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**PROCEDURE FOR IDENTIFICATION AND TRACEABILITY**

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# Purpose, scope and users

The purpose of this Procedure is to describe a system for identification and traceability of the medical device all the way through [the production process of medical devices or through providing the service].

This Procedure applies to materials, parts, subassemblies, and other components, as well as the finished medical device or service.

Users of this document are persons responsible for the process of purchasing, quality control, production, and warehousing in [organization name].

# Reference documents

* ISO 13485:2016 standard, clauses 7.5.8 and 7.5.9
* ISO 14971:2019
* MDR 2017/745 Annex I – Chapter III, and Annex IX – Chapter I
* Procedure for Labeling
* Procedure for Production and Service Provision
* Procedure for UDI System
* Procedure for Vigilance and Adverse Event Investigation and Reporting
* Procedure for Control of Nonconforming Products

# Identification

## Identification of purchased goods

[Job title] is responsible for the identification of purchased goods. [Job title] is responsible for identifying purchased materials, parts, and components with [identification method].

[Job title] must identify the purchased medical devices by marking, labeling, or tagging the packaging or containers holding them and, when appropriate and practical, by labeling the medical devices themselves. [Job title] must identify the area dedicated for storage of the medical devices.

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