Which traceability systems are mandatory for medical devices?

The medical sector is subject to strict rules for tracing medical devices. Traceability systems are mandatory to ensure patient safety and to enable rapid intervention when problems arise. The European Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) have further strengthened these requirements. For manufacturers and distributors, it is crucial to know which systems are mandatory and how they can comply with the regulations.

What are the current traceability requirements for medical devices?

The current traceability requirements for medical devices are established in the European MDR (EU 2017/745) and IVDR (EU 2017/746) regulations. These regulations replace the older directives and impose stricter requirements for tracking medical devices throughout the entire supply chain.

The **key traceability requirements** include:

- Implementation of the UDI system (Unique Device Identification) on all medical devices
- Registration of manufacturers, authorized representatives, and importers in EUDAMED (European Database on Medical Devices)
- Registration of all medical devices in EUDAMED
- Maintaining implant cards for implantable devices
- Post-market surveillance and vigilance reporting
- Traceability throughout the entire distribution chain, from manufacturer to end user

The implementation deadlines for these requirements have been introduced in phases. The MDR has been fully in force since May 2021, while the IVDR applies from May 2022. Some aspects, such as the full functionality of EUDAMED, are being rolled out gradually.

For manufacturers, this means they must provide their products with UDI codes, register them in EUDAMED, and have systems in place to track products throughout the entire supply chain.

How does the UDI system work for medical devices?

The Unique Device Identification (UDI) system is a core component of the traceability requirements for medical devices. It consists of a unique code that must be applied to each medical device or its packaging.

A complete UDI code consists of two main components:

- **UDI-DI** (Device Identifier): A fixed, unique identification number specific to a model or version of a medical device. This part is used for registration in EUDAMED.
- **UDI-PI** (Production Identifier): Variable information such as lot number, serial number, expiration date, or production date.

The UDI must be displayed in both human-readable form (text) and machine-readable form (usually barcode or QR code). This ensures that the information can be read both visually and electronically.

Manufacturers must obtain UDIs through recognized issuing agencies such as GS1, HIBCC, or ICCBBA. The implementation of UDIs is being phased in, starting with the highest risk classes:

- Class III and implantable devices: Since May 2021
- Class IIa and IIb devices: Since May 2023
- Class I devices: From May 2025

The UDI system makes it possible to quickly identify specific devices in case of safety issues, facilitate recalls, and prevent fraud.

What must be registered in EUDAMED?

EUDAMED (European Database on Medical Devices) is the central European database for medical devices. It serves as a platform for registering and exchanging information about medical devices between manufacturers, distributors, competent authorities, and the public.

The following information must be registered in EUDAMED:

1. **Economic operators**: Manufacturers, authorized representatives, importers, and distributors must register with their company details
2. **Devices**: All medical devices must be registered with their UDI-DI, classification, intended use, and other essential information
3. **Certificates**: CE certificates issued by notified bodies
4. **Clinical investigations**: Information on clinical investigations and performance studies
5. **Vigilance and post-market surveillance**: Reports of incidents, safety measures, and periodic safety reports
6. **Market surveillance**: Results of market surveillance activities by authorities

EUDAMED consists of six modules corresponding to the categories above. The database aims to provide transparency and improve coordination between European member states. It enables authorities to respond more quickly to safety issues and gives the public access to certain information about medical devices.

Although EUDAMED is not yet fully operational, manufacturers are encouraged to start registering in the available modules. Full functionality is expected in the coming years.

What penalties apply for non-compliance with traceability rules?

Non-compliance with the traceability requirements for medical devices can lead to serious sanctions. The exact penalties vary by EU member state, but the MDR and IVDR require all member states to establish “effective, proportionate, and dissuasive” sanctions.

Possible sanctions for non-compliance include:

- **Financial fines**: These can amount to hundreds of thousands or even millions of euros, depending on the severity of the violation and the size of the company
- **Mandatory corrective measures**: Companies may be required to adjust their processes or modify products
- **Temporary or permanent market bans**: Products that do not meet requirements may be temporarily or permanently removed from the market
- **Criminal prosecution**: In serious cases, especially when public health has been endangered, responsible individuals may face criminal charges
- **Reputational damage**: In addition to formal sanctions, non-compliance can lead to significant reputational damage and loss of customer trust

Enforcement of these rules is carried out by national competent authorities, such as the Health and Youth Care Inspectorate (IGJ) in the Netherlands. These authorities conduct regular inspections and can also

respond to reports of non-compliance.

It is important to note that the costs of non-compliance are often much higher than the investments needed to comply with the regulations. Besides fines, companies may face recalls, product losses, and legal costs.

How do traceability requirements differ by risk class of medical devices?

The traceability requirements for medical devices vary depending on the risk class of the product. The MDR classifies medical devices into four risk classes: I (lowest risk), IIa, IIb, and III (highest risk).

The main differences in traceability requirements by risk class are:

Class I (low risk)

- UDI implementation required from May 2025
- Self-certification possible for many products (without intervention from a notified body)
- Basic traceability requirements via technical documentation
- Less extensive post-market surveillance requirements

Class IIa and IIb (medium risk)

- UDI implementation required since May 2023
- Intervention of a notified body required
- More extensive technical documentation and traceability
- Periodic safety reports required
- Stricter post-market surveillance

Class III and implantable devices (high risk)

- UDI implementation required since May 2021
- Strictest assessment procedures by notified bodies
- Implant card required for implantable devices
- Extensive clinical evaluation and post-market clinical follow-up
- Annual safety reports
- Possibility of additional checks by expert panels

For implantable devices, additional requirements apply, such as providing an implant card to the patient with information about the device, warnings, and expected lifetime.

The phased implementation of traceability requirements gives manufacturers of lower-risk products more time to comply with the new regulations, while the strictest requirements for high-risk products have come into force first.

Conclusion

The traceability requirements for medical devices have been significantly strengthened with the introduction of the MDR and IVDR. The UDI system and EUDAMED together form the backbone of this new traceability approach. Manufacturers and distributors must be aware of the specific requirements that apply to their products, depending on the risk class.

Implementing these systems requires a thorough approach and possibly adjustments to production, packaging, and logistics processes. Although this requires initial investments, it also offers benefits such as improved product safety, more efficient recalls, and better inventory management.

At Faes, as specialists in industrial packaging, we understand the challenges that these regulations bring. Our expertise in regulated sectors such as medical and defense enables us to develop packaging solutions that not only protect your products but also comply with the relevant traceability requirements.

Frequently Asked Questions

How do I implement UDI codes in my existing packaging process?

Start by selecting an accredited UDI issuing agency such as GS1 or HIBCC. Then evaluate your current labeling process and determine whether you need to print directly on the product, the primary packaging, or both. Invest in appropriate printing technology for both human-readable and machine-readable codes (barcode/QR). Finally, integrate UDI generation into your production management system and perform quality checks to ensure readability.

What should I do if an error is discovered in a registered UDI?

Contact the relevant issuing agency (such as GS1) immediately to report the error. Document the error, its cause, and the corrective actions taken. Inform your notified body about the situation and work with them to determine if an update in EUDAMED is needed. Check if the error impacts the traceability of products on the market and take additional measures if necessary.

What common mistakes do regulatory authorities see during traceability inspections?

Common deficiencies include incomplete or inconsistent UDI information across different packaging levels, inadequate documentation of the supply chain, insufficient linking between UDI and technical documentation, and inadequate systems for post-market surveillance. Problems are also frequently identified with the timely reporting of incidents and the maintenance of distribution records. Ensure regular internal audits to check these points.

How do I prepare for EUDAMED registration if the system is not yet fully operational?

Collect and organize all required product data according to EUDAMED specifications, including UDI-DIs, risk classes, and intended use. Register your organization in the already available modules of EUDAMED such as the Actor Registration Module. Implement internal processes for tracking and updating product data. Stay informed about updates on the launch dates of new EUDAMED modules via the European Commission's website.