HSE National Patient Safety Alert (NPSA)

Date of issue 16 October 2023 *Unique ID* HSENPSA 002/2023

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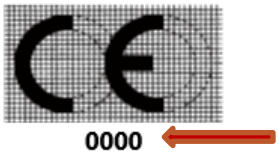
Medical Device Regulation and CE Marking

WHO needs to take action?

Hospital Group Chief Executive Officers
Community Healthcare Organisation Chief Officers
Procurement Leads/Store Managers
Capital & Estate Managers
Biomedical/Clinical Engineers
Senior Accountable Officers
All Clinical Staff
Medical Device Committees
Decontamination Staff

WHAT is the safety issue?

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. Medical devices also include certain software used for diagnosis, prediction, or treatment planning. Within the EU, medical devices are regulated under the Medical Device Regulation (MDR) (EU) 2017/745 which came into effect in Ireland on May 26th 2021*. Medical device regulation is further upheld by the Health Products Regulatory Authority (HPRA). A medical device intended to be used in HSE/HSE funded services must be CE marked to indicate that it meets regulatory safety and performance requirements**. CE certificates are issued by independent certification organisations called notified bodies.



'Notified Body' four-digit identification number ***

Please note: Exemptions apply (see supplement**).
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: clinical research or compassionate use. In both instances, an application to the HPRA for authorisation for use of the medical device is required.

HOW to take action?

1. **Disseminate** this alert to all staff involved in ordering, procurement, management, or the clinical use of medical devices in your service.
2. **Undertake** a local risk assessment (see appendix) and implement required improvement actions to provide assurance that regulatory requirements concerning medical devices are being met in your service. This should examine:
   - Staff awareness of the EU MDR relevant to their role.
   - Staff awareness that medical devices intended to be used in HSE/HSE funded services must be CE marked** (noting exemptions described in supplement).
   - That mandatory requirements for CE marking of medical devices is included in all health tenders.
   - Staff understanding of the role of the HPRA as regulator of medical devices.
   - That any non-compliant medical device identified is reported to the HPRA.
3. **Contact** the HPRA (devices@hpra.ie) to apply for authorisation of use if your service is seeking to use a medical device that is not yet CE marked, for clinical research or compassionate purposes.
4. **Report** any incident/near miss related to medical devices onto the National Incident Management System (NIMS), to the device manufacturer and the HPRA.

WHEN does action need to be completed?

Action 1 should be completed by 31st October 2023.
Action 2 should be completed by 29th January 2024.
Actions 3-4 are not time bound and apply as part of required organisational practice.

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Why is this action required?

This action is required to reinforce the existing processes and regulations in place at both EU and national level. This will further strengthen awareness for the safe use of medical devices within the HSE/HSE funded services. The actions undertaken will help give assurance to the HSE and to those that use our services that medical devices in use within the HSE and its funded services are operating under the appropriate regulations.

A CE mark on a medical device indicates that it conforms to EU medical device regulation. While CE marks may be found on other products (e.g. electrical goods, toys), the CE mark on a medical device indicates that it meets the specific requirements of the medical device regulation (MDR). A medical device CE mark has a **four-digit number***** below it to indicate the specific notified body that assessed and certified it.

Further information is available in the Medical Device Regulation HSENPSA 002/2023 Supplementary Information

What else do I need to do?

If new techniques and/or technologies are being considered, healthcare staff must adhere to their local governance requirements in this regard. Guidance should also be sought from the respective professional bodies.

If a HPRA authorised, but non-CE marked medical device is being considered for use (for clinical research or compassionate use), it is essential that informed consent for its use is obtained from the patient/service user involved.

All incidents/near misses related to the use of a medical device must be managed as per the HSE's Incident Management Framework and reported onto NIMS and to the manufacturer of the medical device. The HPRA also operates a vigilance reporting system to receive reports of adverse incidents or near misses. Reports can be submitted to the HPRA using the online form.

As per the HSE's Open Disclosure Policy any medical device related incident or near miss should also be disclosed to the patient/service user involved, in particular where there was harm.

What evidence supports the issuing of this HSE NPSA?

- Medical Device Regulation (EU) 2017/745
- HSE Medical Device Regulatory Information
- HSE Medical Device Equipment Management Policy
- HSE Medical Device Equipment Management Best Practice, Guidance for Service Areas

What stakeholders were involved in issuing this HSE NPSA?

This alert has been developed collaboratively by the:

- HSE National Quality and Patient Safety Directorate, Office of the Chief Clinical Officer
- Health Products Regulatory Authority
- HSE Acute Operations
- HSE Procurement
- HSE Capital and Estates, National Medical Devices Office
- HSE Clinical Programme in Surgery
- HSE National Patient Safety Alerts Committee

Where can I get further information?

For any queries on the HPRA please see hpra.ie or contact devices@hpra.ie

For queries on this or any HSE NPSA in general please email patientsafetytogether@hse.ie

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Appendix

In the context of this alert a risk assessment will take a measured approach to identifying any issues or practices that may indicate non-compliance with the MDR and CE marking requirements in effect in Ireland since May 26th 2021*, which could lead to harm. It will consider key priorities/proportionate response to risks.

Instead of specifying the exact detail of the assessment requirements in this alert, an organisation should determine what meaningful assurances are required, in particular in relation to the points listed in the actions section of this alert. This will require each organisation to identify and to implement required measures using an investigative approach to confidently determine compliance/assurance.

This requires:

- Review of local governance process (policy, risk management processes, Medical Devices Committee, etc.)
- Staff knowledge assessment/training needs assessment relating to the regulatory requirements relevant to their role
- Review of tender/procurement process
- Audit/spot-check audit of medical devices regarding the CE marking requirement
- Focus on high-risk areas/medical devices/services
- Audit of the reporting rates and management of medical device incidents and near misses
- Services to consider developing or adopting new safety initiatives e.g. safety prompts to help prevent harmful incidents
- Other necessary measures as determined by the organisation

Any risk assessment should be documented and feed into the organisation's compliance, vigilance and quality and safety agenda. Identified issues or risks must be mitigated against and improvement actions implemented.

Further guidance on how to undertake a risk assessment is available in the HSE Risk Management Policy

**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*

***Some specific categories of medical devices are not required to bear a CE mark; however, they are required to meet regulatory requirements as set out in the MDR. Such circumstances relate in particular to custom-made medical devices and in-house manufactured medical devices as well as those exemptions where an application to the HPRA needs to be made (for clinical research and for compassionate use). For further detail see Medical Device Regulation HSENPSA 002/2023 Supplementary Information.*

****A notified body four-digit identification number will not be present on some medical devices such as low-risk (certain Class 1) devices.*