tracekey

EUDAMED UDI COMPLIANCE SIMPLY AUDIT-PROOF

Whitepaper 2026

AUDIT CRITICAL UDI- UPLOAD

Uploading UDI data into EUDAMED appears to be the final step in a long process of implementing MDR and IVDR requirements. However, under MDR Article 27 and IVDR Article 24, manufacturers are required to introduce and maintain a UDI system. This includes not only assigning unique identifiers to products and packaging levels, but also the structured collection and maintenance of the associated master data in the UDI/Device module of EUDAMED. The introduction of a UDI system is therefore audit-critical and should not be overlooked. At the same time, MDR and IVDR require that this data is not only reported once, but continuously updated and kept accurate.

Risks often arise at internal interfaces. If responsibilities are unclear or decision processes are not properly documented, errors can quickly occur during upload. Therefore, MDR and IVDR require a person responsible for regulatory compliance.

If responsibility is too broad or not assigned at all, manual data entry in EUDAMED, informal processes such as Excel and email communication, or fragmented data maintenance across different systems become highly error-prone.

An appropriate tool can help by assigning responsibilities, centralizing data, and eliminating informal processes. In this whitepaper, we show what manufacturers need to consider to implement an audit-proof UDI system.

OVERVIEW

- Software validation in the UDI process
- Which UDI data is actually relevant?
- Traceability in the UDI system
- Validation documents for UDI compliance
- UDI compliance in EUDAMED context

SIMPLY AUDIT-PROOF

Software validation in the UDI process

Software used in the UDI upload process becomes relevant for quality assurance as soon as it processes or transfers MDR or IVDR data. It does not matter whether it is a specialized system, an EUDAMED interface, or a simple Excel file. The latter in particular are rarely considered audit-proof in practice. They lack reliable audit trails, proper versioning, and approval mechanisms.

During an audit, companies are expected to clearly demonstrate:

- **the purpose the software serves in the UDI process**
- **the risks associated with its use**
- **how the suitability of the software has been verified**

Validation is typically based on User Requirements Specification, a risk-based assessment, and testing or vendor documentation.
Another key focus is data consistency across systems. UDI data often exists in multiple applications. To avoid inconsistencies, manual transfers should be avoided. Instead, automated synchronization should be used, as provided by the **mytracekey UDI Manager**.

SIMPLY AUDIT-PROOF

Which UDI data is actually relevant?

UDI compliance requires consistent handling of master data throughout the entire lifecycle. Manufacturers must ensure that all UDI-relevant information is complete, accurate, and clearly assigned to a product in accordance with **MDR Annex VI Part B**. This includes the Basic UDI-DI and UDI-DI. These elements must align logically and be clearly assigned to products, variants, and packaging levels.

In addition, the data must comply with **EUDAMED business rules**. These define specific requirements for structure, completeness, and permitted combinations of mandatory data fields. With manual maintenance, for example using Excel or manual entry in the EUDAMED interface, adherence to these rules is difficult to verify. A tool such as the **mytracekey UDI Manager** can provide support. Through an integrated business rule check, entries are automatically validated. Incomplete datasets can be detected early, and errors avoided. At the same time, centralized data storage ensures that all relevant UDI information is managed consistently in one place.

SIMPLY AUDIT-PROOF

Why UDI data should be entered carefully

If incorrect UDI data is entered into EUDAMED, this can have serious consequences. The MDR requires EU member states to implement effective, proportionate, and dissuasive penalties. Possible examples include fines, sales stops, or even market bans. In cases of incomplete, incorrect, or missing UDI data, market approval is therefore at risk.

SIMPLY AUDIT-PROOF

Traceability in the UDI system

Traceability of a physical medical device is ensured through **UDI-DI, UDI-PI, and machine-readable codes**. Within a UDI system, this objective is achieved through data. It allows companies and auditors to track at any time, and in an audit-proof way, how a UDI dataset was created, how it has changed, and which decisions led to those changes. The basis for this is a continuous audit trail. Were there design changes, software updates, or modifications in the production process? Such details must be documented, and EUDAMED entries adjusted accordingly.

A close link to change management is equally important. Was a product change significant enough to require a new UDI? Every relevant product change triggers a new UDI evaluation, which must be clearly documented. The audit trail records who made which change and when.

In practice, ensuring this level of traceability manually is difficult. The **mytracekey UDI Manager** provides targeted support with an integrated audit trail, structured versioning, and centralized data storage, so that changes are documented automatically and in a compliant manner. Complete traceability is therefore ensured at all times.

SIMPLY AUDIT-PROOF

Validation documents for UDI compliance

In the context of UDI uploads, auditors expect consistent and logically structured documentation throughout the entire validation lifecycle. This typically includes a clear description of the UDI upload process, the definition of the systems used, and key validation documents such as the **User Requirements Specification (URS), Risk Assessment, Installation Qualification (IQ),** and **Operational Qualification (OQ)**. These documents must align in content and demonstrate that the system is fit for its intended purpose.

> **„During the audit, we were able to demonstrate that we not only comply with regulatory requirements, but also proactively work to meet future requirements.“**
>
> **Dr. Arabin GmbH & Co. KG**

SIMPLY AUDIT-PROOF

Validation documents for UDI compliance

A common weakness lies in handling changes. Software updates or adjustments to UDI data fields must be assessed and documented. Not every change requires revalidation, but every change requires a traceable decision. This is exactly where tracekey provides support with the **mytracekey UDI Manager**. It offers structured and up-to-date validation documentation, including URS, risk assessments, and IQ and OQ evidence. This ensures that validation is not only formally present but also audit-ready, current, and consistently implemented.

URS: Definition of system requirements
Risk Assessment: Evaluation of potential risks
IQ: Verification that the system has been installed correctly
OQ: Testing to ensure that the system operates as intended

SIMPLY AUDIT-PROOF

UDI compliance in EUDAMED context

Compliance in UDI upload is only the first step toward audit readiness. As one of six modules, the UDI or Devices module does not stand alone but is closely linked to other EUDAMED modules. Information from **vigilance, clinical investigations,** and **notified bodies and certificates** directly influences the data stored and maintained in the UDI module. Deviations or inconsistencies between these modules are quickly identified during an audit. Is the product linked to the correct certificate and appropriate clinical investigations? Are reported incidents recorded? All of this is relevant and will be reviewed.

SIMPLY AUDIT-PROOF

UDI compliance in EUDAMED context

Audit readiness, therefore, does not result from isolated measures but from the interaction of all involved processes and data sources. An audit-proof strategy for UDI compliance is characterized by the following:

- **validated, fit-for-purpose software or systems**
- **consistent and complete UDI data across all EUDAMED modules**
- **a reliable audit trail**
- **and an effective, integrated change management process**

Companies that understand UDI upload within the broader EUDAMED ecosystem and as an integral part of their quality management system not only reduce audit risks. They ensure that regulatory information is consistent across systems, thereby creating the foundation for sustainable compliance and efficient audit processes.

ABOUT TRACEKEY

The better way to stay compliant.

tracekey solutions develops cloud-based SaaS solutions for the healthcare industry.

We help companies efficiently meet regulatory requirements and digitise complex processes. Building on our expertise in pharmaceutical serialisation, we have expanded our portfolio to include solutions for the medtech industry, including tools for UDI management and EUDAMED compliance. Our goal: secure, scalable and user-friendly platforms with fair pricing that meet the challenges of a dynamic market.

TRACEKEY SOLUTIONS GMBH

Alte Bahnhofstraße 20, 44892 Bochum | +49 234 545003-0

info@tracekey.com | www.tracekey.com