Commented [AES1]: Use this template when writing new documents from scratch.

[Organization logo]

Commented [AES2]: All fields in this document marked by square brackets [ ] must be filled in.

[Organization name]

PROCEDURE FOR IDENTIFICATION AND TRACEABILITY

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

Commented [AES3]: 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 [AES4]: This is only necessary if document is in paper form; otherwise, this table should be deleted.

Copy no.	Distributed to	Date	Signature	Returned	
				Date	Signature

Change history

Date	Version	Created by	Description of change
	0.1	Advisera	Basic document outline

Table of contents

1. 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].

2. 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

3. Identification

3.1. 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].

[illegible]

[Job title] is responsible for ensuring that identification is maintained while the medical devices are in storage and/or staged for production and that information is recorded on a central storage computer.

[illegible]

3.2. Identification during production

Commented [AES5]: Depending on if your organization manufactures medical devices or provides services, delete the part that is not applicable to your organization.

Commented [AES6]: Delete the part that does not apply to your organization.

Commented [AES7]: Include the name of your organization.

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

Commented [AES9]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "12_Production_and_Service_Provision".

Commented [AES10]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "19_Adverse_Event_Investigation".

Commented [AES11]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "18_Nonconformities".

Commented [AES12]: E.g., Quality Manager, Purchasing [illegible]

Commented [AES13]: Include information about the identification method according to your organization's practices.

[illegible]

Commented [AES14]: You can delete this if your organization's [illegible]

Commented [AES15]: E.g., Warehousing Manager

Commented [AES16]: Include the frequency of performing the [illegible]

[Job title] is responsible for writing/providing a proper work order that will identify all manufactured parts and subassemblies during all stages of production. Work orders accompany medical devices as they move from one workstation or production process to the next. [illegible]

The lot number includes [number] of characters representing the following: [description of the lot number].

3.3. Identification of finished medical device

[Job title] is responsible for checking that each medical device is marked with the proper lot number, date of production, and/or validity date in line with the work order, and to check that the label is permanently affixed to the medical device (wherever possible). [Job title] must make sure the identification label includes at least the following information in line with applicable harmonized standards and the Procedure for Labeling:

- the name and model (ref number or dimension) of the medical device
- the name and address of the manufacturer
- [illegible]
- [illegible]

[illegible]

4. Traceability

4.1. General

[Job title] is responsible for assigning the UDI number to each series of medical devices according to the Procedure for UDI System.

When traceability is a regulatory requirement, [job title] selects components for which traceability shall be maintained. [illegible]

4.2. Additional requirements for implantable medical devices

[Job title] is responsible for keeping implantable medical device records (records of components, materials, and conditions for the work environment used), together with records with the name and address of the shipping package consignee for 15 years after the medical device is put on the market.

[illegible]

Commented [AES17]: E.g., Production Manager, Quality Manager

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Commented [AES21]: Put the number of characters included [illegible]

Commented [AES22]: Write a description of the meaning of the number and letters included in the lot number.

[illegible]

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[illegible]

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

Commented [AES32]: E.g., Production Manager, Quality [illegible]

4.3. Traceability records

[Job title] is responsible for ensuring that, for purchased materials and components, their origination and verification records, such as certificates of analysis (COA), testing inspection reports supplied with the medical device, etc., are linked to the medical devices through their purchase orders, and storing all the information in [storage location].

[redacted]

5. Acceptance status identification

[Job title] must ensure that the acceptance status of each medical device is identified with respect to its monitoring and measurement requirements throughout the entire lifecycle of the medical device (production, storage, installation, and servicing of product).

Following every inspection or testing specified, [job title] must identify medical devices to indicate whether they have passed or failed the inspection. This is to prevent mix-ups and/or nonconforming medical devices from being used or dispatched, as well as to ensure orderly handling of medical devices and that only those medical devices that have passed the required inspections and tests, or that have been released under authorized concession, are dispatched, used, or installed.

[redacted]

[job title]
[name]

_____

[signature]

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Commented [AES39]: E.g., Production Manager, Quality

Commented [AES40]: The acceptance status of the medical device can be any of the following:
• Semi-finished

Commented [AES41]: E.g., applying a sticker on the medical

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Commented [AES43]: E.g., Production Manager, Quality

Commented [AES44]: Only necessary if the Procedure for Document and Record Control prescribes that paper documents must be signed.