Standards and guidelines for medical device manufacturing

Streamline your standards management with this expert collection of documents used by the world’s leading medical device manufacturers for engineering and manufacturing compliance.

Choose optional subject sets by publisher to complete your custom collection. Or choose Techstreet™ Building Blocks to easily add single documents to your subscription anytime you need them, without a service request.
Document list

**AAMI**
- AAMI HE75: Human Factors Engineering
- AAMI PB70: Liquid Barrier Performance of Protective Apparel and Drapes
- AAMI ST67: Requirements for Products Labeled ‘STERILE’
- AAMI ST72: Bacterial Endotoxins
- AAMI ST79 & A1, A2: Steam Sterilization and Sterility Assurance
- AAMI ST79 & A1, A2, A3: Comprehensive Guide to Steam Sterilization and Sterility Assurance
- AAMI TIR12: Medical Devices for Reprocessing in Health Care Facilities
- AAMI TIR14: Sterilization Using Ethylene Oxide
- AAMI TIR16: Microbiological Aspects of Ethylene Oxide Sterilization
- AAMI TIR17: Compatibility of Materials Subject to Sterilization
- AAMI TIR28: Product Process Equivalency for Ethylene Oxide Sterilization
- AAMI TIR30: Acceptance Criteria for Cleaning Reusable Medical Devices
- AAMI TIR33: Sterilization – Radiation – Method VDmax
- AAMI/IEC 62366: Application of Usability Engineering to Medical Devices
- AAMI/ISO 15223-1: Symbols to be Used with Medical Device Labels

**ASME**
- ASME B31.3: Process Piping
- ASME Y14.100: Engineering Drawing Practices
- ASME Y14.2M: Line Conventions and Lettering
- ASME Y14.35M: Revision of Engineering Drawings & Associated Documents
- ASME Y14.41: Digital Product Definition Data Practices
- ASME Y14.5.1M: Mathematical Definition of Dimensioning and Tolerancing
- ASME Y14.5: Dimensioning and Tolerancing
ASQ
- ASQ S1: An Attribute Skip-Lot Sampling Program
- ASQ Z1.4: Sampling Procedures and Tables for Inspection by Attributes
- ASQ Z1.9: Inspection by Variables for Percent Nonconforming

ASTM
- ASTM A380: Cleaning, Descaling, and Passivation of Stainless Steel Parts
- ASTM A967: Chemical Passivation Treatments for Stainless Steel Parts
- ASTM B348: Titanium and Titanium Alloy Bars and Billets
- ASTM D2240: Rubber Properties – Durometer Hardness
- ASTM D4169: Performance Testing of Shipping Containers
- ASTM D4332: Conditioning Containers, Packages, or Packaging Components for Testing
- ASTM D5276: Drop Test of Loaded Containers by Free Fall
- ASTM D903: Peel or Stripping Strength of Adhesive Bonds
- ASTM D999: Vibration Testing of Shipping Containers
- ASTM F1264: Intramedullary Fixation Devices
- ASTM F136: Titanium Alloy for Surgical Implant Applications
- ASTM F1608: Microbial Ranking of Porous Packaging Materials
- ASTM F1886/F1886M: Determining Integrity of Seals for Flexible Packaging
- ASTM F1929: Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F1980: Accelerated Aging of Sterile Barrier Systems
- ASTM F2096: Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- ASTM F2097: Design and Evaluation of Primary Flexible Packaging
- ASTM F88/F88M: Seal Strength of Flexible Barrier Materials

BSI
- BS EN 1041: Information Supplied by Manufacturers of Medical Devices
- BS EN 13060 +A2: Small Steam Sterilizers
- BS EN 1422 +A1: Ethylene Oxide Sterilizers
- BS EN 15986: Requirements for Labelling Medical Devices Containing Phthalates
- BS EN 285 +A2: Large Steam Sterilizers
- BS EN 55011+ A1: Radio-Frequency Disturbance Characteristics
- BS EN ISO 14698-2: Cleanrooms – Biocontamination Control – Evaluation and Interpretation of Data
- BS EN ISO 14937: Sterilization – Characterization of a Sterilizing Agent
- BS EN ISO 14971: Application of Risk Management to Medical Devices
- BS EN ISO 15223-1: Symbols to be Used with Medical Device Labels
- BS EN ISO 17665-1: Sterilization – Moist Heat
- BS EN ISO 9001: Quality Management Systems – Requirements

IEC
- IEC 60529 Ed. 2.1 b: Degrees of Protection Provided by Enclosures
- IEC 60601-1 Ed. 3.1 en: Medical Electrical Equipment – Part 1
- IEC 60601-1-1 Ed. 2.0 b: Medical Electrical Equipment – Part 1-1
- IEC 60601-1-11 Ed. 1.0 b: Medical Electrical Equipment – Part 1-11
- IEC 60601-1-2 Ed. 3.0 b: Medical Electrical Equipment – Part 1-2
- IEC 60601-1-4 Ed. 1.1 b: Medical Electrical Equipment – Part 1-4
- IEC 60601-1-6 Ed. 3.0 b: Medical Electrical Equipment – Part 1-6
- IEC 60601-1-8 Ed. 2.0 b: Medical Electrical Equipment – Part 1-8
- IEC 60601-1-SER Ed. 1.0 b: Medical Electrical Equipment – ALL PARTS
- IEC 60601-2-22 Ed. 3.0 b: Medical Electrical Equipment – Part 2-22
- IEC 61000-4-2 Ed. 2.0 b: Electromagnetic Compatibility (EMC) – Part 4-2
- IEC 61000-4-3 Ed. 3.2 b: Electromagnetic Compatibility (EMC) – Part 4-3
- IEC 61000-4-5 Ed. 2.0 b: Electromagnetic Compatibility (EMC) – Part 4-5
- IEC 62304 Ed. 1.0 b: Medical Device Software Life Cycle Processes
- IEC 62366 Ed. 1.0 b: Application of Usability Engineering to Medical Devices
- IEC/TR 60878 Ed. 2.0 b: Graphical Symbols for Electrical Equipment

ISO
- ISO 10993-12: Biological Evaluation – Part 12
- ISO 14155: Good Clinical Practice
- ISO 15223-1: Symbols to be Used with Medical Device Labels – Part 1
- ISO 15223-2: Symbols to be Used with Medical Device Labels
- ISO 25539-2: Cardiovascular Implants – Part 2: Vascular Stents
ISO 594-1: Conical Fittings for Syringes, Needles and Other Medical Equipment – Part 1
ISO 594-2: Conical Fittings for Syringes, Needles and Other Medical Equipment – Part 2
ISO/IEC 17025: Competence of Testing and Calibration Laboratories

Product sets

AAMI
- AAMI Electromedical Equipment
- AAMI General and Miscellaneous
- AAMI Product Set

ASHRAE
- ASHRAE Product Set

ASME
- ASME BPVC Product Set

ASTM
- ASTM Current Product Set
- ASTM Section 12 – Health Care Product Set
- ASTM Volume 13.01 – Medical Devices; Emergency Medical Services

CGA
- CGA Product Set

CLSI
- CLSI Product Set

ICC
- ICC Current Product Set

ISEA
- ISEA Product Set
- ISPE Product Set

ISO
- 01.040.03: Sociology
- 01.040.11: Health Care Technology
- 01.040.25: Manufacturing Engineering
- 01.040.31: Electronics
- 01.070: Color Coding