HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Verifying Device Compliance Information for Entities Sourcing and Using CE Marked Medical Devices and IVDs

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This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

1 BACKGROUND

The Health Products Regulatory Authority (HPRA) is the national competent authority responsible for the application of the Regulations for medical devices and *in vitro* diagnostics (IVDs) (i.e. the MDR and the IVDR).

The purpose of this guide is to provide practical information on how to verify the compliance of CE-marked devices before they are used. In certain scenarios, devices may not be CE marked. For more information about the alternative routes for using devices, visit the HPRA webpage on using medical devices and IVDs in Ireland. For the purpose of this guide, the term 'devices' refers to **both** medical devices as defined under MDR Article 2(1) and IVDs as defined under IVDR Article 2(2).

This guide is intended for any entity that sources devices, including public and private hospitals, laboratories, pharmacists, healthcare professionals or any other person who uses or administers devices. Entities that source and use devices have additional responsibilities, such as the reporting of safety issues.

This guide is not intended for economic operators such as device distributors or importers.

It is important for entities to verify the compliance of medical devices and IVDs so that only compliant devices are used on patients or their samples for diagnostic and therapeutic purposes. Compliance verification checks help ensure devices are safe and perform as intended.

This guide outlines some of the key checks entities should conduct. It explains the importance of each verification check and how to carry them out in practice.

2 SUMMARY

Table 1 below summarises the checks we encourage entities to consider when sourcing devices for use to verify their compliance.

This is a non-exhaustive list. Please consider this table in combination with the written text in this guide.

Table 1. Summary of recommended compliance verification checks

Check item	Why check?	How to check?
CE mark	Indicates a device is in conformity with applicable requirements.	Physical check at goods in/receipt.
Declaration of conformity	Formal statement of compliance. Contains device and manufacturer info.	Request electronic copy for each device. Ensure correct DoC is obtained.
Internal procedures	Ensures correct storage, handling, and management.	Check for compatibility issues, appropriate facilities, and compliance with manufacturer instructions/risk assessments.
UDI traceability system **(Hospitals only)**	Enhances traceability (e.g. in the event of product recalls).	Keep electronic record of UDI information. Requirement for Class III implants.
Implant card information **(Hospitals only)**	Allows patients to identify care needs and informs emergency staff of such.	Physical check at receipt and confirm fields are filled in post-implantation.

2.1 Application of verification checks to legacy devices

The MDR and IVDR became fully applicable in 2021 and 2022, respectively.

The MDR replaced the Medical Devices Directive (MDD 93/42/EEC) and Active Implantable Medical Devices Directive (AIMDD 90/385/EEC), while the IVDR replaced the *In Vitro* Diagnostic Medical Devices Directive (IVDD 98/79/EC).

A legacy device is a device certified under the previous Directives. Manufacturers of legacy devices can continue to place these devices on the market if they meet certain criteria linked to specific deadlines. More information on this topic is available on the HPRA MDR transitional provisions webpage and IVDR transitional provisions webpage.

The checks outlined within this guide apply to legacy devices, except for UDI and implant card checks. UDI and implant card requirements do not apply to legacy devices.

3 COMPLIANCE VERIFICATION CHECKS

3.1 Identifying a compliance concern

If a compliance concern is identified following the completion of the checks outlined in this guidance document, the following steps are recommended:

- Contact the manufacturer or authorised representative (if applicable) to request further information.
- Do not source or use the device if possible until the concern is resolved.
- If the concern cannot be resolved, email the HPRA at devices@hpra.ie.

3.2 CE mark

In most cases, medical devices and IVDs must be CE-marked before they can be placed on the EU market and used in hospitals.

A CE mark indicates that a device has been assessed for its intended purpose and is considered to meet EU safety and performance requirements. A CE-marked device can be made freely available on the EU market.

The physical presence of a CE mark should be checked at goods in/receipt where possible. For hospitals, this check should be part of an established process and quality management system.

Certain devices do not require a CE mark. There are criteria and processes for these exceptional cases which include:

- Compassionate use cases
- Clinical investigations and performance studies
- In house manufacturing
- Custom-made devices

For higher-risk devices, the process of applying a CE mark involves an assessment by an independent entity called a notified body. If a notified body assesses a device and is satisfied the device meets applicable requirements, they will issue a CE certificate. This certificate allows the manufacturer to apply the CE mark to the device.

For higher risk devices, the CE mark will have a unique 4-digit number displayed on the packaging. This number identifies the notified body that issued the certificate.

For some lower-risk devices (i.e. Class I medical devices and Class A IVDs)[1], the manufacturer will self-declare their compliance with applicable regulatory requirements. These devices do not need a notified body assessment, and a 4-digit number will not be visible under the CE mark on the device or its packaging.

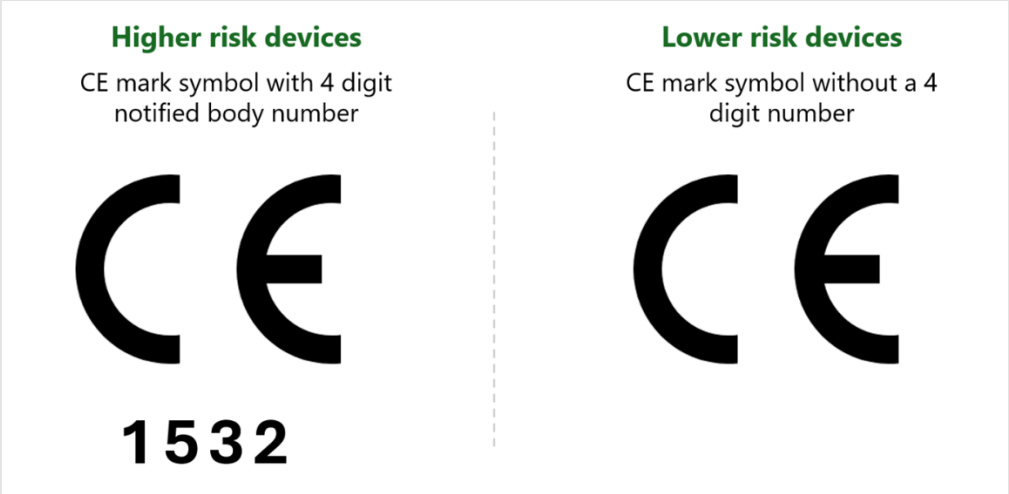


Figure 1: Illustrative example comparing a CE mark with a 4-digit notified body number for higher-risk devices and a CE mark without a notified body number for lower-risk devices.

We encourage all entities sourcing devices for use to check for the physical presence of a CE mark.

The frequency of these checks should be based on a rationalised method taking into account:

- The risk class of the device
- Volume of delivery

3.3 Declaration of conformity

Manufacturers must draw up and sign an EU declaration of conformity (DoC) document to declare their devices comply with applicable regulatory requirements. A DoC must be drawn up and signed before the manufacturer affixes a CE mark to the device.

[1] Class I medical devices with a measuring function, supplied in sterile condition or which are reusable surgical instruments require a notified body assessment and will have a 4-digit notified body number. Class A IVDs supplied in sterile condition will also have a 4-digit notified body number.

When sourcing a device, it is important to request an electronic copy of the DoC. A DoC contains useful information, as summarised in Table 2 below.

Table 2. Information typically included in a declaration of conformity

Category	Information required
Manufacturer details	Manufacturer: Name, registered trade name/mark, registered address, and Single Registration Number (SRN). Authorised representative (if applicable): Name, registered address, and SRN. Contact details and location for both.
Legal responsibility	A specific statement declaring that the DoC is issued under the sole responsibility of the manufacturer.
Traceability	The Basic UDI-DI
Device description	Product identifiers: Product name, trade name, product code, catalogue number, etc. Traceability: Photograph (if appropriate). Purpose: The intended purpose of the device.
Classification	The risk class of the device
Compliance statement	Declaration the device is in conformity with the MDR/IVDR. References to any other applicable Union legislation.
Conformity assessment (as applicable)	Notified Body: Name and identification number. Procedure: Description of the conformity assessment procedure performed. Certificates: Identification of the specific certificate(s) issued.
Additional info	Any additional information required (e.g. specific conditions of use).

We encourage all entities sourcing devices for use to request and retain an electronic DoC document for each device they use.

3.4 Internal procedures

Manufacturers must draw up Instructions for Use (IFU) for their devices. The type of information typically outlined within an IFU document is summarised in Table 3 below.

Table 3. Information typically outlined within an IFU document

Category	Point of information
Device information	Identity: Device name, model, and detailed description. Purpose: Clear intended use, indications, target patient population, and intended users (lay vs. professional). Performance: Expected clinical benefits and performance characteristics. Compatibility: Required accessories, software, or combined devices necessary for function.
Safety information	Restrictions: Contraindications and limitations of use. Risks: Residual risks, undesirable side effects, and warnings regarding specific substances (e.g. CMR) or radiation. Warnings: Specific alerts for single-use devices (risks of re-use) or damaged sterile packaging. Reporting: Instruction to report serious incidents to the manufacturer and competent authority.
Operational information	Preparation: Storage, transport, unpacking, assembly, calibration, and pre-use safety checks. Processing: Cleaning, disinfection, sterilization (for reusables), and maintenance schedules. Disposal: Safe disposal of the device, consumables, and biohazards. IT and security: Cybersecurity measures and IT environment requirements.

It is important to check the manufacturer's IFU, and to subsequently verify:

- Specific device compatibility issues have been identified and accounted for.
- Appropriate facilities are in place to store the device for its lifetime in line with the manufacturer's instructions.
- Any cleaning, disinfection and sterilisation instructions have been reviewed and can be followed if necessary.
- Compliance and risk assessments have been completed as needed.
- Instructions are provided in English.

We encourage entities to verify this information before a device is purchased and used.

We also encourage entities sourcing devices for use to ensure they have appropriate internal procedures in place to allow for their safe storage and use.

IFUs often physically accompany devices. However, for professional-use devices, the IFU may be provided in electronic format. If a copy of the IFU is not available, it should be requested from the supplier.

3.5 Supply disruption notifications

Manufacturers must inform health institutions and healthcare professionals if they anticipate a supply interruption or discontinuation of device supply to the EU market.

This applies to certain devices that could result in serious harm or a risk of serious harm to patients or public health.

Health service personnel involved in the procurement, management and use of devices and IVDs need to be aware of notifications of interruptions or discontinuations of device supply and help prepare for alternative devices or treatment options.

Upon receipt of a device supply disruption notification, relevant health personnel should take steps to manage the notification. This provides health institutions with time to take action and ensure continuity of patient care.

For more information about the supply disruption requirements, and the steps to be taken following receipt of notifications, visit the HPRA medical device and IVD disruptions webpage.

3.6 Statement of compliance for Directive compliant devices

This section is only relevant to devices certified in line with the previous Directives, i.e. the MDD, AIMDD or IVDD. This section is not relevant to devices certified under the MDR or IVDR.

For manufacturers of Directive certified devices to continue to place their devices on the market, they must meet certain criteria by specific deadlines.

Manufacturers of Directive certified devices should provide a statement of compliance to these criteria. They can do this either via a notified body letter or a self-declaration form.

3.6.1 Notified body confirmation letter

This is a document issued by a notified body confirming that a manufacturer has submitted a formal MDR/IVDR application and entered into a written agreement for conformity assessment of specified legacy devices.

3.6.2 Manufacturer self-declaration form

These forms are issued by a manufacturer. MedTech Europe have published templates for manufacturers to declare their compliance for medical devices and IVDs.

For more information about these requirements and deadlines for medical devices, review the HPRA MDR transitional provisions webpage.

For more information about these requirements and deadlines for IVDs, review the HPRA IVDR transitional provisions webpage.

3.7 UDI traceability system

The MDR and IVDR introduce measures to improve and support the traceability of devices. Two of these measures are summarised below.

3.7.1 Unique device identification system (UDI)

The UDI system is a standardised, unique numeric or alphanumeric code affixed to a device and its packaging to enhance its traceability throughout the supply chain and improve patient safety.

A UDI contains two components:

1. Device identifier (UDI-DI): a unique code specific to a model of device.
2. Production identifier (UDI-PI): a code that identifies the unit of device production, e.g. serial number, lot number, software identification and manufacturing or expiry date.

A complete UDI combines the device identifier (UDI-DI) with the production identifier (UDI-PI). This information can be found on the device itself or the device label and its packaging, in the form of a barcode or other means. The UDI is displayed in a machine-readable and human-readable format. Figure 2 provides an illustrative example of the different components of UDI.



Figure 2: Illustrative example of the different components of UDI.

For Class III implantable medical devices, e.g. implantable orthopaedic product or breast implants, hospitals are required to keep, preferably by electronic means, the UDI information associated with the devices that they have been supplied with.

We encourage hospitals, as part of their procurement processes and asset registers, to capture and store the UDI information of all classes of devices they have been supplied and of device they have supplied to patients.

Hospitals should ensure they have a system in place to track and trace all devices in use in the hospital. This may be important in situations such as product recalls to identify patients who have received specific devices.

Hospitals should ensure they can track and trace devices based on whether the device is:

- purchased,
- in use,
- implanted and/or given to a patient at discharge.

3.8 Implant card information

Another measure introduced by the MDR and IVDR to improve and support the traceability of devices is the implant card.

An implant card provides information to patients about an implantable medical device.

An implant card is provided by the manufacturer to a hospital. A hospital must fill in specific information on the implant card and then give it to the patient.

Implant cards achieve three main objectives for patients. They:

1. Allow the patient to identify the implanted device(s) and access related information (e.g. via EUDAMED or other websites).
2. Enable patients to identify themselves as persons requiring special care in relevant situations, such as security checks.
3. Inform emergency clinical staff or first responders about special care or needs for the patient in emergency situations.

Upon receipt of relevant devices, hospitals must ensure that an implant card containing the required information from the manufacturer has been received. Hospitals must also complete the remaining information and provide the implant card to the patient after implantation.

The manufacturer should ensure that it is clear to the hospital how to complete the implant card and may provide an instruction booklet to assist with this.

The information provided on implant cards by the manufacturer and the hospital is summarised in Table 4 below.

Table 4. Information included on implant cards

Provided by	Information
Manufacturer (pre-printed or provided as stickers)	- Device name - Device type (e.g. pacemaker, hip implant, etc.) - Serial number or lot/batch number - Unique Device Identification (UDI) (as AIDC format) and UDI-DI (as HRI) - Name, address, and website of the manufacturer
Health Institution/clinician (filled out post-implantation)	- Name of the patient or patient ID - Name and address of the health institution or healthcare provider that performed the implantation - Date of implantation

An illustrative example of an implant card and the information it might contain is provided In Figure 3 below.

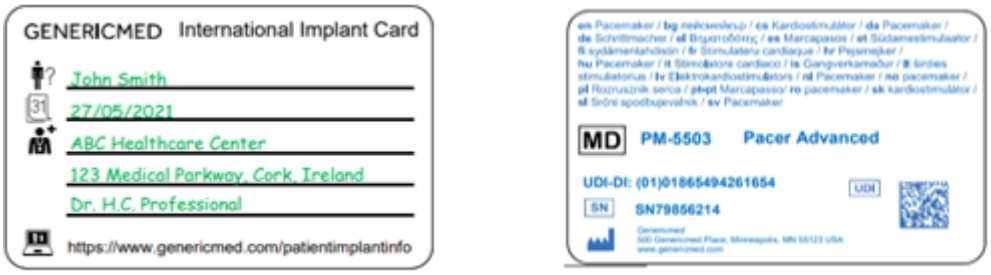


Figure 3: Illustrative example of the front of an implant card containing information hand-written by a clinician and the back of an implant card containing information printed by the manufacturer.

Practical guidance on implant cards and the key role hospitals play in providing them to patients is available in the EU Medical Device Coordination Group (MDCG) document MDCG 2019-8 v2: Guidance document on implant cards.

3.9 EUDAMED

The EUDAMED home page provides access to the European Database on Medical Devices, the IT system established by the Commission to facilitate the application of the MDR and IVDR.

EUDAMED is a useful resource and repository for device related information. It aims to enhance overall transparency and provides access to information for public and healthcare professionals.

3.9.1 Actor module

The EUDAMED actor module is available on the EUDAMED actor search page.

Examples of how the information within the EUDAMED actor module can help entities sourcing and using devices are outlined in Table 5 below.

Table 5. Examples of EUDAMED information benefits

Use	How can it benefit?	Practical example
Verify supplier registration	Hospitals can verify the identity of the legal manufacturer, authorised representative and importer associated with a device before procurement.	Before sourcing a device, entities can confirm that the manufacturer and authorised representative are properly registered.
Managing safety issues	When a device safety issue, recall or Field Safety Corrective Action (FSCA) occurs, hospitals can quickly identify the responsible economic operator and obtain the relevant contact details.	A hospital receives a safety notice and uses EUDAMED to identify and contact the correct manufacturer about affected devices in use.

3.9.2 Device module

The EUDAMED device module is available on the EUDAMED device search page.

Examples of how the information within the EUDAMED device module can help entities sourcing and using devices are outlined in Table 6 below.

Table 6. How the EUDAMED device module can support compliance verification

Use	How can it benefit?	Practical example
Verify device registration	Hospitals can check if a device or IVD is registered in EUDAMED and review key information such as device description, intended purpose, risk class and UDI details.	Before purchasing a device, entities can verify the device is registered and that its intended purpose matches the proposed clinical use.

Use	How can it benefit?	Practical example
Managing safety issues	The Device Module contains UDI information that enables accurate identification of devices. This supports implant traceability and rapid identification of affected products during recalls or Field Safety Corrective Actions (FSCAs).	In the event of a safety issue, entities can use the UDI to determine exactly which devices in stock or in use are affected.

3.9.3 Certificate module

The EUDAMED certificate module is available on the EUDAMED certificates search page.

Examples of how the information within the EUDAMED certificate module can help entities sourcing and using devices are outlined in Table 7 below.

Table 7. How the EUDAMED certificate module can support compliance verification

Use	How can it benefit?	Practical example
Verify certificate validity	Hospitals can confirm that a device's MDR or IVDR certificate is valid and has been issued by an authorised Notified Body. This provides assurance that the device has undergone the required conformity assessment.	Before purchasing a device, an entity can check that the certificate is active and applicable to the product being offered.
Monitor certificate status	The module provides visibility of certificate status, including amendments, suspensions, restrictions or withdrawals. This helps to identify potential regulatory issues affecting devices in use.	Entities can identify whether a device in use is affected by a certificate suspension and assess any resulting risks.