Ultimate Cheat Sheet
for Medical Device Standards

cleio

Mechanical, Electrical & Performance

IEC 60601 (Series) — IEC
Medical Electrical Equipment - General Requirement for Basic Safety and Essential Performance

Other Specific Safety Standards

FDA Class II Special Controls Documents — FDA

Cybersecurity

IEC 81001-5-1 — IEC
Health SW: Security - Activities in the PLC

IEC/TR 60601-4-5 — IEC
Safety-Related Technical Security Specifications

UL 2900-2-1 — UL
SW Cybersecurity for Healthcare and Wellness Systems

Content of Premarket Submissions for Mgt. of Cybersecurity in Medical Devices — FDA

Postmarket Management of Cybersecurity in Medical Devices — FDA

Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software — FDA

Principles and Practices for Medical Device Cybersecurity — IMDRF

Design and Development Activities & Design Controls

ISO 13485:2016 — ISO
Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

SOR/98-282 — CA
Medical Devices Regulations

US FDA 21 CFR 820 — FDA
Quality System Regulation
Section 30 Design Controls

Risk Management

ISO 14971:2019 — ISO
Medical Devices - Application of Risk Management to Medical Devices

ISO/TR 24971:2019 — ISO
Medical Devices - Guidance on the Application of ISO 14971

IEC 60812:2018 — IEC
Procedure for FMEA (Failure Mode and Effects Analysis)

Software

IEC 62304 — IEC
Medical Device Software - SW Life Cycle Processes

IEC/TR 80002-1 — IEC
Guidance on the Application of ISO 14971 to Medical Device Software

Content of Premarket Submissions for Device Software Functions — FDA

Off-The-Shelf Software Use in Medical Devices — FDA

AAMI TIR45 — AAMI
Guidance on the Use of AGILE Practices in the Development of Medical Device Software

Home Healthcare Environment

IEC 60601-1-11 — IEC
Requirements for MEE & MES Used in the Home Healthcare Environment

Design Considerations for Devices Intended for Home Use — FDA

Health Software, SaMD, MDDS, AI/ML

IEC 82304-1:2016 — IEC
Health Software - Part 1: General Requirements for Product Safety

ANSI/AAMI SW91 — AAMI
Classification of Defects in Health Software

Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices — FDA

Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML) - Enabled Device Software — FDA

Drug Device Combination Products

Application of Human Factors Engineering Principles for Combination Products: Q&A — FDA

Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development — FDA

Other CDER Guidances — FDA

Usability

IEC 62366-1 — IEC
Medical Devices - Part 1: Application of Usability Eng. to Medical Devices

IEC/TR 62366-2 — IEC
Guidance on the Application of Usability Eng. to Medical Devices

AAMI HE75 — AAMI
Human Factors Engineering Design of Medical Devices

Applying Human Factors and Usability Engineering to Medical Devices — FDA

Content of Human Factors Information in Medical Device Marketing Submissions — FDA

Biocompatibility

ISO 10993-1 — ISO
Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process

Use of International Standard ISO 10993-1 — FDA

This list is not exhaustive and primarily focuses on the design and development stages of the medical device lifecycle.