

COMMONLY REFERENCED STANDARDS, REGULATIONS AND GUIDANCE DOCUMENTS

QUALITY SYSTEMS
ISO 13485 Medical devices – Quality Management Systems
FDA Title 21- Part 820 Quality System Regulation (QSR)
ISO 10005 Quality Management Systems – Quality Plans

BIOCOMPATIBILITY
ISO 10993 Biological evaluation of medical devices

STERILIZATION
FDA Guidance 1615 Sterility Info in 510(k) Subs Guidance
ISO 11135 Sterilization of health care products – EtO
ISO 11137 Sterilization of health care products - Radiation
ISO 14161 Sterilization of health care products-biological indicators

PACKAGING AND LABELING
ISO 11607 Packaging for terminally sterilized medical devices
ISTA 1, 2 3 ISTA Pre-shipment Test Procedures
ASTM F1886 Determining Integrity of Seals by Visual Inspection
ASTM F88 Test Method for Seal Strength of Flexible Materials
ASTM F2096 Pouch Bubble Test
ASTM F1929 Pouch Dye Penetration Test
ASTM F2503 MRI label marking
ISO 15223 Symbols to be used with medical device labels

ACCELERATED AGING
ASTM F1980 Standard guide for accelerated aging

CLEANROOMS / CONTROLLED ENVIRONMENTS
ISO 14644 Cleanroom and associated controlled environments
ISO 14698 Cleanroom-Biocontamination Control

ELECTRICAL, SOFTWARE
IEC 60601 Medical electrical equipment
IEC 62304 Medical devices software

RISK MANAGEMENT
ISO 14971 Application of risk management to medical devices

STATISTICAL TECHNIQUES
ISO 16269 Statistical interpretation of data

HUMAN FACTORS
ANSI/AAMI HE75 Human factors engineering

CONNECTORS
ISO 80369 Small-bore connectors for liquids and gases

VASCULAR DEVICES
ISO 25539 Cardiovascular implants – Endovascular devices
ISO 10555 Intravascular catheters – Sterile and single-use
FDA Guidance 1545 Intravascular Stents and Delivery System
FDA Guidance 1608 PTCA Catheters
AAMI TIR42 Particulates - vascular devices
ASTM F2081 Dimensional Attributes of Vascular Stents
ASTM F2942 Axial, Bending, Torsional Durability -Vascular Stents
ASTM F2942 Axial, Bending and Torsional Durability - Stents
ISO 5840 Cardiovascular implants – Cardiac valve prostheses
ISO 7198 Vascular prostheses – Tubular vascular grafts and patches
ISO 12417 Vascular device-drug combination products
ASTM F2477 In vitro pulsatile durability testing of vascular stents

ORTHOPEDIC DEVICES
ISO 7206 Partial and total hip joint prosthesis
ISO 7207 Partial and total knee prosthesis
ISO 14242 Wear of total hip-joint prostheses
ISO 14243 Wear of total knee-joint prostheses
ASTM F1800 Cyclic fatigue –metal tibial tray, total knee joint repl.
ASTM F543-13E1 Metallic medical bone screws
ISO 17853 Wear of implant materials-Polymer and metal wear part.

ACTIVE IMPLANTS
ISO5841 Cardiac pacemakers
ISO 10310 Marking and packaging of implantable neurostimulators
ISO /TS 10974 MRI safety of patients with active device
ISO 11318 Connector assembly DF-1, implantable defibrillators
ISO 27185 Symbols for cardiac rhythm mngt. device labels

This list is intended as a quick reference for the most general and commonly used standards and guidance documents. It is by no means a comprehensive list. It is the responsibility of the user to verify the validity and applicability of each standard.