

FDA Recognized Consensus Standards List 057

Date of Recognition	Specialty Task Group	Recognition Number	Standard Developing Organization	Standard Designation Number/Date	Title of Standard
12/20/21	Cardiovascular	3-172	AAMI	TIR42:2021	Evaluation of Particulates Associated with Vascular Medical Devices
12/20/21	Ophthalmic	10-127	ANSI	Z80.21-2020	American National Standard for Ophthalmics - Instruments - General-Purpose Clinical Visual Acuity Charts
12/20/21	Ophthalmic	10-130	ANSI	Z80.36-2021	American National Standard for Ophthalmics - Light Hazard Protection for Ophthalmic Instruments
12/20/21	Software/Informatics	13-120	ANSI AAMI	2700-1:2019	Medical Devices and Medical Systems - Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) - Part 1: General requirements and conceptual model
12/20/21	Dental/ENT	4-285	ANSI ADA	Standard No. 37-1986 (R2020)	Dental Abrasive Powders
12/20/21	Dental/ENT	4-286	ANSI ADA	Standard No. 87-1995 (R2014)	Dental Impression Trays
12/20/21	Dental/ENT	4-287	ANSI ADA	Standard No. 116-2020	Oral Rinses (Modified adoption of ISO 16408:2015 Dentistry Oral Care Products - Oral Rinses)
12/20/21	General II (ES/EMC)	19-44	ANSI IEEE	C63.24-2021	American National Standard - Recommended Practice for In Situ RF Immunity Evaluation of Electronic Devices and Systems
12/20/21	General II (ES/EMC)	19-41	ANSI UL	61010-1 3rd Ed dated May 12 2012 with revision through July 19 2019	Standard for Safety for Electrical Equipment For Measurement Control and Laboratory Use; Part 1: General Requirements
12/20/21	Cardiovascular	3-171	ASTM	F2514-21	Standard Guide for Finite Element Analysis (FEA) of Metallic Vascular Stents Subjected to Uniform Radial Loading
12/20/21	Materials	8-574	ASTM	F2820-12(2021)e1	Standard Specification for Polyetherketoneketone (PEKK) Polymers for Surgical Implant Applications
12/20/21	Materials	8-575	ASTM	F3160-21	Standard Guide for Metallurgical Characterization of Absorbable Metallic Materials for Medical Implants
12/20/21	Materials	8-576	ASTM	F451-21	Standard Specification for Acrylic Bone Cement
12/20/21	Materials	8-578	ASTM	F2848-21	Standard Specification for Medical-Grade Ultra-High Molecular Weight Polyethylene Yarns
12/20/21	Cardiovascular	3-177	ASTM	F2606 - 08 (Reapproved 2021)	Standard Guide for Three-Point Bending of Balloon-Expandable Vascular Stents and Stent Systems
12/20/21	Cardiovascular	3-178	ASTM	F3067 - 14 (Reapproved 2021)	Standard Guide for Radial Loading of Balloon-Expandable and Self-Expanding Vascular Stents
12/20/21	Cardiovascular	3-179	ASTM	F3172 - 15 (Reapproved 2021)	Standard Guide for Design Verification Device Size and Sample Size Selection for Endovascular Devices
12/20/21	Ophthalmic	10-128	ASTM	D882-18	Standard Test Methods for Tensile Properties of Thin Plastic Sheeting
12/20/21	Ophthalmic	10-129	ASTM	D790-17	Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials
12/20/21	Nanotechnology	18-20	ASTM	E3275-21	Standard Guide for Visualization and Identification of Nanomaterials in Biological and Nonbiological Matrices Using Darkfield Microscopy/Hyperspectral Imaging (DFM/HSI) Analysis
12/20/21	Cardiovascular	3-180	ASTM	F3505 - 21	Standard Test Method for Stent and Endovascular Prosthesis Kink Resistance
12/20/21	General Plastic Surgery/General Hospital	6-474	ASTM	F3352-19	Standard Specification for Isolation Gowns Intended for Use in Healthcare Facilities
12/20/21	Orthopedic	11-392	ASTM	F2723-21	Standard Test Method for Evaluating Mobile Bearing Knee Tibial Baseplate/Bearing Resistance to Dynamic Disassociation
12/20/21	Materials	8-569	ASTM	F648-21	Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants
12/20/21	Orthopedic	11-393	ASTM	F2724-21	Standard Test Method for Evaluating Mobile Bearing Knee Dislocation
12/20/21	Orthopedic	11-391	ASTM	F2722 - 21	Standard Practice for Evaluating Mobile Bearing Knee Tibial Baseplate Rotational Stops

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12/20/21	Orthopedic	11-385	ASTM	F2345-21	Standard Test Methods for Determination of Cyclic Fatigue Strength of Ceramic Modular Femoral Heads
12/20/21	Orthopedic	11-386	ASTM	F2665-21	Standard Specification for Total Ankle Replacement Prosthesis
12/20/21	Orthopedic	11-387	ASTM	F1781-21	Standard Specification for Elastomeric Flexible Hinge Finger Total Joint Implants
12/20/21	Orthopedic	11-388	ASTM	F1717-21	Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
12/20/21	Materials	8-563	ASTM	F1801-20	Standard Practice for Corrosion Fatigue Testing of Metallic Implant Materials
12/20/21	Materials	8-564	ASTM	F2005-21	Standard Terminology for Nickel-Titanium Shape Memory Alloys
12/20/21	Materials	8-565	ASTM	F2754/F2754M-21	Standard Test Method for Measurement of Camber Cast Helix and Direction of Helix of Coiled Wire
12/20/21	Materials	8-566	ASTM	F1813-21	Standard Specification for Wrought Titanium - 12 Molybdenum - 6 Zirconium - 2 Iron Alloy for Surgical Implant (UNS R58120)
12/20/21	Materials	8-567	ASTM	F86-21	Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants
12/20/21	Materials	8-568	ASTM	F1586-21	Standard Specification for Wrought Nitrogen Strengthened 21 Chromium-10 Nickel-3 Manganese-2.5 Molybdenum Stainless Steel Bar for Surgical Implants (UNS S31675)
12/20/21	Materials	8-570	ASTM	F1108-21	Standard Specification for Titanium-6Aluminum-4Vanadium Alloy Castings for Surgical Implants (UNS R56406)
12/20/21	Materials	8-571	ASTM	F2052-21	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
12/20/21	Materials	8-572	ASTM	F2565-21	Standard Guide for Extensively Irradiation-Crosslinked Ultra-High Molecular Weight Polyethylene Fabricated Forms for Surgical Implant Applications
12/20/21	Materials	8-573	ASTM	F2695-12(2020)	Standard Specification for Ultra-High Molecular Weight Polyethylene Powder Blended With Alpha-Tocopherol (Vitamin E) and Fabricated Forms for Surgical Implant Applications
12/20/21	InVitro Diagnostics	7-311	CLSI	EP39 1st Edition	A Hierarchical Approach to Selecting Surrogate Samples for the Evaluation of In Vitro Medical Laboratory Tests
12/20/21	Materials	8-580	IEC	63145-20-10 Edition 1.0 2019-08	Eyewear display -- Part 20-10: Fundamental measurement methods -- Optical properties
12/20/21	Materials	8-581	IEC	63145-20-20 Edition 1.0 2019-09	Eyewear display -- Part 20-20: Fundamental measurement methods -- Image quality
12/20/21	Materials	8-582	IEC	63145-22-10 Edition 1.0 2020-01	Eyewear display -- Part 22-10: Specific measurement methods for AR type -- Optical properties
12/20/21	General II (ES/EMC)	19-42	IEC	61326-1 Edition 3.0 2020-10	Electrical equipment for measurement control and laboratory use - EMC requirements - Part 1: General requirements
12/20/21	General II (ES/EMC)	19-43	IEC	61326-2-6 Edition 3.0 2020-10	Electrical equipment for measurement control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
12/20/21	Radiology	12-341	IEC	62563-1 Edition 1.2 2021-07 CONSOLIDATED VERSION	Medical electrical equipment - Medical image display systems - Part 1: Evaluation methods
12/20/21	Physical Medicine	16-232	IEC	80601-2-78 Edition 1.0 2019-07	Medical electrical equipment - Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation assessment compensation or alleviation
12/20/21	Cardiovascular	3-174	ISO	5840-1 Second edition 2021-01	Cardiovascular implants - Cardiac valve prostheses - Part 1: General requirements
12/20/21	Cardiovascular	3-173	ISO	5840-3 Second edition 2021-01	Cardiovascular implants - Cardiac valve prostheses - Part 3: Heart valve substitutes implanted by transcatheter techniques

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12/20/21	Cardiovascular	3-175	ISO	5840-2 Second edition 2021-01	Cardiovascular implants - Cardiac valve prostheses - Part 2: Surgically implanted heart valve substitutes
12/20/21	Materials	8-577	ISO	13179-1 Second Edition 2021-09	Implants for surgery -- Coatings on metallic surgical implants -- Part 1: Plasma-sprayed coatings derived from titanium or titanium-6 aluminum-4 vanadium alloy powders
12/20/21	Materials	8-579	ISO	13779-3 Second Edition 2018-12	Implants for surgery -- Hydroxyapatite -- Part 3: Chemical analysis and characterization of crystallinity ratio and phase purity [Including AMENDMENT 1 (2021)]
12/20/21	Cardiovascular	3-176	ISO	18193 First edition 2021-08	Cardiovascular implants and artificial organs - Cannulae for extracorporeal circulation
12/20/21	General Plastic Surgery/General Hospital	6-464	ISO	11040-4 Third edition 2015-04-01	Prefilled syringes - Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling [Including AMENDMENT 1 (2020)]
12/20/21	Nanotechnology	18-19	ISO	19749 First edition 2021-07	Nanotechnologies - Measurements of particle size and shape distributions by scanning electron microscopy
12/20/21	Dental/ENT	4-284	ISO	10873 Second edition 2021-07	Dentistry - Denture adhesives
12/20/21	InVitro Diagnostics	7-309	ISO	17099 First edition 2014-11-15	Radiological protection - Performance criteria for laboratories using the cytokinesis block micronucleus (CBMN) assay in peripheral blood lymphocytes for biological dosimetry
12/20/21	Dental/ENT	4-288	ISO	7488 Second edition 2018-04	Dentistry - Mixing machines for dental amalgam
12/20/21	Dental/ENT	4-289	ISO	18556 First edition 2016-04	Dentistry - Intraoral spatulas
12/20/21	Dental/ENT	4-290	ISO	28158 Second edition 2018-09	Dentistry - Integrated dental floss and handles
12/20/21	Dental/ENT	4-291	ISO	28399 First edition 2011-01	Dentistry - Products for external tooth bleaching
12/20/21	Dental/ENT	4-292	ISO	28888 First edition 2013-10	Dentistry - Screening method for erosion potential of oral rinses on dental hard tissues
12/20/21	Sterility	14-563	ISO	13408-6 Second edition 2021-04	Aseptic processing of health care products - Part 6: Isolator systems
12/20/21	General I (QS/RM)	5-134	ISO	15223-1 Fourth edition 2021-07	Medical devices - Symbols to be used with medical device labels labelling and information to be supplied - Part 1: General requirements
12/20/21	InVitro Diagnostics	7-310	ISO	19238 Second edition 2014-02-01	Radiological protection - Performance criteria for service laboratories performing biological dosimetry by cytogenetics
12/20/21	Orthopedic	11-390	ISO	23089-2 First edition 2021-05	Implants for surgery - Preclinical mechanical assessment of spinal implants and particular requirements - Part 2: Spinal intervertebral body fusion devices
12/20/21	Orthopedic	11-389	ISO	7206-10 Second edition 2018-08	Implants for surgery - Partial and total hip-joint prostheses - Part 10: Determination of resistance to static load of modular femoral heads [Including AMENDMENT 1 (2021)]
12/20/21	Sterility	14-571	ISO	11138-8 First edition 2021-07	Sterilization of health care products - Biological indicators - Part 8: Method for validation of a reduced incubation time for a biological indicator
12/20/21	Radiology	12-342	NEMA	PS 3.1 - 3.20 2021e	Digital Imaging and Communications in Medicine (DICOM) Set
12/20/21	Sterility	14-564	USP-NF	M98910_01_01	<161> Medical Devices-Bacterial Endotoxin and Pyrogen Tests
12/20/21	Sterility	14-565	USP-NF	M98802_01_01	<62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms
12/20/21	Sterility	14-566	USP-NF	M98795_02_01	<55> Biological Indicators -- Resistance Performance Tests
12/20/21	Sterility	14-567	USP-NF	M7414_01_01	<1229.5> Biological Indicators for Sterilization
12/20/21	Sterility	14-568	USP-NF	M98800_01_01	<61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests
12/20/21	Sterility	14-569	USP-NF	M98810_01_01	<71> Sterility Tests
12/20/21	Sterility	14-570	USP-NF	M98830_02_01	<85> Bacterial Endotoxins Test
12/20/21	General Plastic Surgery/General Hospital	6-465	USP-NF	M76090_03_01	Sodium Chloride Irrigation
12/20/21	General Plastic Surgery/General Hospital	6-466	USP-NF	M76070_03_01	Sodium Chloride Injection

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12/20/21	General Plastic Surgery/General Hospital	6-467	USP-NF	M80200_04_01	Nonabsorbable Surgical Suture
12/20/21	General Plastic Surgery/General Hospital	6-468	USP-NF	M99670_02_01	<881> Tensile Strength
12/20/21	General Plastic Surgery/General Hospital	6-469	USP-NF	M99650_02_01	<861> Sutures - Diameter
12/20/21	General Plastic Surgery/General Hospital	6-470	USP-NF	M99660_03_01	<871> Sutures - Needle Attachment
12/20/21	General Plastic Surgery/General Hospital	6-471	USP-NF	M88880_05_01	Sterile Water for Irrigation
12/20/21	General Plastic Surgery/General Hospital	6-472	USP-NF	M36660_04_01	Heparin Lock Flush Solution
12/20/21	General Plastic Surgery/General Hospital	6-473	USP-NF	M80190_04_01	Absorbable Surgical Suture
12/20/21	Biocompatibility	2-292	USP-NF	M98833_01_01	<87> Biological Reactivity Test In Vitro - Direct Contact Test
12/20/21	Biocompatibility	2-293	USP-NF	M98833_01_01	<87> Biological Reactivity Test In Vitro - Elution Test
12/20/21	Biocompatibility	2-294	USP-NF	M98834_01_01	<88> Biological Reactivity Tests In Vivo
12/20/21	Biocompatibility	2-295	USP-NF	M98900_01_01	<151> Pyrogen Test (USP Rabbit Test)