Standard Organistion	*Reference*	*title*	*Type*	**topic**
ASTM	**ASTM D4169**	Standard Practice for Performance Testing of Shipping Containers and Systems.	Guidance	testing
ASTM	**ASTM D4332**	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing	Guidance	testing
ASTM	**ASTM D7386**	Standard Practice for Performance Testing of Packages for single parcel Delivery Systems	Guidance	testing
ASTM	**ASTM F17 - 13a**	Standard Terminology Relating to Flexible Barrier Packaging	Guidance	packaging & materials
ASTM	**ASTM F1980**	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.	Guidance	testing
ASTM	**ASTM F2097**	Standard Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products.	Guidance	testing
ASTM	**ASTM F2475**	Standard Guide for Biocompatibility Evaluation of Medical Device Packaging Materials	Guidance	biological evaluation
ASTM	**ASTM F2559/F2559M**	Standard Guide for Writing a Specification for sterilizable peel pouches	Guidance	packaging & materials
ASTM	**ASTM F2825**	Standard practice for climatic stressing of Packaging systems for Single Parcel Delivery	Guidance	testing
ASTM	**ASTM F99**	Standard Guide for Writing a Specification for flexible barrier rollstock materials	Guidance	packaging & materials
CEN	**CEN/TR 13688**	Packaging - Material recycling - Report on requirements for substances and materials to prevent a sustained impediment to recycling.	technical report	environment
CEN	**CEN/TR 13695-1**	Packaging - Requirements for measuring and verifying the four heavy metals and other dangerous substances present in packaging and their release into the environment - Part 1: Requirements for measuring and verifying the four heavy metals present in packaging.	technical report	environment
CEN	**CEN/TR 13695-2**	Packaging - Requirements for measuring and verifying the four heavy metals and other dangerous substances present in packaging, and their release into the environment - Part 2: Requirements for measuring and verifying dangerous substances present in packaging, and their release into the environment	technical report	environment
CEN	**CEN/TR 13910**	Packaging - Report on criteria and methodologies for life cycle analysis of packaging.	technical report	environment
CEN	**EN 13427**	Packaging - Requirements for the use of European Standards in the field of packaging and packaging waste.	standard	environment
CEN	**EN 13428**	Packaging — Requirements specific to manufacturing and composition — Prevention by source reduction.	standard	environment
CEN	**EN 13429**	Packaging - Reuse.	standard	environment
CEN	**EN 13430**	Packaging - Requirements for packaging recoverable by material recycling.	standard	environment
CEN	**EN 13431**	Packaging - Requirements for packaging recoverable in the form of energy recovery, including specification of minimum inferior calorific value.	standard	environment
CEN	**EN 868-10**	Packaging for terminally sterilized medical devices - Part 10: Adhesive coated nonwoven materials of polyolefines - Requirements and test methods.	standard	packaging & materials
CEN	**EN 868-2**	Packaging for terminally sterilized medical devices - Part 2: Sterilization wrap - Requirements and test methods.	standard	packaging & materials
CEN	**EN 868-3**	Packaging for terminally sterilized medical devices - Part 3: Paper for use in the manufacture of paper bags (specified in EN 868-4) and in the manufacture of pouches and reels (specified in EN 868-5) - Requirements and test methods.	standard	packaging & materials
CEN	**EN 868-4**	Packaging for terminally sterilized medical devices - Part 4: Paper bags - Requirements and test methods.	standard	packaging & materials
CEN	**EN 868-5**	Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction — Requirements and test methods.	standard	packaging & materials
CEN	**EN 868-6**	Packaging for terminally sterilized medical devices - Part 6: Paper for low temperature sterilization processes - Requirements and test methods.	standard	packaging & materials
CEN	**EN 868-7**	Packaging for terminally sterilized medical devices - Part 7: Adhesive coated paper for low temperature sterilization processes - Requirements and test methods.	standard	packaging & materials
CEN	**EN 868-8**	Packaging for terminally sterilized medical devices - Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 - Requirements and test methods.	standard	packaging & materials
CEN	**EN 868-9**	Packaging for terminally sterilized medical devices - Part 9: Uncoated nonwoven materials of polyolefines - Requirements and test	standard	packaging & materials
CEN	**EN 980**	Symbols for use in the labelling of medical devices	standard	labelling
ISO	**EN ISO 15223-1**	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements	standard	labelling
ISO	**EN ISO 14937**	Sterilization of health care products -- General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices	standard	sterilisation
ISO	**EN ISO 15225**	"Nomenclature - specification for a nomenclature system for medical devices for the purpose of regulatory data exchange"	standard	nomenclature
CEN	**EN ISO 17025**	General requirements for the competence of testing and calibration laboratories	standard	testing
ISO	**ISO 10993-1**	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process	standard	biological evaluation
ISO	**ISO 10993-10**	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization	standard	biological evaluation
ISO	**ISO 10993-11**	Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity	standard	biological evaluation
ISO	**ISO 10993-12**	Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials	standard	biological evaluation
ISO	**ISO 10993-13**	Biological evaluation of medical devices -- Part 13: Identification and quantification of degradation products from polymeric medical devices	standard	biological evaluation
ISO	**ISO 10993-16**	Biological evaluation of medical devices -- Part 16: Toxicokinetic study design for degradation products and leachables	standard	biological evaluation

ISO	**ISO 10993-17**	Biological evaluation of medical devices -- Part 17: Establishment of allowable limits for leachable substances	standard	biological evaluation
ISO	**ISO 10993-18**	Biological evaluation of medical devices -- Part 18: Chemical characterization of materials	standard	biological evaluation
ISO	**ISO 10993-2**	Biological evaluation of medical devices -- Part 2: Animal welfare requirements	standard	biological evaluation
ISO	**ISO 10993-3**	Biological evaluation of medical devices -- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	standard	biological evaluation
ISO	**ISO 10993-5**	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity	standard	biological evaluation
ISO	**ISO 10993-6**	Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation	standard	biological evaluation
ISO	**ISO 10993-7**	Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals	standard	biological evaluation
ISO	**ISO 10993-9**	Biological evaluation of medical devices -- Part 9: Framework for identification and quantification of potential degradation products	standard	biological evaluation
ISO	**ISO 11607-1:2006**	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems	standard	packaging & materials
ISO	**ISO 11607-2:2006**	Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembling processes	standard	packaging & materials
ISO	**ISO 11607-1:2006/Amd 1:2014**	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems	standard	packaging & materials
ISO	**ISO 11607-2:2006/Amd 1:2014**	Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembling processes	standard	packaging & materials
ISO	**ISO 14006**	Environmental management systems – Guidelines for incorporating ecodesign	standard	environment
ISO	**ISO 14971**	Medical devices – Application of risk management to medical devices	standard	risk management
ISO	**ISO 186**	Paper and board — Sampling to determine average quality	standard	statistics
ISO	**ISO 18601**	Packaging and the environment -- General requirements for the use of ISO standards in the field of packaging and the environment	standard	environment
ISO	**ISO 18602**	Packaging and the environment -- Optimization	standard	environment
ISO	**ISO 18603**	Packaging and the environment -- Reuse	standard	environment
ISO	**ISO 18604**	Packaging and the environment -- Material recycling	standard	environment
ISO	**ISO 18605**	Packaging and the environment -- Energy recovery	standard	environment
ISO	**ISO 18606**	Packaging and the environment -- Organic recycling	standard	environment
ISO	**ISO 187**	Paper, board and pulps -- Standard atmosphere for conditioning and testing and procedure for monitoring the atmosphere and conditioning of samples	standard	testing
ISO	**ISO 2233**	Packaging -- Complete, filled transport packages and unit loads -- Conditioning for testing	standard	testing
ISO	**ISO 22442-1**	Medical devices utilizing animal tissues and their derivatives -- Part 1: Application of risk management	standard	risk management
ISO	**ISO 2859-1**	Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection	standard	statistics
ISO	**ISO 4180**	Packaging - Complete,filles transport packages - general rules for the compilation of performance test shedules	standard	testing
ISO	**ISO 9001**	Quality management systems — Requirements	standard	quality management
ISO	**ISO/TR 16218**	Chemical recovery	standard	environment
ISO	**ISO/TR 17098**	Report on substances and materials which may impede recycling	technical report	environment
ISO	**ISO/TS 10993-19**	Part 19: Physico-chemical, morphological and topographical characterization of materials	technical specification	biological evaluation
ISO	**ISO/TS 10993-20**	Part 20: Principles and methods for immunotoxicology testing of medical devices	technical specification	biological evaluation
ISO	**ISO/TS 16775:2014**	Packaging for terminally sterilized medical devices -- Guidance on the application of ISO 11607-1 and ISO 11607-2	technical specification	packaging & materials
ISO	**ISO14040**	Environmental management -- Life cycle assessment -- Principles and framework	standard	environment
ISO	**ISO 13485**	Medical devices – Quality management systems – Requirements for regulatory purposes	standard	quality management
ISO	**ISO 18472**	Sterilization of health care products -- Biological and chemical indicators -- Test equipment	standard	indicators
ISO	**ISO 20857**	Sterilization of health care products -- Dry heat -- Requirements for the development, validation and routine control of a sterilization process for medical devices	standard	sterilisation
ISO	**ISO 25424**	Sterilization of medical devices -- Low temperature steam and formaldehyde -- Requirements for development, validation and routine control of a sterilization process for medical devices	standard	sterilisation
ISO	**ISO 11137-1**	Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	standard	sterilisation
ISO	**ISO 11137-2**	Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose	standard	sterilisation
ISO	**ISO 11137-3**	Sterilization of health care products -- Radiation -- Part 3: Guidance on dosimetric aspects	standard	sterilisation
ISO	**ISO 11138-1**	Sterilization of health care products -- Biological indicators -- Part 1: General requirements	standard	indicators
ISO	**ISO 11138-2**	Sterilization of health care products -- Biological indicators -- Part 2: Biological indicators for ethylene oxide sterilization processes	standard	indicators
ISO	**ISO 11138-3**	Sterilization of health care products -- Biological indicators -- Part 3: Biological indicators for moist heat sterilization processes	standard	indicators
ISO	**ISO 11138-4**	Sterilization of health care products -- Biological indicators -- Part 4: Biological indicators for dry heat sterilization processes	standard	indicators
ISO	**ISO 11138-5**	Sterilization of health care products -- Biological indicators -- Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes	standard	indicators
ISO	**ISO/TS 11139**	Sterilization of health care products -- Vocabulary	technical specification	vocabulary

ISO	**ISO 11140-1**	Sterilization of health care products -- Chemical indicators -- Part 1: General requirements	standard	indicators
ISO	**ISO 11140-3**	Sterilization of health care products -- Chemical indicators -- Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test	standard	indicators
ISO	**ISO 11140-4**	Sterilization of health care products -- Chemical indicators -- Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration	standard	indicators
ISO	**ISO 11140-5**	Sterilization of health care products -- Chemical indicators -- Part 5: Class 2 indicators for Bowie and Dick-type air removal tests	standard	indicators
ISO	**ISO 11737-1**	Sterilization of medical devices -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products	standard	bioburden
ISO	**ISO 11737-2**	Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	standard	sterility testing
ISO	**ISO/TS 13004**	Sterilization of health care products -- Radiation -- Substantiation of selected sterilization dose: Method VDmaxSD	technical specification	sterilisation
ISO	**ISO 13408-1**	Aseptic processing of health care products -- Part 1: General requirements	standard	Aseptic processing
ISO	**ISO 13408-2**	Aseptic processing of health care products -- Part 2: Filtration	standard	Aseptic processing
ISO	**ISO 13408-6**	Aseptic processing of health care products -- Part 6: Isolator systems	standard	Aseptic processing
ISO	**ISO 13408-7**	Aseptic processing of health care products -- Part 7: Alternative processes for medical devices and combination products	standard	Aseptic processing
ISO	**ISO 14160**	Sterilization of health care products -- Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives -- Requirements for characterization, development, validation and routine control of a sterilization process for medical devices	standard	sterilisation
ISO	**ISO 14161**	Sterilization of health care products -- Biological indicators -- Guidance for the selection, use and interpretation of results	standard	indicators
ISO	**ISO 14937**	Sterilization of health care products -- General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices	standard	sterilisation
ISO	**ISO 15882**	Sterilization of health care products -- Chemical indicators -- Guidance for selection, use and interpretation of results	standard	indicators
ISO	**ISO 17664**	Sterilization of medical devices -- Information to be provided by the manufacturer for the processing of resterilizable medical devices	standard	reprocessing
ISO	**ISO 17665-1**	Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	standard	sterilisation
ISO	**ISO/TS 17665-2**	Sterilization of health care products -- Moist heat -- Part 2: Guidance on the application of ISO 17665-1	technical specification	sterilisation
ISO	**ISO/TS 17665-3**	Sterilization of health care products -- Moist heat -- Part 3: Guidance on the designation of a medical device to a product family and processing category for steam sterilization	technical specification	sterilisation
ISO	**ISO 11135**	Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices	standard	sterilisation