Identification and Traceability Policy

Role	Position/Department	Name	Date
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Reviewer			DD YYYY
Approver			DD YYYY

[Company Name], Inc.

Revision History

Ver.	Effective Date Revision Details (Reason, Changes, Affected Documents) Author/Reviewer/ Approver			
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	Role	**Author**	**Reviewer**	**Approver**
	Department	XXX	XXX	XXX
	Position	XXX	XXX	XXX

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1. Purpose

The purpose of this policy is to establish the requirements for [Company Name], Inc. (hereinafter referred to as "the Company") to properly identify products and ensure traceability throughout all stages of the product lifecycle, thereby preventing mix-ups of products, and contributing to the effectiveness of the Quality Management System (QMS) and ensuring the safety and efficacy of medical device products.

2. Scope

This policy applies to the identification and traceability of all medical devices and their components and materials (hereinafter referred to as "materials") handled by the Company throughout all stages of the product lifecycle, including design and development, receiving, manufacturing, storage, distribution, installation, servicing, and disposal.

The extent of identification and traceability requirements shall be determined based on the results of risk management, applicable regulatory requirements, and product characteristics.

3. Normative References

Regulation/Standard	Title	Issuing Body	Year
21 CFR Part 820	Quality Management System Regulation (QMSR)	U.S. FDA	2026
ISO 13485:2016	Medical devices — Quality management systems — Requirements for regulatory purposes	ISO	2016
21 CFR Part 830	Unique Device Identification	U.S. FDA	2013
21 CFR Part 821	Medical Device Tracking Requirements	U.S. FDA	2014
21 CFR Part 11	Electronic Records; Electronic Signatures	U.S. FDA	1997
ISO 14971:2019	Medical devices — Application of risk management to medical devices	ISO	2019

4. Definitions

Term	Definition
Serial Number	A unique number assigned to each individual product unit at the time of manufacture. Also referred to as a serial number or S/N.
Lot Number	A unique number assigned to a group of products produced under the same conditions. Also referred to as a lot number or batch number.
Control Number	"Distinctive symbols, such as a distinctive combination of letters and/or numbers, that permit each unit, lot, or batch of a finished device to be traced through all stages of manufacturing, packaging, labeling, and distribution." (21 CFR 820.3(b), per QMSR)
Traceability	"Ability to trace the history, application, or location of that which is under consideration." (ISO 9000:2015, 3.6.13) For medical devices, this includes forward traceability (from materials to customer) and backward traceability (from customer to materials).
Unique Device	"An identifier that adequately identifies a device through its distribution and use by

Identifier (UDI)	meeting the requirements of 21 CFR 830.20. A unique device identifier is composed of: (1) A device identifier — a mandatory, fixed portion that identifies the specific version or model of a device and the labeler of that device; and (2) A production identifier — a conditional, variable portion that identifies one or more of the following when included on the label of the device: the lot or batch number, the serial number, the expiration date, the manufacturing date, the distinct identification code required by §1271.290(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device." (21 CFR 830.3)
UDI-DI (Device Identifier)	A mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device.
UDI-PI (Production Identifier)	A conditional, variable portion of a UDI that identifies the lot/batch number, serial number, expiration date, manufacturing date, or distinct identification code.
GUDID	Global Unique Device Identification Database. The FDA database that serves as a repository of key device identification information submitted by device labelers.
Color Control	The use of color-coded areas, labels, or tags to visually identify the status or category of products, materials, and work areas, facilitating quick identification and preventing mix-ups.
Nonconforming Product	"Product that does not fulfill a requirement." (ISO 9000:2015, 3.6.9) A product that does not meet its specified requirements.
Returned Product	A product returned from a customer due to complaint, warranty, repair, modification, or other reasons.
Concession (Use-As-Is)	Authorization to use or release a product that does not conform to specified requirements, following documented evaluation and approval.
Process Deviation Product	A product that was manufactured under conditions that deviated from the approved manufacturing process.
ALCOA+ Principles	Data integrity principles: Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, and Available.
Medical Device File (MDF)	Per QMSR (21 CFR 820.10), a compilation of records containing the complete design, manufacturing specifications, process requirements, quality assurance requirements, and labeling for a finished device. (Replaces the former Device Master Record (DMR).)
Design and Development File (DDF)	Per QMSR (21 CFR 820.10), a compilation of records that describes the design history of a finished device. (Replaces the former Design History File (DHF).)

5. Identification and Traceability

Medical devices shall be uniquely identified by product name (including model number), product number, lot number, or serial number throughout all stages including design and development, receiving, manufacturing, storage, distribution, installation, and servicing. Traceability shall be maintained and mix-ups prevented. The method and extent of identification shall be determined based on the results of risk management.

5.1 Risk-Based Approach to Identification and Traceability

The level of identification and traceability shall be determined based on the risk class of the medical device, its intended use, and the severity of potential harm to patients, in accordance with ISO 14971:2019. The following risk-based framework shall apply: