

فهرست استانداردهای هماهنگ با الزامات اساسی

به تاریخ ۱۳۸۷/۱/۲۸

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<http://www.iso.org>

<http://www.iec.ch>

<http://ec.europa.eu/enterprise/newapproach/standardization/harmstds/reflist/meddevic.html>

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

شماره	عنوان	استاندارد قبلی	تاریخ جایگزینی
ISO ۱۳۴۸۵:۲۰۰۳	Medical devices - Quality management systems - Requirements for regulatory purposes		
ISO ۱۴۹۷۱:۲۰۰۷	Medical devices - Application of risk management to medical devices		
ISO ۱۴۱۵۵-۱:۲۰۰۳	Clinical investigation of medical devices for human subjects - Part ۱: General requirements		
ISO ۱۴۱۵۵-۲:۲۰۰۳	Clinical investigation of medical devices for human subjects - Part ۲: Clinical investigation plans		
ISO ۱۵۲۲۵:۲۰۰۰ + A۱:۲۰۰۴	Nomenclature - Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange		
ISO ۱۰۹۹۳-۱:۲۰۰۳	Biological evaluation of medical devices - Part ۱: Evaluation and testing		
ISO ۱۰۹۹۳-۳:۲۰۰۳	Biological evaluation of medical devices - Part ۳: Tests for genotoxicity, carcinogenicity and reproductive toxicity		
ISO ۱۰۹۹۳-۴:۲۰۰۲ + A۱:۲۰۰۶	Biological evaluation of medical devices - Part ۴: Selection of tests for interactions with blood		
ISO ۱۰۹۹۳-۵:۱۹۹۹	Biological evaluation of medical devices - Part ۵: Tests for in vitro cytotoxicity		
ISO ۱۰۹۹۳-۶:۲۰۰۷	Biological evaluation of medical devices - Part ۶: Tests for local effects after implantation		
ISO ۱۰۹۹۳-۹:۱۹۹۹	Biological evaluation of medical devices - Part ۹: Framework for identification and quantification of potential degradation products		
ISO ۱۰۹۹۳-۱۰:۲۰۰۲ + A۱:۲۰۰۶	Biological evaluation of medical devices - Part ۱۰: Tests for irritation and delayed-type hypersensitivity		
ISO ۱۰۹۹۳-۱۱:۲۰۰۶	Biological evaluation of medical devices - Part ۱۱: Tests for systemic toxicity		
ISO ۱۰۹۹۳-۱۲:۲۰۰۴	Biological evaluation of medical devices - Part ۱۲: Sample preparation and reference materials		
ISO ۱۰۹۹۳-۱۳:۱۹۹۸	Biological evaluation of medical devices - Part ۱۳: Identification and quantification of degradation products from polymeric medical devices		
ISO ۱۰۹۹۳-۱۴:۲۰۰۱	Biological evaluation of medical devices - Part ۱۴: Identification and quantification of degradation products from ceramics		

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ISO ۱۰۹۹۳-۱۶:۱۹۹۷	Biological evaluation of medical devices - Part ۱۶: Toxicokinetic study design for degradation products and leachables		
ISO ۱۰۹۹۳-۱۷:۲۰۰۲	Biological evaluation of medical devices - Part ۱۷: Establishment of allowable limits for leachable substances		
ISO ۱۰۹۹۳-۱۸:۲۰۰۵	Biological evaluation of medical devices - Part ۱۸: Chemical characterization of materials		
ISO ۱۱۱۳۵-۱:۲۰۰۷	Sterilization of health care products - Ethylene oxide - Part ۱: Requirements for development, validation and routine control of a sterilization process for medical devices		
ISO ۱۱۱۳۷-۱:۲۰۰۶	Sterilization of health care products - Radiation - Part ۱: Requirements for development, validation and routine control of a sterilization process for medical devices		
ISO ۱۱۱۳۷-۲:۲۰۰۶	Sterilization of health care products - Radiation - Part ۲: Establishing the sterilization dose		
ISO ۱۱۱۳۸-۲:۲۰۰۶	Sterilization of health care products - Biological indicators - Part ۲: Biological indicators for ethylene oxide sterilization processes		
ISO ۱۱۱۳۸-۳:۲۰۰۶	Sterilization of health care products - Biological indicators - Part ۳: Biological indicators for moist heat sterilization processes		
ISO ۱۱۱۴۰-۱:۲۰۰۵	Sterilization of health care products - Chemical indicators - Part ۱: General requirements		
ISO ۱۱۱۴۰-۳:۲۰۰۷	Sterilization of health care products - Chemical indicators - Part ۳: Class ۲ indicator systems for use in the Bowie and Dick-type steam penetration test		
ISO ۴۰۷۴:۲۰۰۲	Natural latex rubber condoms - Requirements and test methods		
ISO ۴۱۳۵:۲۰۰۱	Anaesthetic and respiratory equipment - Vocabulary		
ISO ۵۳۵۶-۱:۲۰۰۴	Anaesthetic and respiratory equipment - Conical connectors - Part ۱: Cones and sockets		
ISO ۵۳۵۶-۲:۲۰۰۶	Anaesthetic and respiratory equipment - Conical connectors - Part ۲: Screw-threaded weight-bearing connectors		
ISO ۵۳۶۶-۱:۲۰۰۰	Anaesthetic and respiratory equipment - Tracheostomy tubes - Part ۱: Tubes and connectors for use in adults		
ISO ۵۸۴۰:۲۰۰۵	Cardiovascular implants - Cardiac valve prostheses		
ISO ۷۱۹۷:۲۰۰۶	Neurosurgical implants - Sterile, single-use hydrocephalus shunts and components		
ISO ۷۱۹۸:۱۹۹۸	Cardiovascular implants - Tubular vascular prostheses		
ISO ۷۳۷۶:۲۰۰۳	Anaesthetic and respiratory equipment - Laryngoscopes for tracheal intubation		
ISO ۷۳۹۶-۱:۲۰۰۷	Medical gas pipeline systems - Part ۱: Pipeline systems for compressed medical gases and vacuum		
ISO ۷۳۹۶-۲:۲۰۰۷	Medical gas pipeline systems - Part ۲: Anaesthetic gas scavenging disposal systems		
ISO ۷۴۳۹:۲۰۰۲	Copper-bearing intra-uterine contraceptive devices -		

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	Requirements, tests		
ISO ۷۸۸۶-۳:۲۰۰۵	Sterile hypodermic syringes for single use - Part ۳: Auto-disable syringes for fixed-dose immunization		
ISO ۷۸۸۶-۴:۲۰۰۶	Sterile hypodermic syringes for single use - Part ۴: Syringes with re-use prevention feature		
ISO ۸۱۸۵:۲۰۰۷	Respiratory tract humidifiers for medical use - Particular requirements for respiratory humidification systems		
ISO ۸۳۵۹:۱۹۹۶	Oxygen concentrators for medical use - Safety requirements		
ISO ۸۵۳۶-۴:۲۰۰۷	Infusion equipment for medical use - Part ۴: Infusion sets for single use, gravity feed		
ISO ۸۸۳۵-۲:۲۰۰۷	Inhalational anaesthesia systems - Part ۲: Anaesthetic breathing systems		
ISO ۸۸۳۵-۳:۲۰۰۷	Inhalational anaesthesia systems - Part ۳: Transfer and receiving systems of active anaesthetic gas scavenging systems		
ISO ۸۸۳۵-۴:۲۰۰۴	Inhalational anaesthesia systems - Part ۴: Anaesthetic vapour delivery devices		
ISO ۸۸۳۵-۵:۲۰۰۴	Inhalational anaesthesia systems - Part ۵: Anaesthesia ventilators		
ISO ۹۳۶۰-۱:۲۰۰۰	Anaesthetic and respiratory equipment - Heat and moisture exchangers (HMEs) for humidifying respired gases in humans - Part ۱: HMEs for use with minimum tidal volumes of ۲۵۰ ml		
ISO ۹۳۶۰-۲:۲۰۰۱	Anaesthetic and respiratory equipment - Heat and moisture exchangers (HMEs) for humidifying respired gases in humans - Part ۲: HMEs for use with tracheostomized patients having minimum tidal volumes of ۲۵۰ ml		
ISO ۹۷۱۳:۲۰۰۲	Neurosurgical implants - Self-closing intracranial aneurysm clips		
ISO ۹۹۱۹:۲۰۰۵	Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use		
ISO ۱۰۰۷۹-۱:۱۹۹۹	Medical suction equipment - Part ۱: Electrically powered suction equipment - Safety requirements		
ISO ۱۰۰۷۹-۲:۱۹۹۹	Medical suction equipment - Part ۲: Manually powered suction equipment		
ISO ۱۰۰۷۹-۳:۱۹۹۹	Medical suction equipment - Part ۳: Suction equipment powered from vacuum or pressure source		
ISO ۱۰۳۲۸:۲۰۰۶	Prosthetics - Structural testing of lower-limb prostheses - Requirements and test methods		
ISO ۱۰۵۲۴-۱:۲۰۰۶	Pressure regulators for use with medical gases - Part ۱: Pressure regulators and pressure regulators with flow-metering devices		
ISO ۱۰۵۲۴-۲:۲۰۰۵	Pressure regulators for use with medical gases - Part ۲: Manifold and line pressure regulators		
ISO ۱۰۵۲۴-۳:۲۰۰۵	Pressure regulators for use with medical gases - Part ۳: Pressure regulators integrated with cylinder valves		
ISO ۱۰۵۳۵:۲۰۰۶	Hoists for the transfer of disabled persons - Requirements and test methods		
ISO ۱۰۵۵۵-۱:۱۹۹۶ + A1:۱۹۹۹ +	Sterile, single-use intravascular catheters - Part ۱: General requirements		

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A2:2004			
ISO 10651-2:2004	Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 2: Home care ventilators for ventilator-dependent patients		
ISO 10651-4:2002	Lung ventilators - Part 4: Particular requirements for operator-powered resuscitators		
ISO 10651-6:2004	Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 6: Home-care ventilatory support devices		
ISO 11197:2004	Medical supply units		
ISO 11607-1:2006	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems		
ISO 11607-2:2006	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes		
ISO 11737-1:2006	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products		
ISO 11810-2:2007	Lasers and laser-related equipment - Test method and classification for the laser-resistance of surgical drapes and/or patient-protective covers - Part 2: Secondary ignition		
ISO 11979-8:2006	Ophthalmic implants - Intraocular lenses - Part 8: Fundamental requirements		
ISO 11990:2003	Optics and optical instruments - Lasers and laser-related equipment - Determination of laser resistance of tracheal tube shafts		
ISO 14160:1998	Sterilization of single-use medical devices incorporating materials of animal origin - Validation and routine control of sterilization by liquid chemical sterilants		
ISO 14408:2005	Tracheal tubes designed for laser surgery - Requirements for marking and accompanying information		
ISO 14534:2002	Ophthalmic optics - Contact lenses and contact lens care products - Fundamental requirements		
ISO 14602:1998	Non-active surgical implants - Implants for Osteosynthesis - Particular requirements		
ISO 14607:2007	Non-active surgical implants - Mammary implants - Particular requirements		
ISO 14630:2005	Non-active surgical implants - General requirements		
ISO 14889:2003	Ophthalmic optics - Spectacle lenses - Fundamental requirements for uncut finished lenses		
ISO 14937:2000	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		
ISO 15001:2004	Anaesthetic and respiratory equipment - Compatibility with oxygen		
ISO 15004-1:2006	Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments		

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ISO ۱۵۷۴۷:۲۰۰۳	Plastics containers for intravenous injection		
ISO ۱۵۸۸۲:۲۰۰۳	Chemical indicators - Guidance on the selection, use, and interpretation of results		
ISO ۱۵۸۸۳-۱:۲۰۰۶	Washer-disinfectors - Part ۱: General requirements, terms and definitions and tests		
ISO ۱۵۸۸۳-۲:۲۰۰۶	Washer-disinfectors - Part ۲: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.		
ISO ۱۵۸۸۳-۳:۲۰۰۶	Washer-disinfectors - Part ۳: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers		
ISO ۱۶۲۰۱:۲۰۰۶	Technical aids for disabled persons - Environmental control systems for daily living		
ISO ۱۷۵۱۰-۱:۲۰۰۲	Sleep apnoea breathing therapy - Part ۱: Sleep apnoea breathing therapy devices		
ISO ۱۷۵۱۰-۲:۲۰۰۳	Sleep apnoea breathing therapy - Part ۲: Masks and application accessories		
ISO ۱۷۶۶۴:۲۰۰۴	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices		
ISO ۱۷۶۶۵-۱:۲۰۰۶	Sterilization of health care products - Moist heat - Part ۱: Requirements for the development, validation and routine control of a sterilization process for medical devices		
ISO ۱۸۷۷۷:۲۰۰۵	Transportable liquid oxygen systems for medical use - Particular requirements		
ISO ۱۸۷۷۸:۲۰۰۵	Respiratory equipment - Infant monitors - Particular requirements		
ISO ۱۸۷۷۹:۲۰۰۵	Medical devices for conserving oxygen and oxygen mixtures - Particular requirements		
ISO ۱۹۰۵۴:۲۰۰۶	Rail systems for supporting medical equipment		
ISO ۲۱۱۷۱:۲۰۰۶	Medical gloves - Determination of removable surface powder		
ISO ۲۱۵۳۴:۲۰۰۷	Non-active surgical implants - Joint replacement implants - Particular requirements		
ISO ۲۱۵۳۵:۲۰۰۷	Non-active surgical implants - Joint replacement implants - Specific requirements for hip-joint replacement implants		
ISO ۲۱۵۳۶:۲۰۰۷	Non-active surgical implants - Joint replacement implants - Specific requirements for knee-joint replacement implants		
ISO ۲۱۶۴۷:۲۰۰۴	Medical electrical equipment - Particular requirements for the basic safety and essential performance of respiratory gas monitors		
ISO ۲۱۶۴۹:۲۰۰۶	Needle-free injectors for medical use - Requirements and test methods		
ISO ۲۱۹۶۹:۲۰۰۶	High-pressure flexible connections for use with medical gas systems		
ISO ۲۲۵۲۳:۲۰۰۶	External limb prostheses and external orthoses - Requirements and test methods		
ISO ۲۲۶۱۰:۲۰۰۶	Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment - Test method to determine the resistance		

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	to wet bacterial penetration		
ISO ۲۲۶۱۲:۲۰۰۵	Clothing for protection against infectious agents - Test method for resistance to dry microbial penetration		
ISO ۲۲۶۷۵:۲۰۰۶	Prosthetics - Testing of ankle-foot devices and foot units - Requirements and test methods		
ISO ۲۳۷۴۷:۲۰۰۷	Anaesthetic and respiratory equipment - Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans		
ISO ۷۷۴۰:۱۹۸۵	Instruments for surgery, scalpels with detachable blades, fitting dimensions		
EN ۹۸۰:۲۰۰۳	Graphical symbols for use in the labelling of medical devices		
EN ۱۰۴۱:۱۹۹۸	Information supplied by the manufacturer with medical devices		
EN ۲۸۵:۲۰۰۶	Sterilization - Steam sterilizers - Large sterilizers		
EN ۳۷۵:۲۰۰۱	Information supplied by the manufacturer with in vitro diagnostic reagents for professional use		
EN ۳۷۶:۲۰۰۲	Information supplied by the manufacturer with in vitro diagnostic reagents for self-testing		
EN ۴۵۵-۱:۲۰۰۰	Medical gloves for single use - Part ۱: Requirements and testing for freedom from holes		
EN ۴۵۵-۲:۲۰۰۰	Medical gloves for single use - Part ۲: Requirements and testing for physical properties (including Technical Corrigendum ۱:۱۹۹۶)		
EN ۴۵۵-۳:۲۰۰۶	Medical gloves for single use - Part ۳: Requirements and testing for biological evaluation		
EN ۵۵۶-۱:۲۰۰۱ + AC:۲۰۰۶	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part ۱: Requirements for terminally sterilized medical devices		
EN ۵۵۶-۲:۲۰۰۳	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part ۲: Requirements for aseptically processed medical devices		
EN ۵۹۱:۲۰۰۱	Instructions for use for in vitro diagnostic instruments for professional use		
EN ۵۹۲:۲۰۰۲	Instructions for use for in vitro diagnostic instruments for self-testing		
EN ۷۳۷-۱:۱۹۹۸	Medical gas pipeline systems - Part ۱: Terminal units for compressed medical gases and vacuum		
EN ۷۳۷-۴:۱۹۹۸	Medical gas pipeline systems - Part ۴: Terminal units for anaesthetic gas scavenging systems		
EN ۷۳۸-۴:۱۹۹۸ + A۱:۲۰۰۲	Pressure regulators for use with medical gases - Part ۴: Low-pressure regulators intended for incorporation into medical equipment		
EN ۷۳۹:۱۹۹۸ + A۱:۲۰۰۲	Low-pressure hose assemblies for use with medical gases		
EN ۷۹۴-۱:۱۹۹۷ + A۱:۲۰۰۰	Lung ventilators - Part ۱: Particular requirements for critical care ventilators		
EN ۷۹۴-۳:۱۹۹۸ + A۱:۲۰۰۵	Lung ventilators - Part ۳: Particular requirements for emergency and transport ventilators		
EN ۱۰۶۰-۱:۱۹۹۵	Non-invasive sphygmomanometers - Part ۱: General		

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+ A1:۲۰۰۲	requirements		
EN ۱۰۶۰-۲:۱۹۹۵	Non-invasive sphygmomanometers - Part ۲: Supplementary requirements for mechanical sphygmomanometers		
EN ۱۰۶۰-۳:۱۹۹۷ + A1:۲۰۰۵	Non-invasive sphygmomanometers - Part ۳: Supplementary requirements for electro-mechanical blood pressure measuring systems		
EN ۱۰۶۰-۴:۲۰۰۴	Non-invasive sphygmomanometers - Part ۴: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers		
EN ۱۰۸۹-۳:۲۰۰۴	Transportable gas cylinders - Gas cylinder identification (excluding LPG) - Part ۳: Colour coding		
EN ۱۲۸۰-۱:۱۹۹۷ + A1:۲۰۰۰	Agent specific filling systems for anaesthetic vaporizers - Part ۱: Rectangular keyed filling systems		
EN ۱۲۸۲-۲:۲۰۰۵	Tracheostomy tubes - Part ۲: Paediatric tubes (ISO ۵۳۶۶-۳:۲۰۰۱), modified)		
EN ۱۴۲۲:۱۹۹۷	Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods		
EN ۱۶۱۸:۱۹۹۷	Catheters other than intravascular catheters - Test methods for common properties		
EN ۱۶۳۹:۲۰۰۴	Dentistry - Medical devices for dentistry - Instruments		
EN ۱۶۴۰:۲۰۰۴	Dentistry - Medical devices for dentistry - Equipment		
EN ۱۶۴۱:۲۰۰۴	Dentistry - Medical devices for dentistry - Materials		
EN ۱۶۴۲:۲۰۰۴	Dentistry - Medical devices for dentistry - Dental implants		
EN ۱۷۰۷:۱۹۹۶	Conical fittings with a ۶ % (Luer) taper for syringes, needles and certain other medical equipment - Lock fittings		
EN ۱۷۸۲:۱۹۹۸	Tracheal tubes and connectors		
EN ۱۸۲۰:۲۰۰۵	Anaesthetic reservoir bags (ISO ۵۳۶۲:۲۰۰۰, modified)		
EN ۱۸۶۵:۱۹۹۹	Specifications for stretchers and other patient handling equipment used in road ambulances		
EN ۱۹۷۰:۲۰۰۰ + A1:۲۰۰۵	Adjustable beds for disabled persons - Requirements and test methods		
EN ۱۹۸۵:۱۹۹۸	Walking aids - General requirements and test methods		
EN ۱۲۰۰۶-۲:۱۹۹۸	Non active surgical implants - Particular requirements for cardiac and vascular implants - Part ۲: Vascular prostheses including cardiac valve conduits		
EN ۱۲۰۰۶-۳:۱۹۹۸	Non active surgical implants - Particular requirements for cardiac and vascular implants - Part ۳: Endovascular devices		
EN ۱۲۰۱۱:۱۹۹۸	Instrumentation to be used in association with non-active surgical implants - General requirements		
EN ۱۲۱۸۲:۱۹۹۹	Technical aids for disabled persons - General requirements and test methods		
EN ۱۲۳۲۲:۱۹۹۹ + A1:۲۰۰۱	In vitro diagnostic medical devices - Culture media for microbiology - Performance criteria for culture media		
EN ۱۲۳۴۲:۱۹۹۸	Breathing tubes intended for use with anaesthetic apparatus and ventilators		
EN ۱۲۴۴۲-۱:۲۰۰۰	Animal tissues and their derivatives utilized in the manufacture of medical devices - Part ۱: Analysis and		

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	management of risk		
EN ۱۲۴۴۲-۲:۲۰۰۰	Animal tissues and their derivatives utilized in the manufacture of medical devices - Part ۲: Controls on sourcing, collection and handling		
EN ۱۲۴۴۲-۳:۲۰۰۰	Animal tissues and their derivatives utilized in the manufacture of medical devices - Part ۳: Validation of the elimination and/or inactivation of viruses and transmissible agents		
EN ۱۲۴۷۰-۱:۲۰۰۰	Clinical thermometers - Part ۱: Metallic liquid-in-glass thermometers with maximum device		
EN ۱۲۴۷۰-۲:۲۰۰۰	Clinical thermometers - Part ۲: Phase change type (dot matrix) thermometers		
EN ۱۲۴۷۰-۳:۲۰۰۰	Clinical thermometers - Part ۳: Performance of compact electrical thermometers (non-predictive and predictive) with maximum device		
EN ۱۲۴۷۰-۴:۲۰۰۰	Clinical thermometers - Part ۴: Performance of electrical thermometers for continuous measurement		
EN ۱۲۴۷۰-۵:۲۰۰۳	Clinical thermometers - Part ۵: Performance of infrared ear thermometers (with maximum device)		
EN ISO ۱۲۸۷۰:۲۰۰۴ + AC:۲۰۰۵	Ophthalmic optics - Spectacle frames - Requirements and test methods (ISO ۱۲۸۷۰:۲۰۰۴)		
EN ۱۳۰۱۴:۲۰۰۰	Connections for gas sampling tubes to anaesthetic and respiratory equipment		
EN ۱۳۰۶۰:۲۰۰۴	Small steam sterilizers		
EN ۱۳۲۲۰:۱۹۹۸	Flow-metering devices for connection to terminal units of medical gas pipeline systems		
EN ۱۳۲۲۸-۱:۲۰۰۱	Breathing system filters for anaesthetic and respiratory use - Part ۱: Salt test method to assess filtration performance		
EN ۱۳۲۲۸-۲:۲۰۰۲ + A1:۲۰۰۳	Breathing system filters for anaesthetic and respiratory use - Part ۲: Non-filtration aspects		
EN ۱۳۵۴۴-۱:۲۰۰۷	Respiratory therapy equipment - Part ۱: Nebulizing systems and their components		
EN ۱۳۵۴۴-۲:۲۰۰۲	Respiratory therapy equipment - Part ۲: Tubing and connectors		
EN ۱۳۵۴۴-۳:۲۰۰۱	Respiratory therapy equipment - Part ۳: Air entrainment devices		
EN ۱۳۶۲۴:۲۰۰۳	Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants for instruments used in the medical area - Test method and requirements (phase ۲, step ۱)		
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IEC ۶۰۶۰۱-۲-۱:۱۹۹۸ + A1:۲۰۰۲	Medical electrical equipment - Part ۲-۱: Particular requirements for the safety of electron accelerators in the range of ۱ MeV to ۵۰ MeV		
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AAMI EC۱۱:۱۹۹۱	Diagnostic electrocardiographic devices		
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AAMI ST۲۴:۲۰۰۵	Automatic, general purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities, ۳ed.		
AAMI ST۳۵:۲۰۰۳	Safe handling and biological decontamination of reusable medical devices in health care facilities and in nonclinical settings		
AAMI ST۴۰:۲۰۰۴	Table-top dry heat (heated air) sterilization and sterility assurance in dental and medical facilities, ۲ed.		
AAMI ST۴۱: ۲۰۰۵	Ethylene Oxide Sterilization in Health Care Facilities: Safety and Effectiveness		
AAMI ST۵۰:۲۰۰۴	Dry heat (heated air) sterilizers		
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AAMI ST۵۸:۲۰۰۵	Chemical sterilization and high-level disinfection in health care facilities		
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AAMI ST۶۷:۲۰۰۳	Sterilization of health care products - Requirements for products labeled 'sterile' ۱st edition		
AAMI ST۷۲:۲۰۰۱	Bacterial endotoxins - Test methodologies, routine monitoring, and alternatives to batch testing		
AAMI ST۷۷:۲۰۰۶	Containment devices for reusable medical device sterilization		
AAMI ST۷۹:۲۰۰۶	Comprehensive guide to steam sterilization and sterility assurance in health care facilities		
AAMI ST۸۱:۲۰۰۴	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable devices		