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**PROCEDURE FOR UDI SYSTEM**

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# 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.

# 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

# UDI system

[Job title] is responsible for ensuring that all medical devices from [organization name] are properly identified and include a label showing the plain-text version and automatic identification and data capture of the assigned UDI number.

## 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
* …

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