



Standards & regulatory analysis

Requirements that inform a medical device investigation.

Scope of the review

We select standards for the intended use, device configuration, relevant hazards, market, and time period. We confirm the applicable editions, amendments, and recognition or transition dates.

Engineering and regulatory evidence

Device classification, clearance or approval, and conformity records answer different questions. None establishes the cause of an incident by itself.

Quality system requirements

FDA's Quality Management System Regulation took effect on February 2, 2026 and incorporates ISO 13485:2016. Earlier incidents may involve the previous Quality System Regulation.

Alpha Devices experience

Our work includes IEC 60601 and ISO 14971 analysis. This reference describes possible investigation scope. We confirm any specialist needs separately; inclusion does not imply certification or accredited testing under every standard.

[FDA device classification](#) | [FDA QMSR](#)



Safety and essential performance

IEC 60601-1

Basic safety and essential performance of medical electrical equipment. Electrical, mechanical, thermal, and system-level safeguards. [Official reference](#)

IEC 60601-1-2

Electromagnetic compatibility and disturbances. Emissions, immunity, intended environment, and performance during disturbance. [Official reference](#)

IEC 60601-1-6

Usability of medical electrical equipment. Safety-related interaction with controls and interfaces. [Official reference](#)

IEC 60601-1-8

Medical electrical alarm systems. Alarm conditions, signals, priorities, and distributed alarm behavior. [Official reference](#)

IEC 60601-1-10

Physiologic closed-loop controllers. Performance and safeguards of physiologic feedback control. [Official reference](#)

IEC 60601-1-11

Medical electrical equipment in the home healthcare environment. Environmental and user conditions specific to intended use. [Official reference](#)

IEC 60601-1-12

Medical electrical equipment in emergency medical services. Environmental and operating requirements for emergency use. [Official reference](#)

References reviewed September 2026. Confirm the applicable edition and full text for each investigation.



Design, software, and quality

ISO 14971 / ISO/TR 24971

Medical device risk management and supporting guidance. Hazards, risk controls, residual risk, and production or postproduction information. [ISO 14971](#) | [ISO/TR 24971](#)

ISO 13485

Medical device quality management systems. Design and development, verification, validation, complaints, and corrective action records. [Official reference](#)

IEC 62304

Medical device software life-cycle processes. Software requirements, architecture, testing, change control, and problem resolution. [Official reference](#)

IEC 62366-1

Usability engineering for medical devices. Safety-related use scenarios, interface characteristics, and use errors. [Official reference](#)

IEC 81001-5-1

Security activities in the health-software life cycle. Security-related development and maintenance evidence where relevant. [Official reference](#)

References reviewed September 2026. Confirm the applicable edition and full text for each investigation.



Device-specific standards

ISO 80601-2-12

Critical-care ventilator safety and essential performance. Therapy delivery, alarms, and essential performance in the applicable environment. [Official reference](#)

ISO 80601-2-72

Home ventilators for ventilator-dependent patients. Therapy delivery, essential performance, and home-use conditions. [Official reference](#)

IEC 60601-2-35

Heating devices using blankets, pads, and mattresses. Temperature and heating safeguards. Replaced IEC 80601-2-35 in 2020; older editions may matter to historical devices. [Official reference](#)

IEC 80601-2-52

Medical beds for adults. Mechanical and electrical safety. The 2026 publication replaced IEC 60601-2-52; assess the historical edition separately. [Official reference](#)

IEC 60601-2-2

High-frequency surgical equipment and accessories. Electrosurgical performance and energy-related hazards; not a general standard for all surgical tools. [Official reference](#)

IEC 60601-2-24

Infusion pumps and controllers. Delivery performance and alarms. Its scope excludes extracorporeal blood-circulation devices. [Official reference](#)

References reviewed September 2026. Confirm the applicable edition and full text for each investigation.



Materials, interfaces, and labeling

ISO 10993 series

Biological evaluation of medical devices. Material-contact risks, chemical characterization, and biological-safety evidence. Part selection depends on contact type and duration. [Official reference](#)

ISO 18562 series

Biocompatibility of breathing-gas pathways. Emissions and pathway-material risks. Distinguish device emissions from contaminants entering from outside. [Official reference](#)

ISO 80369 series

Small-bore healthcare connectors. Connection performance and misconnection hazards; select the application-specific part. [Official reference](#)

ISO 5356 / ISO 5367

Conical respiratory connectors and breathing sets. Interface geometry, circuit components, connection, and breathing-tube performance. [ISO 5367](#) | [ISO 5356-1](#)

ISO 15223-1

Symbols used with manufacturer-supplied information. Interpretation and consistency of labels and accompanying symbols. [Official reference](#)

ISO 20417

Information supplied by the device manufacturer. Identification, labeling, instructions, and accompanying information; confirm the applicable edition. [Official reference](#)

References reviewed September 2026. Confirm the applicable edition and full text for each investigation.



Processing and sterile barriers

ISO 17664 series

Manufacturer information for device processing. Cleaning, disinfection, and sterilization instructions appropriate to device classification and use. [ISO 17664-1](#)

ISO 11135

Ethylene-oxide sterilization. Development, validation, and routine process control. [ISO 11135](#)

ISO 11137 series

Radiation sterilization. Process validation, dose establishment, and routine controls. [ISO 11137-1](#)

ISO 17665

Moist-heat sterilization. Process definition, validation, and ongoing control. [Official reference](#)

ISO 11607-1 / -2

Packaging for terminally sterilized devices. Sterile-barrier systems and validation of forming, sealing, and assembly processes. [ISO 11607-1](#) | [ISO 11607-2](#)

ISO 11737 series / ISO 14937

Microbiological methods and general sterilization-process requirements. Review of bioburden, sterilization studies, and process-validation evidence. [ISO 11737-1](#) | [ISO 14937](#)

References reviewed September 2026. Confirm the applicable edition and full text for each investigation.
