dDraft Guidance on implementation of UDI in an organisation's quality management system

[S1] megjegyzést írt: define which organization it means, for example manufacturer, importer, EC REP, healthcare provider,…

Purpose

In accordance with Article 27 of the MDR and Article 24 of the IVDR 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 or performance study devices as well as shipping containers.[1] This guidance document promotes a common approach to the implementation of the UDI obligations as an essential part of an organisation's Quality Management System (QMS) as required by Article 10(9h) MDR and Article 10(~~9h~~8h) IVDR. It is intended for manufacturers and 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: The corresponding Articles and Annexes of the IVDR are included for references purposes only. Elaborating on the specific text of the IVDR is not detailed is outside the scope of this document.

Relevance

The Unique Device Identification (UDI) System should in accordance with Recital (41):

- allow the identification of medical devices,
- facilitate appropriate traceability of medical devices,
- enhance the effectiveness of the post-market safety-related activities for devices,
- improve incident reporting,
- enhance targeting field safety corrective actions,
- lead to better monitoring by competent authorities~~better surveillance~~,
- reduce medical errors, ~~and~~
- help the fight against falsified devices~~,~~ and
- improve purchasing and waste disposal policies and stock-management by health institutions and other economic operators

References

- IMDRF/UDIWG/N7FINAL:2013: UDI Guidance Unique Device Identification (UDI) of Medical Devices
- MDCG 2018-1 v3 Guidance on basic UDI-DI and changes to UDI-DI
- MDCG 2018-3 Guidance on UDI for systems and procedure packs
- MDCG 2018-4 Annex: UDI database Definitions/Descriptions and formats of the UDI core elements for systems or procedure packs
- MDCG 2018-5 UDI Assignment to Medical Device Software
- 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

[1] In-house devices

- 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
- Further Guidance on UDI is available at https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en

Definitions:

- UDI system, UDI, UDI-DI, UDI-PI, Basic UDI-DI

Impact of UDI implementation on the Quality Management System

When implementing the requirements of the MDR and IVDR related to the QMS of a manufacturer, a "UDI process" shall simultaneously be implemented as the assignment of UDI, ~~UDI-DI or~~ Basic UDI-DI and the UDI related information management can determine the design of many other lifecycle QMS processes.[2] A manufacturer should establish a project plan for UDI implementation, to ensure continuous compliance. The plan should include but is not limited to:

- ~~gathering expectations and needs of the different stakeholders such as economic operators other than manufacturers, healthcare institutions/professionals, patients/users, insurance providers, etc.~~
- analysis of requirements of issuing agencies.
- definition of the responsibilities for the implementation and the subsequent process management
- setting milestones for the implementation and if necessary updates of the implementation plan.
- description of methods, use cases, etc. by which the proper running of UDI related QMS processes and continuous compliance can be verified.
- gathering expectations and needs of the different stakeholders such as economic operators other than manufacturers, healthcare institutions/professionals, patients/users, insurance providers, etc.
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The manufacturer should assess the applicable UDI responsibilities when determining and documenting external roles (e.g. third party suppliers, authorised representative, importers, distributor, systems and procedure packs producers).

The following sections outline the integration of the UDI obligations arising from the MDR and IVDR in the different areas of the Quality Management System.

Design and Development

According to Article 27 (3) MDR and Article 24 (3) IVDR, before placing a device, other than a custom-made, investigational or performance study device, on the Union market, the manufacturer shall assign to the device and, if applicable, to all higher levels of packaging except

[S2] megjegyzést írt: UDI comprises UDI-DI and UDI-PI → line 90

[S3] megjegyzést írt: Companies should first know the expectations in order to evaluate expectations meaningfully

[2] These aspects should be taken into particular consideration when setting the appropriate level of management of UDI implementation

shipping containers, a UDI created in compliance with the rules of the issuing entity designated by the Commission in accordance with paragraph 2 of the above mentioned Articles.[3]

The assignment of UDI and the corresponding degree of traceability should be an output of the manufacturer's risk assessment. The determination of the required level of traceability and the appropriate level of product serialisation should not only be done on the basis of proper risk management but shall also consider the regulatory requirements (e.g. for active implants serial numbers are required – Annex I Article 23.2.s MDR) and the expectations or requirements of other stakeholders such as registries.

Manufacturers should consider the objectives 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 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 (Article 27(7) MDR, Article 24(7) IVDR) aside from the Basic UDI-DI (Annex II Article 1.1.b MDR/IVDR), preferably by electronic means. According to Article 10(8) MDR and Article 10(~~9~~7) IVDR, manufacturers shall keep the technical documentation available for the competent authorities for a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the Union market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the Union market.

With reference to Article 27(1) MDR and Art 24(1) IVDR, UDI comprises UDI-DI and UDI-PI. On this basis, the storage period applicable to UDI-DI and UDI-PI should be differentiated: (i) UDI-PIs assigned shall be kept for a period of 10 years after the expiry date of the corresponding device and for implantable devices for a period of 15 years after the expiry date of the corresponding device; (ii) UDI-DIs assigned shall be kept for a period of 10 years after placing the last device on the Union market and for implantable devices for a period of 15 years after placing the last device on the Union market.

Production and process

To make effective use of the UDI System and to minimise efforts related to the management of UDI or product related information, manufacturers should consider using the UDI and UDI-DI from the outset of the production phase and using the UDI or the UDI-DI as reference or article numbers.

Some devices need to be directly marked, other devices do not require direct marking at all. Several packages will need to have the UDI carrier. The manufacturer should decide for each individual type/model when, where, and how the UDI carrier will be applied following various timelines per risk class, as indicated in the legal requirements of the MDR/IVDR:

MDs Class	IVDs Class	Placement of the UDI carrier

[3] The Issuing entities were designated on 6 June 2019 via the Commission Implementing Decision (EU) 2019/939.

Implantable and III	D	26 May 2021/26 May 2023
IIa and IIb	C and B	26 May 2023/26 May 2025
I	A	26 May 2025/26 May 2027
Reusable that shall bear the UDI Carrier on the device itself		2 years after the deadline applicable to the respective class of that device

Devices need to comply with the requirements at the moment when they are placed on the Union market. Manufacturers should ensure that the change from the manufacturing stage to placing on the Union market is defined in accordance with the relevant requirements.

As the UDI carrier may have an impact on manufacturing processes it should be determined in advance if it is possible to use one of the permitted exemptions (e.g. not technically feasible) to ensure that the requirements are fulfilled at the time the device is placed on the Union market.

Manufacturers should ensure as part of their quality management process that the label printing process is validated, and the equipment used is calibrated in accordance with relevant procedures.

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

The software used in implementing the UDI system (e.g. UDI labelling, automatic uploading UDI data to EUDAMED) should remain in a validated state in accordance with relevant procedures.

Serious incidents and field safety corrective actions

According to Article 27(5) of the MDR and Article 24(5) of the IVDR, the UDI shall be used for reporting serious incidents and field safety corrective actions in accordance with Article 87 MDR and Article 82 IVDR. The organisation's ~~tnternal~~internal procedures should detail these requirements.

Purchasing controls

While parts of purchased components[4] are not subject to UDI obligations unless otherwise required by legislation, a review of the purchasing procedures should be undertaken based on the following considerations:

- assess, approve and document suppliers of products used within the UDI system, e.g. printers, bar code readers, labels, etc.
- if there are any purchased components that would be subject to UDI obligations.[5]

Documentation and records

The Basic UDI-DI of the device shall appear on the EU declaration of conformity, (Annex IV MDR/IVDR), the technical documentation (Annex II MDR/IVDR), summary of Safety and Clinical

[4] IVDR/MDR Annex VI Part C 3.6. Each component that is considered to be a device and is commercially available on its own shall be assigned a separate UDI unless the components are part of a configurable device that is marked with its own UDI.
[5] Article 16(1) MDR & IVDR describes cases in which obligations of manufacturers apply to importers, distributors and other persons.

Performance (Article 32(2) MDR, Article 29(2) IVDR), Certificate of free sale (Article 60 MDR, Article 55 IVDR) and certain types of EC Certificate, i.e. EU technical documentation assessment certificates, EU type-examination certificates and EU product verification certificates (Annex XII). The UDI shall be included on the implant card, in accordance with Article 18 of the MDR. Internal procedures should detail those requirements for which the manufacturer is responsible.

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.

Procedures used for the assignment of UDI, the change of UDI[6] and the corresponding degree of traceability (grouping of devices under a Basic UDI-DI or definition of their UDI-PI) should be appropriately documented.

Integration of the UDI data to EUDAMED database

According to MDR and IVDR respectively before a device, other than a custom-made, investigational or performance study device, is placed on the Union market the manufacturer shall ensure that the information referred to in Part A and Part B of Annex VI MDR/IVDR relevant to the device in question is correctly submitted and transferred to the UDI database.

QMS process implementing UDI at the manufacturer's site

The manufacturer should establish, define, maintain and document the UDI related processes of the Quality Management system. The following processes need to be established either as specific processes or embedded in other QMS processes:

1. Strategy for product traceability

On the basis of the analysis of

a. legal requirements,
b. internal production process needs,
c. expectations and needs from the market (including the different logistic pathways),
d. liability aspects,
e. and in particular patient needs,

A strategy should be developed by which the level of traceability for every device or device component will be defined as part of the product design process.

The responsible function(s) will determine technical attributes to be published to the regulator.

2. Basic UDI-DI and UDI assignment process

a. On the basis of the strategy for product traceability the products or components which require UDI assignment and labelling need to be systematically identified.
~~a.~~b. Grouping of devices under Basic UDI-DI(s)
~~b.~~c. For each product the responsible function(s), should establish/define the production control methods required for traceability of a product: e.g. lot number, serial number,

[6] Please see MDCG 2018-1 v3 'Guidance on basic UDI-DI and changes to UDI-DI'

batch number or revision number, date of manufacture and expiration date in accordance with the strategy.

d. Procedures should be in place to ensure the uniqueness of the assigned Basic UDI-DI and UDI.

~~c.~~e. A Basic UDI-DI and UDI-DI change management process shall be established. This ensures, that necessary actions are triggered upon a change in the device or its packaging.

f. Training must be provided and documented (internally audited) to ensure that the Basic UDI-DI and the UDI assignment is done in accordance with rules provided by the issuing entities and the legislation.

~~d.~~g. verification of the Basic UDI-DI and the UDI assignments shall be performed

3. UDI Marking process

a. The responsible function(s) should define the format, specifications and location of the UDI label or permanent marking on the device in compliance with Annex VI Part C of the MDR/IVDR.

b. The responsible function(s) should implement a procedure for UDI marking/labelling on the device and its packaging.

c. UDI marking procedures should cover the general case as well as specific device types (e.g. implantable, Systems and Procedure packs, software).

4. UDI Capture process

a. Procedures should be implemented in order to record the UDI of medical devices in the applicable quality records. The responsible function should:

i. capture the UDI in the device manufacturing quality records (Device History Record).

ii. capture the UDI in the service records.

iii. capture the UDI in the Complaint Records.

iv. capture the UDI in the required Post Market Reports.

b. When repackaging and/or relabelling UDI marked medical devices, the original device UDI should be recorded within the quality records that support repackaging or relabelling activities.

5. UDI publication process

Procedures should be implemented and documented:

a. To ensure that all Basic UDI-DI and UDI-DI attributes are published in EUDAMED.

b. To ensure that where a change in the design of a device affects the Basic UDI-DI and UDI-DI ~~UDI~~ attributes, those impacted ~~UDI~~ attributes are updated and the impacted attributes are published in EUDAMED.

~~b.~~c. To ensure that UDI data is communicated to all economic operators in the supply chain and to make effective use of the UDI System and to minimise efforts related to the management of UDI or product related information (see “Production and process” – line 98)

Example of a UDI implementation plan

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

1. Read and assess the MDR/IVDR UDI requirements. Identify additional documents like guidance documents from the European Commission. Documents published by the IMDRF may also be used as input.
2. Define 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 (limited to medical devices in their own right) 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 or when direct marking of the reusable device is needed.
6. Determine where the device master data are located and who owns that data.
7. Select an issuing agency. In the selection process, the manufacturer shall take into consideration whether the issuing agency is recognised by the European Commission.
8. Review current labels and packages to determine where and how UDI will be applied.
9. Develop appropriate barcode implementation strategies, including barcode verification.
10. ~~9. Select an issuing agency. In the selection process, the manufacturer shall take into consideration whether the issuing agency is recognised by the European Commission.~~
11. Quality System - Review current Standard Operating Procedures and systems for the inclusion of the UDI System. New Standard Operating Procedures may need to be generated to cover all requirements.

[S4] megjegyzést írt: Latest after defining and determining the "as is", an issuing agency shall be selected! Proper knowledge of the barcoding and labelling standards are crucial upon developing new or changing processes

Auditing the implementation of the UDI system

The Notified Body ensures that its personnel involved in auditing the UDI requirements, as defined by the regulations, are sufficiently trained. The documented assessment procedures shall clearly outline the topics regarding the UDI system that needs to be covered by the auditors.

The Notified Body shall audit the QMS of the manufacturer and may choose the type of audit for this specific topic. It can be a complete or partial audit, either on site or as a desk audit. The audit shall cover sufficiently the documentation and implementation of the processes of the QMS.

The QMS of the manufacturer shall include all applicable requirements of the UDI-system as part of the processes which are audited by the Notified Body. Those processes include the following aspects (documentation and records), but is not limited to:

- selection of an issuing agency ~~supplier~~ for the UDI codes;
- ~~structure~~ assignment of the Basic UDI-DI and the UDI-DI ~~system (e.g. granularity of the basic UDI-DI, grouping of UDI-DI);~~
- ~~assignment of the UDI-DI codes;~~
- definition of UDI-PI;
- process for the registration of the devices referred to in Article 29(4) MDR and in Article 26 IVDR
- process for the registration of the devices into the ~~process into the~~ UDI Database referred to in Article 28 MDR and in Article 25 IVDR;
- record keeping procedures;
- issuing the Declaration of Conformity with Basic UDI-DI;
- Change management of the UDI system, including update of the technical documentation and the European database on medical devices
- Labelling/marking process, including barcode reference code and software validation
- maintenance of printing equipment, and
- training of personnel on the adopted UDI system.

These elements are mandatory parts of the initial, surveillance and renewal audits of the quality system.

QMS process implementing UDI at the importer (data verification, data storage, data transmission)

QMS process implementing UDI at the EC REP (data verification, data storage, data transmission)

QMS process implementing UDI at the healthcare provider (data verification, data storage, data transmission)