The Summary of Labeling Requirements by Authority

A Scilife Guide

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Labeling Requirements by Authority

The best way to review and approve labeling content is to create a labeling checklist for each regulatory requirement applicable to your device.

U.S. Food and Drug Administration FDA 21 CFR

21 CFR Part 801 21 CFR Part 801.15	General Device Labeling - Use of Symbols
21 CFR Part 809	In Vitro Diagnostic Products
21 CFR Part 812	Investigational Device Exemptions
21 CFR Part 820 21 CFR Part 820.120	Good Manufacturing Practices - Device labeling
21 CFR Part 830	Unique Device Identification
21 CFR Part 1010	General Electronic Products

The European Union Medical Device Regulation EU MDR 2017/745

Annex I, Chapter II • Sector 10.4.1 • Sector 10.4.5	General Safety And Performance Requirements Requirements Regarding Design And Manufacture Design And Manufacture Of Devices Labeling
Chapter III • Section 23	Requirements Regarding The Information Supplied With The Device Label and instructions for use
Annex VI Part C	The UDI System

International Organization for Standardization

ISO 20417:2021	Medical devices-Information to be supplied by the manufacturer
ISO 15223 series • ISO 15223-1 • ISO 15223-2	Medical devices-Symbols to be used with information to be supplied by the manufacturer
ISO 18113 • ISO 18113-1 • ISO 18113-2	IIn vitro diagnostic medical devices-Information supplied by the manufacturer (labelling)
ISO/IEC 15459 series • ISO/IEC 15459-2 • ISO/IEC 15459-4 • ISO/IEC 15459-6	Information technology-Automatic identification and data capture techniques — Unique identification Part 2: Registration procedures Part 4: Individual products and product packages Part 6: Groupings
ISO 80601-2 Series	Medical electrical equipment: Particular requirements for the basic safety and essential performance of ...
IEC 60601-1 Series	Medical electrical equipment - General requirements for basic safety and essential performance

The Global Harmonization Task Force GHTF SG1 N70

Global Harmonization Task Force is a voluntary international group of representatives from medical device regulatory authorities and trade associations from Europe, the US, Canada, Japan, and Australia. The document is intended to provide non-binding guidance to regulatory authorities for use in the regulation of medical devices and has been subject to consultation throughout its development.

To provide guidance to medical device manufacturers and RAs on the label and the instruction for use that provide users, both professional and lay as appropriate, and/or patients, and any relevant third parties. This document provides guidance with information such as

- the device's identity
- the identity of the manufacturer
- the device's intended use/purpose
- how the device should be used, maintained, and stored
- any residual device risks, warnings, limitations or contraindications
- the device's performance. whilst also promoting
- labeling commensurate with the technical knowledge, experience, education or training of intended users
- consistent use of terminology
- use of symbols
- the avoidance of prescriptive country-specific requirements for text, content, or format of labelling that offers no benefit to the device user or, where applicable, the patient.

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