRA) as the regulator of medical devices in Ireland. A medical device intended to be placed on the market or put into service in Ireland must bear the CE mark to indicate that it meets the safety and performance requirements of the MDR and can be sold and supplied appropriately.

[1] Medical Device Regulation (MDR), (EU) 2017/745 and HSE Medical Devices Regulation information website

Note: Prior to May 2021, medical devices were regulated under the Medical Devices Directive 93/42/EEC and the Active Implantable Medical Devices Directive 90/385/EEC and specific provisions relating to devices/procedures under this regulatory framework are outside of the scope of this supplementary information. *In Vitro* Diagnostics are also outside scope as they are regulated under Regulation (EU) 2017/746

Under the MDR, most medical devices require assessment and certification to indicate that they conform to these requirements. Assessment and certification activities for medical devices are undertaken by independent certification organisations called notified bodies. Once a notified body issues a certificate for a medical device, the manufacturer can affix the CE mark and the device can be made available across Europe, without a specific national notification or authorisation. Notified bodies are appointed to assess specific types of medical device technologies based on their expertise and competence[2]. It is also important to note that a manufacturer can select any EU notified body with the requisite competence to certify its device. A medical device CE mark has a four-digit number accompanying it to indicate the specific notified body that assessed and certified it, when applicable, see Fig. 1.



0000

Fig 1: *CE mark for a device where a notified body* is involved *in the assessment of the device*

Under the MDR, certain low-risk (Class 1) medical devices do not require assessment by a notified body, and as such there is no four-digit notified body number accompanying the CE mark on these devices, as outlined in Fig. 2.

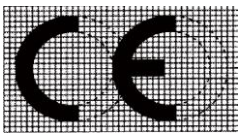


Fig 2: *CE mark for a device where a notified body* is not involved *in the assessment of the device*

3. CE marking exemptions under the MDR

There are a number of exemptions outlined in the Regulation in relation to CE marking: -

3.1 Medical Devices under development that do not yet have a CE Mark

When a medical device is in development and does not yet have a CE mark, there are two exceptional circumstances under which it can be used. These exceptional circumstances are clinical research and compassionate use. In both instances, the device is intended by its manufacturer to be a medical device, and an application to the relevant Competent Authority (the HPRA in Ireland) for authorisation for use is required.

Clinical research: As part of the development process for medium and high-risk medical devices, a manufacturer is obliged to conduct a clinical investigation (akin to a clinical trial). Clinical investigations are required to determine the clinical safety and performance of the medical device and to demonstrate that the device meets the General Safety and Performance Requirements (GSPR) of the MDR. Applications are made following completion by the manufacturer of a range of technical, pre-clinical, and biocompatibility/safety testing. In certain instances, device manufacturers may also need to conduct clinical investigations on lower risk devices in development.

[2] List of EU medical device notified bodies

Prior to a clinical investigation commencing in Ireland, it must be authorised by the HPRA and separately by the National Research Ethics Committee (NREC) and fulfil any relevant institutional requirements. This requires submission of individual applications to the HPRA and the NREC. Such applications are typically received from medical device manufacturers as the sponsor of the study, as they are developing a medical device as part of a development process and are compiling the relevant data to seek a subsequent CE certification from a notified body.

Clinical investigation applications to the HPRA detail the pre-clinical, technical and any clinical testing that has been completed up to the point of application. The applications also describe the medical device, the investigational protocol, investigation design, information on use, and the various risk mitigations that the manufacturer has introduced to minimise risks to participants.

Clinical investigation applications may also be received directly from clinicians or other academic developers. In such instances, the relevant health institution or academic research centre acts as the sponsor of the study. It is important to have the support of the relevant medical device manufacturer to ensure access to the various technical documents required as outlined above.

In either case, the HPRA assesses the application and if the information is deemed satisfactory, may issue an authorisation for its use. This authorisation will have associated conditions, including the obligation on applicants to report to the HPRA, serious adverse events occurring during the course of the investigation. Further information on clinical investigations for medical devices, including pre-submission meetings which the HPRA offers, is available on the HPRA website.

Compassionate use: The HPRA has legal provision to authorise the making available in Ireland of medical devices in exceptional circumstances when it is deemed to be in the interest of public health or patient safety. These applications typically relate to use of a single device on an individual named patient basis in instances where the clinician believes that use of the non-CE marked device is in the best interest of that patient. For example, a cardiologist may be aware of a US FDA-approved medical device used appropriately in clinical practice in the US that is not available in Europe and may consider it necessary to request use of the device in a specific patient under their care.

An application must be made to the HPRA from both the clinician (to explain the rationale for clinical use and lack of available CE marked alternatives and why alternative therapeutic options are not suitable) and from the manufacturer (to provide information on the relevant technical, pre-clinical, clinical testing etc. and information on any certification or authorisation outside of Europe).

The HPRA assesses this information and, if deemed satisfactory, may issue an authorisation for its use. This authorisation will have associated conditions, including the obligation on applicants to report serious adverse events arising from use of the device to the HPRA.

Further information on the Compassionate Use application process is available on the HPRA website.

3.2 Devices that do not require a physical CE Mark to be present on the label or on the device itself.

Custom-made medical devices: Sometimes, medical devices may be manufactured to an individual patient's needs, for example orthotics or dental devices. These devices are specifically made in accordance with a written prescription for an individual patient provided to the manufacturer who then produces the custom-made device. These medical devices do not need a CE mark on their labelling as they are for an individual patient, but they must undergo assessment under the MDR, including quality system certification by a notified body for the highest risk devices.

In-house manufactured medical devices: The MDR sets out specific conditions and obligations for health institutions manufacturing and using medical devices in-house. There is no requirement to place a CE mark on the labelling of in-house devices, however strict conditions apply to both the device and the health institution including that the General Safety and Performance Requirements (GSPR) set out in the MDR must be met.

4. The HPRA's role as the regulator of medical devices

The HPRA is the regulator of medical devices in Ireland. Its primary role is as a market surveillance authority to monitor the safety and performance of medical devices once they are placed on the market. The HPRA operates a vigilance reporting system to receive reports of adverse incidents which have occurred that are potentially attributable or associated with use of a medical device (this includes reports where incidents could have occurred but were avoided). If such an incident occurs, it should be reported by the healthcare professional or user to the manufacturer of the medical device. The HPRA strongly encourages healthcare professionals to also report such events to them directly, reports can be submitted to the HPRA using the online form. Assessment of these reported incidents by the manufacturer and the HPRA's evaluation determines if any corrective action is needed to improve the safety of the device and prevent recurrence of the event. Incident reports also help target the HPRA's market surveillance activities. In addition to review of applications for clinical investigations, and compassionate use, as outlined above, the HPRA has other roles including appointment and supervision of notified bodies.

The HPRA is available to discuss applications for clinical investigations, or compassionate use with potential applicants or indeed to provide advice on other medical device regulatory issues. The HPRA can be contacted at devices@hpra.ie and further information/contact details are available on hpra.ie.