[Organization logo]

[Organization name]

Commented [AES1]: All fields in this document marked by square brackets [ ] must be filled in.

# PROCEDURE FOR UDI SYSTEM

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| Code: | |
| Version: | 0.1 |
| Created by: | |
| Approved by: | |
| Date of version: | |
| Signature: | |

Commented [AES2]: The document coding system should be in line with the organization's existing system for document coding; in case such a system is not in place, this line may be deleted.

## Distribution list

Commented [AES3]: This is only necessary if document is in paper form; otherwise, this table should be deleted.

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## Change history

| Date | Version | Created by | Description of change |
|---|---|---|---|
| | 0.1 | Advisera | Basic document outline |
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## Table of contents

## 1. Purpose, scope and users

The purpose of this Procedure is to provide the details and specifications necessary to ensure the application of the requirements for a Unique Device Identification (UDI) system.

The users of this Procedure are the Quality Manager, the person responsible for regulatory requirements, the CEO, and anyone else designated by top management.

## 2. Reference documents

- ISO 13485:2016 standard, clauses 7.5.8 and 7.5.9
- ISO 14971:2019
- Procedure for Labeling
- MDR 2017/745, articles 10(9), 27, 28, 29, 31, Annex I – Chapter III, and Annex VI
- MDCG 2018-1 Rev. 4 – Guidance on BASIC UDI-DI and changes to UDI-DI
- MDCG 2018-3 Rev. 1 – Guidance on UDI for systems and procedure packs
- MDCG 2018-5 – UDI assignment to medical device software

## 3. UDI system

[Job title] is responsible for ensuring that all medical devices from [organization name] are properly identified [illegible]

### 3.1. UDI system

[Job title] is responsible for setting up a UDI system that comprises the following three parts:

- the development of the UDI using globally accepted standards
- [illegible]
- [illegible]

There are two types of UDI numbers: Basic UDI-DI and UDI-DI.

Basic UDI-DI is used for regulatory purposes; it is constructed from the company/organization prefix assigned by the UDI issuing agency (see section 3.5), the model reference mark (group), and two control digits. [illegible]

UDI-DI is used for traceability purposes. [Job title] is responsible for defining a unique numeric/alphanumeric code (UDI-DI), for each medical device, that consists of two parts:

- **DI (Device Identifier):** the fixed portion of the UDI, which identifies the manufacturer and a device. [illegible]
- [illegible]

**Commented [AES4]:** Delete this if your organization does not need to be compliant with MDR.

You can find the full text of the MDR on the following link: https://advisera.com/13485academy/mdr/

**Commented [AES5]:** Always check for the latest version of the MDCG. https://health.ec.europa.eu/system/files/2021-04/md_mdcg_2018-1_guidance_udi-di_en_0.pdf

**Commented [AES6]:** If your medical devices are not systems and procedure packs, you can delete this reference.

You can find the latest version of the MDCG-3 on the following link: https://health.ec.europa.eu/system/files/2020-08/md_2018-3-guidance-udi-spp_en_0.pdf

**Commented [AES7]:** If your medical device is not software, you can delete this reference.

You can find the latest version of the MDCG 2018-5 on the following link: https://ec.europa.eu/docsroom/documents/31926

**Commented [AES8]:** Include the name of your organization.

**Commented [AES9]:** E.g., Quality Manager, person responsible [illegible]

**Commented [AES10]:** These are mandatory. Do not delete any item.

**Commented [AES11]:** E.g., PRRC, Quality Manager, person [illegible]

**Commented [AES12]:** Choose the one that applies to your [illegible]

**Commented [AES13]:** Include here the elements that your UDI will have according to your organization's practices.

[illegible]

### 3.2. Basic UDI-DI

[Job title] is responsible for putting the Basic UDI-DI on the Declaration of Conformity and any other document that requires precise identification of the medical product (e.g., on the Clinical Evaluation Report, Risk Management Report, or Post-Market Surveillance System). [illegible]

Commented [AES14]: E.g., Quality Manager, person [illegible]

### 3.3. UDI-DI

In [organization name], UDI-DI is applied to the [device itself/primary package of the device]. [illegible]

Commented [AES15]: Include the name of your organization.

Commented [AES16]: Choose the one that applies to your [illegible]

[Job title] is responsible for defining a new UDI-DI for any type of medical device every time one of the following changes:

- brand name
- device version or model
- clinical size (including volume, length, gauge, or diameter)
- changes in the number of allowed uses (single use or multiple uses)
- [illegible]

Commented [AES17]: Delete if this is not applicable for your device.

For some types of medical devices (e.g., software medical devices, implantable medical devices, etc.), there are specific rules when [job title] must define and apply the UDI-DI, as explained in sections 3.3.1, 3.3.2, 3.3.3, and 3.3.4.

[illegible]

Commented [AES18]: E.g., Quality Manager, person [illegible]

Commented [AES19]: Include the name of your organization.

#### 3.3.1. *UDI rules for software*

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[Job title] is responsible for evaluating the possible impact of any changes to the function of software qualified as medical device software, its classification, its intended purpose, and essential design and manufacturing characteristics, which could trigger the creation of a new UDI-DI.

Commented [AES21]: E.g., Quality Manager, person [illegible]

[illegible]

Commented [AES22]: E.g., Quality Manager, person [illegible]

#### 3.3.2. *UDI rules for implantable medical devices*

Commented [AES23]: You can delete this section if your [illegible]

[Job title] is responsible for identifying implantable devices at the lowest level of packaging with a UDI-DI and UDI-PI. For implantable medical devices, the UDI-PI must have at least the following characteristics:

- the serial number for active implantable devices
- [illegible]

#### 3.3.3. *UDI rules for reusable devices*

[Job title] is responsible for defining the place where the UDI should be applied on the reusable medical devices [illegible]

#### 3.3.4. *UDI rules for procedure packs and systems*

For configurable devices, [job title] is responsible for assigning the UDI to the device in its entirety, and that kind of UDI is called "configurable device UDI." The configurable device UDI-DI must be assigned to groups of configurations, which are defined as collections of possible configurations for a given device as described in the technical documentation. [Job title] must assign a configurable device UDI-PI to each individual configurable device.

[illegible]

### 3.4. UDI carrier

[Job title] must ensure that the UDI carriers used on medical devices in [organization name] include:

- easily readable plain text, and
- [illegible]

[illegible]

### 3.5. UDI-DI issuing agency

[Job title] is responsible for communicating with [agency], which provides UDI-DI. [illegible]

## 4. Submission of UDI-DI information to EUDAMED

[Job title] must submit in the EUDAMED online database the following information for each version or model required to have a UDI-DI on its label:

**Commented [AES24]:** E.g., Quality Manager, person [illegible]

**Commented [AES25]:** You can delete this section if your [illegible]

**Commented [AES26]:** E.g., Quality Manager, person [illegible]

**Commented [AES27]:** You can delete this section if your [illegible]

**Commented [AES28]:** E.g., Quality Manager, person [illegible]

**Commented [AES29]:** E.g., Quality Manager, person [illegible]

**Commented [AES30]:** The carrier of the configurable device [illegible]

**Commented [AES31]:** E.g., Quality Manager, person [illegible]

**Commented [AES32]:** Include the name of your organization.

**Commented [AES33]:** These are mandatory. Do not delete any of these items.

**Commented [AES34]:** Choose the appropriate one according [illegible]

**Commented [AES35]:** E.g., Quality Manager, person [illegible]

**Commented [AES36]:** Include the name of the agency with which you are in contact. E.g. GS1; Health Industry Business [illegible]

**Commented [AES37]:** Include the name of your organization.

**Commented [AES38]:** E.g., Quality Manager, person [illegible]

**Commented [AES39]:** E.g., Quality Manager, person [illegible]

**Commented [AES40]:** You can find the EUDAMED online database on the following link: [illegible]

1. Information related to the economic operator:
   - type of economic operator (manufacturer, authorized representative, or importer)
   - name, address, and contact details of the economic operator
   - [illegible]
   - [illegible]
2. Information related to the device:
   - Basic UDI-DI
   - type, number, and expiration date of the certificate issued by the Notified Body, the name or identification number of that Notified Body, and the link to the information that appears on the certificate and was entered by the Notified Body in the electronic system on Notified Bodies and certificates
   - Member State of the European Union in which the device has been or will be placed on the market
   - [illegible]
   - [illegible]
   - [illegible]
   - the summary of safety and clinical performance
   - risk class of the device
   - reprocessed single-use device
   - [illegible]
   - [illegible]
   - [illegible]
   - presence of tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012 (y/n)
   - the single identification number of the clinical investigation or investigations conducted in relation to the device, or a link to the clinical investigation registration in the electronic system on clinical investigations
   - [illegible]

**Commented [AES41]:** On the following link, you can find the [illegible]

**Commented [AES42]:** Delete this if your medical device is not [illegible]

**Commented [AES43]:** Delete this if your medical device is not listed in Annex XVI of the MDR 2017/745.

**Commented [AES44]:** Delete this if your device is not designed [illegible]

**Commented [AES45]:** Delete this if your medical device is not [illegible]

**Commented [AES46]:** Delete any of these that are not [illegible]

## 5. Managing records kept on the basis of this document

| Record name | Code | Storage | | [illegible] |
|---|---|---|---|---|
| | | [illegible] | [illegible] | |

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|---|---|---|---|---|
| List of UDI-DI | PR13.4 | [illegible] | [illegible] | [illegible] |

## 6. Appendices

- Appendix 1 - List of UDI-DI

[job title]
[name]

_____
[signature]

**Commented [AES47]:** The mandatory retention time for the [illegible]

**Commented [AES48]:** If the record is in electronic form, write [illegible]

**Commented [AES49]:** Only necessary if the Procedure for Document and Record Control prescribes that paper documents must be signed.