**Guidance on implementation of UDI in an organisation’s quality management system**

**Purpose**

In accordance with MDR Article 27 and IVDR Article 24 as well as Annex VI Part C (MDR and IVDR), the Unique Device Identification system shall allow the identification and facilitate the traceability of devices, other than custom-made and investigational devices. This guidance document promotes a common approach to the integration of the UDI obligation in an organisation’s Quality Management System. It is meant for the manufacturer, any distributor, importer or other natural or legal person that assumes the obligations incumbent on manufacturers in accordance with MDR Article 16 (1) and the Notified Body.

*Note: For the purpose of referencing, the corresponding Articles and Annexes of the IVDR are included. However, in order for clarity in this document, the specific text of the IVDR is not detailed.*

**Relevance**

The Unique Device Identification (UDI) System will:

* allow the identification of medical devices,
* ensure appropriate traceability of medical devices,
* enhance the effectiveness of the post-market safety-related activities for devices,
* enhance targeting field safety corrective actions,
* will lead to better monitoring of related activities by competent authorities,
* reduce medical errors, and
* help the fight against falsified devices

for the benefit of manufacturers, other economic operators, authorities, users and Notified Bodies.

**References**

* [UDI Guidance Unique Device Identification (UDI) of Medical Devices](http://www.imdrf.org/docs/imdrf/%1Fnal/technical/imrf-tech-131209-udi-guidance-140901.pdf)
* [MDCG 2018-1 Draft guidance on basic UDI-DI and changes to UDI-DI](https://ec.europa.eu/docsroom/documents/28667)
* [MDCG 2018-3 Guidance on UDI for systems and procedure packs](https://ec.europa.eu/docsroom/documents/31924)
* [MDCG 2018-4 Annex: UDI database Definitions/Descriptions and formats of the UDI core elements for systems or procedure packs](https://ec.europa.eu/docsroom/documents/31925)
* [MDCG 2018-5 UDI Assignment to Medical Device Software](https://ec.europa.eu/docsroom/documents/31926)
* [MDCG 2018-6 Clarifications of UDI related responsibilities in relation to Article 16 of the Medical Device Regulation 2017/745 and the In-Vitro Diagnostic Medical Devices Regulation 2017/746](https://ec.europa.eu/docsroom/documents/31927)
* [MDCG 2018-7 Provisional considerations regarding the language issues associated with the UDI database (Annex VI, Part A Section 2 and Part B of the Medical Devices Regulation 2017/745 and the In-Vitro Diagnostic Medical Device Regulation 2017/745](https://ec.europa.eu/docsroom/documents/31928)

**Impact of UDI implementation on the Quality Management System**

The manufacturer should develop an internal UDI programme and establish a project plan. The project plan should be developed to facilitate the UDI implementation project and continuous compliance. Duties and responsibilities will include gathering expectations and requirements of the stakeholders, set the project plan and run the implementation project. The following sections outline the integration of the UDI obligation in the different areas of the Quality Management System.

*Management*

The manufacturer should determine and document the external roles (e.g. manufacturer, 3rd party suppliers, authorized representative, importers, distributor, assembler of systems and procedure packs) and the applicable UDI responsibilities.*Design and Development*

According to MDR Article 27 (3) and IVDR Article 24 (3), before placing a device, other than a custom-made device, on the market, the manufacturer shall assign to the device and, if applicable, to all higher levels of packaging, a UDI created in compliance with the rules of the issuing entity designated by the Commission in accordance with paragraph 2.

The assignment of UDI and corresponding degree of traceability (grouping of devices under a Basic UDI-DI or definition of their UDI-PI) should be the result of the manufacturer’s risk assessment.

Manufacturers should consider the goals and anticipated effects of the UDI system. It is important to define design inputs which are based on the UDI system. Successful implementation of the UDI system is easier if, for example, critical safety parts/components are identified and the handling in case of field safety corrective actions are considered. Root cause analysis is more effective, and the traceability of such critical safety parts/components is easier.

*Product documentation*

As part of the technical documentation, the manufacturer shall keep up-to-date a list of all UDIs that it has assigned.

*Production and process*

Some devices need to be direct marked, some devices are not marked at all. Several packages will need to have the UDI carrier. The manufacturer should establish for each individual type/model a strategy when, where and how the UDI carrier will be applied.

Devices that are placed on the European single market need to comply with the requirements. Manufacturers should ensure that the change from manufacturing stage to placing on the market is well understood.

As the UDI carrier may interfere with manufacturing processes it should be ensured that the requirements are fulfilled at the time the device is placed on the market.

Manufacturers should ensure that the label printing process is validated, and the equipment used are calibrated and tagged per procedure.

Re-validation of processes (e.g. sterilisation) should be accompanied by a review of the labelling.

The software used in the UDI process (e.g. UDI labelling, uploading UDI data to EUDAMED) should be validated / re-validated.

*Corrective and preventive actions*

According to Article 27 (7) MDR, the UDI shall be used for reporting serious incidents and field safety corrective actions in accordance with Article 87.

*Purchasing controls*

While parts of purchased components may not need a UDI label, a review of the purchasing procedures should be undertaken based on the following considerations:

* The manufacturer should consider which of the suppliers of products used within the UDI system, e.g. printers, bar code readers, labels etc., should be assessed and approved as supplier.
* Are there any purchased components that would benefit from a UDI label e.g. in case of future spare part supplies to the medical device?
* Does the organization purchase any 3rd party medical devices for distribution? If this is the case the corresponding agreement/contract should be agreed/updated with the supplier of these 3rd party medical devices. The system in place which captures a company’s UDI needs to be structured to capture/read the 3rd party’s medical device UDI.

*Documentation and records*

The Basic UDI-DI of the device shall appear on the EU declaration of conformity, the technical documentation (Annex II), summary of Safety and Clinical Performance (Article 32.2), Free Sale Certificate (Article 60) and EC Certificate (Annex XII). Internal procedures should detail these requirements.

If the manufacturer uses an Enterprise-Resource-Planning system to capture the UDI data, they should maintain validation documentation for linking the printers’ software, collecting UDI metadata, validating connectivity to EUDAMED, and other steps.

*UDI database*

Before a device, other than a custom-made or investigational device, is placed on the market the manufacturer shall ensure that the information referred to in Part B of Annex VI of the device in question are correctly submitted and transferred to the UDI database.

**Example of a project plan**

*Note: This is meant as illustration. Manufacturers could have their own versions/format encompassing these elements.*

1. Read and understand the MDR/IVDR UDI requirements. Identify additional documents like guidance documents from the European Commission. Documents published by IMDRF may also be used as input.
2. Understand the roles and responsibilities with respect to legal requirements in your organisation.
3. Define the responsibilities within your organisation and the interfaces. Make sure that all internal procedures that are affected by the UDI requirements are identified. Make sure that all affected departments are involved in the implementation process. Some departments may have a higher priority than others (e.g. Service may have for some topics a higher priority in case of a safety related device issue reported from the field).
4. Develop an accurate stock keeping units (SKUs) list of all devices and accessories, and their packages.
5. Determine the classification of each of these devices and accessories – this will dictate when the label and packages will need to be UDI compliant.
6. Determine where the device master data are located and who owns that data.
7. Review current labels and packages to determine where and how UDI will be applied.
8. Develop appropriate barcode implementation strategies, including barcode verification.
9. Select an issuing agency. Some considerations when selecting an issuing agency could be:
	* Is the issuing agency recognized by the European Commission?
	* Is the issuing agency globally recognized?
10. Quality System - Review current Standard Operating Procedures and systems for inclusion of UDI System. New Standard Operating Procedures may need to be generated to cover all requirements.