FDA

ASCA-Accredited Testing Laboratories

This page lists ASCA-accredited testing laboratories and their respective scopes of accreditation.

Notes:

- Testing laboratories who wish to participate in ASCA should demonstrate that they have been accredited by an ASCA-recognized accreditation body to the currently FDA-recognized versions of the standards and test methods included in ASCA. Please check the Recognized Consensus Standards database for the currently recognized versions.
- Some FDA-recognized consensus standards included in ASCA have an identical U.S. adoption (for example, IEC 60601-2-47, ANSI/AAMI/IEC 60601-2-47). If a testing laboratory has an international (e.g., IEC, ISO) version of a standard in their scope of ASCA Accreditation, any identical US adoption associated with the FDA Recognition number is also considered included in the testing laboratory's scope. For example, if IEC 60601-2-47 with FDA Recognition number 3-155 is listed in a testing laboratory's scope of ASCA Accreditation, testing to the associated ANSI AAMI IEC version is also acceptable even if it is not explicitly listed in the testing lab's scope.
- Some FDA-recognized international consensus standards (e.g., IEC, ISO) included in ASCA are recognized specifically with U.S. national differences applied (e.g., IEC 60601-1, IEC 61010-1). When U.S. national differences are applied to the international versions, they are considered equivalent to the corresponding U.S. adoptions of those standards (e.g., ANSI AAMI ES60601-1, ANSI UL 61010-1). For testing laboratories listed below with such standards in their scope, both the US adoptions and the international versions of the standards are considered as part of their scope of *ASCA Accreditation*.
- As of January 3,2024, Bay Area Compliance Lab has been withdrawn from the ASCA program.

Learn more...[6]

Search ASCA-Accredited Testing Laboratories Search

Test Lab: Eurofins Electrical Testing Service (Shanghai) Co., Ltd. [TL-122]
Accreditation Status: Accreditation Granted - Date: 11/14/2023
Accreditation Body Organization Name: A2LA
Test Lab Primary Contact: June Fan, june.fan@cpt.eurofinscn.com, Building 18, No. 2168 Chenghang Highway Minhang District Shanghai CN

Scope of ASCA Accreditation

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Standards Development Organization	Status	Status Date	Category	Biocompatibility Test Method	Recognition Number	Standard Designation Number and Date	Title	Exclusions
ISO	Accreditation Granted	11/14/2023	Basic safety and essential performance		1-138	80601-2-74 First edition 2017-05	Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment[23]	Excluding subclauses 201.12.1.101 / Humidification output 201.12.1.105 / Dynamic temperature stability
ISO	Accreditation Granted	11/14/2023	Basic safety and essential performance		1-139	80601-2-61 Second edition 2017-12 (Corrected version 2018-02)	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment[24]	Please see the exclusions listed for 60601-1
ISO	Accreditation Granted	11/14/2023	Basic safety and essential performance		1-140	80601-2-55 Second edition 2018-02	Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors[25]	Excluding subclause 201.12 / Accuracy of controls and instruments and protection against hazardous outputs
ISO	Accreditation Granted	11/14/2023	Basic safety and essential performance		1-146	80601-2-12 Second edition 2020-02	Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators[26]	Excluding subclauses 201.9.101 / Additional requirements for suction procedures 201.12.1.101 / Volume-control inflation-type 201.12.1.102 / Pressure-control inflation-type 201.12.1.105 / Response of the ventilator to an increase in
ISO	Accreditation Granted	11/14/2023	Basic safety and essential performance		1-148	80601-2-69 Second edition 2020-11	Medical electrical equipment - Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment[27]	Please see the exclusions listed for 60601-1
IEC	Accreditation Granted	11/14/2023	Basic safety and essential performance		12-242	60601-2-57 Edition 1.0 2011-01	Medical Electrical Equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use[28]	Please see the exclusions listed for 60601-1
IEC	Accreditation Granted	11/14/2023	Basic safety and essential performance		12-268	60601-2-22 Edition 3.1 2012-10	Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment[29]	Please see the exclusions listed for 60601-1
IEC	Accreditation Granted	11/14/2023	Basic safety and essential performance		12-293	60601-2-37 Edition 2.1 2015	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment[30]	Please see the exclusions listed for 60601-1
IEC	Accreditation Granted	11/14/2023	Basic safety and essential performance		12-294	60601-2-45 Edition 3.1 2015	Medical electrical equipment - Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices[31]	Excluding subclauses 201.8.5.4.101 / Stator and stator circuit dielectric strength testing 201.8.8.3 / Dielectric strength 201.9.2.101 / Three

							dimensional localization and interventional mammographic guidance 203 / Radiation
IEC	Accreditation Granted	11/14/2023	Basic safety and essential performance	12-302	60601-2-44 Edition 3.2: 2016	Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of x-ray equipment for computed tomography[32]	Excluding subclauses 201.8.8.3 / Dielectric strength 203 / General requirements for RADIATION protection in diagnostic X-ray equipment
IEC	Accreditation Granted	11/14/2023	Basic safety and essential performance	12-309	60601-2-28 Edition 3.0 2017-06	Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis[33]	Excluding subclauses 201.8.8.3 / Dielectric strength 201.12.4.5.2 / Diagnostic X-RAY EQUIPMENT 203 / RADIATION protection in diagnostic X-RAY EQUIPMENT
IEC	Accreditation Granted	11/14/2023	Basic safety and essential performance	12-339	60601-2-63 Edition 1.2 2021-05 CONSOLIDATED VERSION	Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment[34]	Excluding subclauses 201.8.5.4.101 / Stator and stator circuit dielectric strength testing 201.8.8.3 / Dielectric strength 203 / Radiation protection in diagnostic X-ray equipment
IEC	Accreditation Granted	11/14/2023	Basic safety and essential performance	12-340	60601-2-65 Edition 1.2 2021-05 CONSOLIDATED VERSION	Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral-X-ray equipment[35]	Excluding subclauses 201.8.8.3 Dielectric strength 203 Radiation protection in diagnostic X-ray equipment
IEC	Accreditation Granted	11/14/2023	Basic safety and essential performance	12-348	60601-2-54 Edition 2.0 2022-09	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy[36]	Excluding subclauses 201.8.5.4.101 / Stator and stator circuit dielectric strength testing 201.8.8.3 / Dielectric strength 203 / Radiation protection in diagnostic X-ray equipment
IEC	Accreditation Granted	11/14/2023	Basic safety and essential performance	17-16	60601-2-10 Edition 2.1 2016-04	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators[37]	Please see the exclusions listed for 60601-1
IEC	Accreditation Granted	11/14/2023	Basic safety and essential performance	19-34	61010-1 Edition 3.1 2017-01 CONSOLIDATED VERSION	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements [Including: Corrigendum 1 (2019)] - Note: This standard is recognized with relevant US national differences applied, see reference #1 in Relevant FDA Guidance and/or Supportive Publication section[38]	Excluding subclauses 9.5 / flammable liquid 10.5.3(2) / Vi cat softening test 12.2./ Ionizi ng radiation test 12.4 / Microwave radiation test 12.5 / Sonic and ultrasonic pressure 13.2.3
IEC	Accreditation Granted	11/14/2023	Basic safety and essential performance	19-38	60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment[39]	
IEC	Accreditation Granted	11/14/2023	Basic safety and essential performance	19-39	60601-1-12 Edition 1.1 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment[40]	
ANSI, UL	Accreditation Granted	11/14/2023	Basic safety and essential performance	19-41	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[41]	Excluding subclauses 9.5 / flammable liquid 10.5.3(2) / Vi cat softening test 12.2./ Ionizi ng radiation test 12.4 / Microwave radiation test 12.5 / Sonic and ultrasonic pressure 13.2.3
ANSI, AAMI	Accreditation Granted	11/14/2023	Basic safety and essential performance	19-46	ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)][42]	Excluding subclauses 9.6.2.1 / Audible acoustic energy 8.8.4.2 Resistance to environmental stress 10.1.1 ME EQUIPMENT not intended to produce diagnostic or therapeutic X-radiation 10.3 / Microwave radiation 11.2.2.1
AAMI, ANSI	Accreditation Granted	11/14/2023	Basic safety and essential performance	19-47	HA60601-1-11:2015 [Including AMD1:2021]	Medical Electrical Equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral Standard: Requirements for medical electrical equipment and medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC 60601-1-11:2015 MOD) [Including Amendment1 (2021)][43]	
IEC	Accreditation Granted	11/14/2023	Basic safety and essential performance	19-49	60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Note: This standard is recognized with relevant US national differences applied, see references #1 and #2 in the Relevant FDA Guidance and/or Supportive Publication section below.[44]	Excluding subclauses 9.6.2.1 / Audible acoustic energy 8.8.4.2 Resistance to environmental stress 10.1.1 ME EQUIPMENT not intended to produce diagnostic or therapeutic X-radiation 10.3 / Microwave radiation 11.2.2.1
IEC	Accreditation Granted	11/14/2023	Basic safety and essential performance	3-105	60601-2-25 Edition 2.0 2011-10	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs[45]	Please see the exclusions listed for 60601-1
IEC	Accreditation Granted	11/14/2023	Basic safety and essential performance	3-115	60601-2-34 Edition 3.0 2011-05	Medical electrical equipment - Part 2-34: Particular requirements for the basic safety, including essential performance, of invasive blood pressure monitoring equipment[46]	Excluding subclauses 201.12.1.101 / Accuracy of pressure measurements 208.6.6.2.101 / Physiological ALARM CONDITIONS, ALARM LIMITS and delay time of physiological ALARM SIGNALS
IEC	Accreditation Granted	11/14/2023	Basic safety and essential performance	3-123	80601-2-30: Edition 2.0 2018-03	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers[47]	Please see the exclusions listed for 60601-1

IEC	Accreditation Granted	11/14/2023	Basic safety and essential performance		3-126	60601-2-27 Edition 3.0 2011-03	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment [Including: Corrigendum 1 (2012)][48]	Please see the exclusions listed for 60601-1
IEC	Accreditation Granted	11/14/2023	Basic safety and essential performance		3-155	60601-2-47 Edition 2.0 2012-02	Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performanceof ambulatory electrocardiographic systems[49]	Please see the exclusions listed for 60601-1
IEC	Accreditation Granted	11/14/2023	Basic safety and essential performance		4-262	80601-2-60 Edition 2.0 2019-06	Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment[50]	Please see the exclusions listed for 60601-1
IEC	Accreditation Granted	11/14/2023	Basic safety and essential performance		5-131	60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems[51]	
IEC	Accreditation Granted	11/14/2023	Basic safety and essential performance		5-132	60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability[52]	
IEC	Accreditation Granted	11/14/2023	Basic safety and essential performance		6-321	60601-2-52 Edition 1.0 2009-12	Medical electrical equipment - Part 2-52: Particular requirements for basic safety and essential performance of medical beds [Including: Technical Corrigendum 1 (2010)][53]	Excluding subclause 201.11.6.6.101 / Machine washable medical bed
IEC	Accreditation Granted	11/14/2023	Basic safety and essential performance		6-389	60601-2-2 Edition 6.0 2017-03	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories[54]	Please see the exclusions listed for 60601-1
ISO	Accreditation Granted	11/14/2023	Basic safety and essential performance		6-421	80601-2-56 Second edition 2017-03	Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. [Including: Amendment 1 (2018)].[55]	Please see the exclusions listed for 60601-1
IEC	Accreditation Granted	11/14/2023	Basic safety and essential performance		6-450	60601-2-50 Edition 3.0 2020-09	Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment[56]	Please see the exclusions listed for 60601-1
IEC	Accreditation Granted	11/14/2023	Basic safety and essential performance		6-461	60601-2-19 Edition 3.0 2020-09	Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators[57]	Excluding subclauses 201.12.1.109 / Accuracy of indication of relative humidity 201.12.1.110 / Oxygen control 201.12.1.111 / Air velocity 201.12.4.2.101 / CO2-concentration
IEC	Accreditation Granted	11/14/2023	Basic safety and essential performance		6-462	60601-2-20 Edition 3.0 2020-09	Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators[58]	Excluding subclauses 201.12.1.109 / Accuracy of indication of relative humidity 201.12.1.110 / Oxygen control 201.12.1.111 / Air velocity 201.12.1.113 / Provision of oxygen 201.12.4.2.101 / CO2 concentration
IEC	Accreditation Granted	11/14/2023	Basic safety and essential performance		6-463	60601-2-21 Edition 3.0 2020-09	Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers[59]	Excluding subclauses 201.12.1.104 / Oxygen control 201.12.4.2.101 / CO2 concentration
IEC	Accreditation Granted	11/14/2023	Basic safety and essential performance		9-114	60601-2-18: Edition 3.0 2009-08	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment[60]	Please see the exclusions listed for 60601-1

Scope History

Action Type	ASCA Status	Effective Start Date	Biocompatibility Test Method	Recognition Number	Designation Number	Exclusions
Transition	Inactive	12/17/2023		1-102	80601-2-69 First edition 2014-07-15	Please see the exclusions listed for 60601-1
Transition	Inactive	12/17/2023		12-310	60601-2-63 Edition 1.1 2017-07 CONSOLIDATED VERSION	Excluding subclauses 201.8.5.4.101 / Stator and stator circuit dielectric strength testing 201.8.8.3 / Dielectric strength 203 / Radiation protection in diagnostic X-ray equipment
Transition	Inactive	12/17/2023		12-311	60601-2-65 Edition 1.1 2017-05 CONSOLIDATED VERSION	Excluding subclauses 201.8.8.3 Dielectric strength 203 Radiation protection in diagnostic X-ray equipment
Transition	Inactive	12/17/2023		12-317	60601-2-54 Edition 1.2 2018-06 CONSOLIDATED VERSION	Please see the exclusions listed for 60601-1
Transition	Inactive	12/17/2023		19-14	60601-1-11 Edition 2.0 2015-01	
Transition	Inactive	12/17/2023		19-15	60601-1-12 Edition 1.0 2014-06	
Transition	Inactive	12/17/2023		19-16	HA60601-1-11:2015	
Transition	Inactive	12/17/2023		19-4	ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)	Excluding subclauses 9.6.2.1 / Audible acoustic energy 8.8.4.2 Resistance to environmental stress 10.1.1 ME EQUIPMENT not intended to produce diagnostic or therapeutic X-radiation 10.3 / Microwave radiation 11.2.2.1

Transition	Inactive	12/17/2023	5-76	60601-1-8 Edition 2.1 2012-11	
Transition	Inactive	12/17/2023	5-89	60601-1-6 Edition 3.1 2013-10	
Transition	Inactive	12/17/2023	6-385	60601-2-19 Edition 2.1 2016-04	Excluding subclauses 201.12.1.109 / Accuracy of indication of relative humidity 201.12.1.110 / Oxygen control 201.12.1.111 / Air velocity 201.12.4.2.101 / CO2-concentration
Transition	Inactive	12/17/2023	6-386	60601-2-20 Edition 2.1 2016-04	Excluding subclauses 201.12.1.109 / Accuracy of indication of relative humidity 201.12.1.110 / Oxygen control 201.12.1.111 / Air velocity 201.12.1.113 / Provision of oxygen 201.12.4.2.101 / CO2 concentration
Transition	Inactive	12/17/2023	6-387	60601-2-50 Edition 2.1 2016-04	Please see the exclusions listed for 60601-1
Transition	Inactive	12/17/2023	6-388	60601-2-21 Edition 2.1 2016-04	Excluding subclauses 201.12.1.104 / Oxygen control 201.12.4.2.101 / CO2 concentration
Transition	Inactive	07/09/2023	1-98	80601-2-12 First edition 2011-04-15	Excluding subclauses 201.9.101 / Additional requirements for suction procedures 201.12.1.101 / Volume-control inflation-type 201.12.1.102 / Pressure-control inflation-type 201.12.1.105 / Response of the ventilator to an increase in

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