CERTIFICATE OF ACCREDITATION

This is to attest that

CSA GROUP KOREA LTD.

494, WIRYESUNHWAN-RO, SONGPA-GU
SEOUL, 05814, SOUTH KOREA

Testing Laboratory TL-633

has met the requirements of AC89, *IAS Accreditation Criteria for Testing Laboratories as well as the FDA ASCA Program specifications*, and has demonstrated compliance with ISO/IEC Standard 17025:2017, *General requirements for the competence of testing and calibration laboratories.* This organization is accredited to provide the services specified in the scope of accreditation.

Effective Date March 7, 2025

IAS ACCREDITED

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SCOPE OF ACCREDITATION

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Accredited to ISO/IEC 17025:2017 *Effective Date March 7, 2025*

FDA ASCA Program

FDA ASCA Program Scope

Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems and Laboratory Medical Equipment	
ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] [19-46]	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 MOD) [Including Amendment 2 (2021)]
IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION [19-49]	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.
ANSI AAMI HA60601-1-11:2015 [Including AMD1:2021] [19-47]	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)]
IEC 60601-1-3 Edition 2.2 2021-01 CONSOLIDATED VERSION [12-336]	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION [5-132]	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION [5-131]	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.
ANSI AAMI IEC 60601-1-8:2006 and	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements tests and

A1:2012 [Including AMD 2:2021] [5-131]	guidance for alarm systems in medical electrical equipment and medical electrical systems.
IEC 60601-1-10 Edition 1.2 2020-07 CONSOLIDATED VERSION [19-37]	Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers.
IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION [19-38]	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.
IEC 60601-1-12 Edition 1.1 2020-07 CONSOLIDATED VERSION [19-39]	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.
ANSI AAMI IEC 60601-1-12:2016 [Including AMD 1:2021] [19-39]	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 [Including Amendment 1(2021)]
IEC 60601-2-2 Edition 6.0 2017-03 [6-389]	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.
ANSI AAMI IEC 60601-2-2:2017 [6-389]	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.
IEC 60601-2-5 Edition 3.0 2009-07 [12-205]	Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment.
IEC 60601-2-10 Edition 2.1 2016-04 [17-16]	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators.
IEC 60601-2-18 Edition 3.0 2009-08 [9-114]	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment.
IEC 60601-2-22 Edition 3.1 2012-10 [12-268]	Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical cosmetic therapeutic and diagnostic laser equipment.
IEC 60601-2-25 Edition 2.0 2011-10 [3-105]	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs.
ANSI AAMI IEC 60601-2-25:2011/ (R)2016 [3-105]	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs.
IEC 60601-2-27 Edition 3.0 2011-03 [3-126]	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment.

ANSI AAMI IEC 60601-2-27:2011 (R)2016 [3-126]	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment.
IEC 60601-2-28 Edition 3.0 2017-06 [12-309]	Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis.
IEC 60601-2-34 Edition 3.0 2011-05 [3-115]	Medical electrical equipment - Part 2-34: Particular requirements for the basic safety including essential performance of invasive blood pressure monitoring equipment.
IEC 60601-2-37 Edition 2.1 2015 [12-239]	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.
IEC 60601-2-43 Edition 2.2 2019-10 CONSOLIDATED VERSION [12-293]	Medical electrical equipment - Part 2-43: Particular requirements for the safety and essential performance of X-ray equipment for interventional procedures
IEC 60601-2-43 Edition 3.0 2022-12 [12-351]	Medical electrical equipment - Part 2-43: Particular requirements for the safety and essential performance of X-ray equipment for interventional procedures
IEC 60601-2-44 Edition 3.2: 2016 [12-302]	Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of x-ray equipment for computed tomography.
IEC 60601-2-45 Edition 3.1 2015 [12-294]	Medical electrical equipment - Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices.
IEC 60601-2-47 Edition 2.0 2012-02 [3-155]	Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems.
ANSI AAMI IEC 60601-2-47:2012/(R)2016 [3-155]	Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems.
IEC 60601-2-54 Edition 2.0 2022-09 [12-348]	Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
IEC 60601-2-57 Edition 1.0 2011-01 [12-242]	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.
IEC 60601-2-63 Edition 1.2 2021-05 CONSOLIDATED VERSION [12-339]	Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment
IEC 60601-2-65 Edition 1.2 2021-05 CONSOLIDATED VERSION [12-340]	Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral-X-ray equipment

IEC 80601-2-30 Edition 2.0 2018-03 [3-123]	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.
ANSI AAMI IEC 80601-2-30:2018 [3-123]	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.
IEC 80601-2-60 Edition 2.0 2019-06 [4-262]	Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment.
IEC 80601-2-77 Edition 1.0 2019-07 [6-438]	Medical electrical equipment - Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment
ANSI AAMI IEC 80601-2-77:2020 [6-438]	Medical electrical equipment - Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment
IEC 80601-2-78 Edition 1.0 2019-07 [16-232]	Medical electrical equipment - Part 2-78: Particular requirements for the basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation
ISO 80601-2-56 Second edition 2017-03 [6-421]	Medical electrical equipment - Part 2-56: Particular requirements for the basic safety and essential performance of clinical thermometers for body temperature measurement (Including: Amendment 1 (2018)
ISO 80601-2-61 Second edition 2017-12 (Corrected version 2018-02) [1-139]	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.
ANSI/UL 61010-1 3rd Ed, dated May 12, 2012, with revision through July 19, 2019 [19-41]	Safety requirements for electrical equipment for measurement control and laboratory use - Part 1: General requirements.
IEC 61010-1 Edition 3.1 2017-01 CONSOLIDATED VERSION [19-34]	Safety requirements for electrical equipment for measurement control and laboratory use - Part 1: General requirements [Including: Corrigendum 1 (2019)] – Note: This standard us recognized with relevant US national differences applied see reference #1 and #2 in Relevant FDA Guidance and/or Supportive Publication section

Regular Scope

ENERGY STAR
ENERGY STAR Program Requirements Product Specification for Consumer Refrigeration Products Version 5.1, 10 CFR 430, Subpart B, Appendix A & B
ENERGY STAR Program Requirements Product Specification for Commercial Refrigerators and Freezers Version 5.0, 10 CFR Part 431, Subpart C, Appendix B
ENERGY STAR Program Requirements Product Specification for Laboratory Grade Refrigerators and Freezers Version 2.0, ENERGY STAR Test Method for Laboratory Grade Refrigerators, Freezers, and Ultra-Low Temperature Freezers

Electrical and Electronics	
10 CFR 430, Subpart B, Appendix I	Uniform Test Method for Measuring the Energy Consumption of Conventional Ranges, Conventional Cooking Tops, Conventional Ovens, and Microwave Ovens
10 CFR Part 431, Subpart C	Commercial Refrigerators, Freezers and Refrigerator-Freezers
16 CFR 1263	Part 1263 – Safety standard for button cell or coin batteries and consumer products containing such batteries
AHAM HRF-1	Household Refrigerators, Refrigerator-Freezers and Freezers
ANSI/AAMI ES60601-1	Medical electrical equipment-Part 1: General requirements for basic safety and essential performance
ANSI/AAMI HA60601-1-11	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
ANSI/AAMI/IEC 80601-2-77	Medical electrical equipment - Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment
ANSI/AAMI/IEC 80601-2-78	Medical electrical equipment - Part 2-78: Particular requirements for the basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation
ANSI/AHRI 1200	Standard for Performance Rating of Commercial Refrigerated Display Merchandisers and Storage Cabinets
ANSI/AHRI 1200 (I-P)-2010	Performance Rating of Commercial Refrigerated Display Merchandisers and Storage Cabinets
ANSI/ASHRAE 72	Method of Testing Open and Closed Commercial Refrigerators and Freezers
ANSI/UL 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements
ANSI/UL 61010-2-010	Safety requirements for electrical equipment for measurement, control and laboratory use –Part 2-010: Particular requirements for laboratory equipment for the heating of materials
ANSI/UL 61010-2-051	Safety requirements for electrical equipment for measurement, control and laboratory use –Part 2-051: Particular requirements for laboratory equipment for mixing and stirring
ANSI/UL 61010-2-081	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
ANSI/UL 61010-2-091	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-091: Particular requirements for cabinet X-ray systems

ANSI/UL 61010-2-101	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
AS/NZS 60065	Audio, video and similar electronic apparatus – Safety requirements
AS/NZS 60950.1	Information technology equipment – Safety – Part 1: General requirements
CAN/CSA C22.2 No. 120	Refrigeration equipment
CAN/CSA-C22.2 No. 60065	Audio, video and similar electronic apparatus – Safety requirements
CAN/CSA C22.2 No. 60335-1	Household and similar electrical appliances – Safety – Part 1: General requirements [Excluded: Clauses 15.1, 29.1, and Annex B]
CAN/CSA C22.2 No. 60335-2-24	Safety requirements for household and similar electrical appliances, Part 2: Particular requirements for refrigerating appliances, ice-cream appliances and ice-makers [Excluded: Clauses 22.103, 22.104, 22.109, 24.101, 24.102, and 30.101]
CAN/CSA-C22.2 No. 60601-1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
CAN/CSA-C22.2 No 60601-1-3	Medical Electrical Equipment – Part 1-3: General Requirements For Basic Safety And Essential Performance – Collateral Standard: Radiation Protection In Diagnostic X-Ray Equipment
CAN/CSA-C22.2 No. 60601-1-6	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
CAN/CSA-C22.2 No. 60601-1-8	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
CAN/CSA-C22.2 No. 60601-1-9	Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral standard: Requirements for environmentally conscious design
CAN/CSA-C22.2 No. 60601-1-10	Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral standard: Requirements for the development of physiologic closed-loop controllers
CAN/CSA-C22.2 No. 60601-1-11	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
CAN/CSA-C22.2 No. 60601-1-12	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

CAN/CSA-C22.2 No. 60601-2-2	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
CAN/CSA-C22.2 No. 60601-2-4	Medical electrical equipment – Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators
CAN/CSA-C22.2 No. 60601-2-5	Medical electrical equipment – Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment
CAN/CSA-C22.2 No. 60601-2-10	Medical electrical equipment – Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
CAN/CSA-C22.2 No. 60601-2-18	Medical electrical equipment – Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
CAN/CSA-C22.2 No. 60601-2-22	Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
CAN/CSA-C22.2 No. 60601-2-24	Medical Electrical equipment – Part 2-24: Particular Requirements for the Safety of Infusion Pumps and Controllers
CAN/CSA-C22.2 No. 60601-2-25	Medical electrical equipment – Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
CAN/CSA-C22.2 No. 60601-2-27	Medical electrical equipment = Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
CAN/CSA-C22.2 No. 60601-2-28	Medical electrical equipment – Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
CSA-C22.2 No. 80601-2-30	Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
CAN/CSA-C22.2 No. 60601-2-34	Medical Electrical Equipment – Part 2-34: Particular Requirements for the Safety, Including Essential Performance, of Invasive Blood Pressure Monitoring Equipment
CAN/CSA-C22.2 No. 60601-2-37	Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
CAN/CSA-C22.2 No. 60601-2-43	Medical electrical equipment – Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures
CAN/CSA-C22.2 No. 60601-2-44	Medical electrical equipment – Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography

CAN/CSA-C22.2 No. 60601-2-45	Medical electrical equipment – Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices
CAN/CSA-C22.2 No. 60601-2-47	Medical Electrical Equipment – Part 2-47: Particular Requirements for the Safety, Including Essential Performance, of Ambulatory Electrocardiographic Systems
CAN/CSA-C22.2 No. 60601-2-49	Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
CAN/CSA-C22.2 No. 60601-2-54	Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
CAN/CSA-C22.2 No. 60601-2-57	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
CAN/CSA-C22.2 No. 60601-2-63	Medical electrical equipment – Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment
CAN/CSA-C22.2 No. 60601-2-65	Medical electrical equipment – Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral x-ray equipment
CAN/CSA-C22.2 No. 60950-1	Information technology equipment – Safety – Part 1: General requirements
CAN/CSA-C22.2 No. 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements
CAN/CSA-C22.2 No. 61010-2-010	Safety requirements for electrical equipment for measurement, control and laboratory use –Part 2-010: Particular requirements for laboratory equipment for the heating of materials
CAN/CSA-C22.2 No. 61010-2-051	Safety requirements for electrical equipment for measurement, control and laboratory use –Part 2-051: Particular requirements for laboratory equipment for mixing and stirring
CAN/CSA-C22.2 No. 61010-2-081	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
CAN/CSA-C22.2 No. 61010-2-091	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-091: Particular requirements for cabinet X-ray systems
CAN/CSA-C22.2 No. 61010-2-101	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

CAN/CSA-C22.2 No. 80601-2-56	Medical electrical equipment - Part 2-56: Particular requirements for the basic safety and essential performance of clinical thermometers for body temperature measurement
CAN/CSA-C22.2 No. 80601-2-60	Medical electrical equipment – Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment
CAN/CSA-C22.2 No. 80601-2-77	Medical electrical equipment - Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment
CAN/CSA-C22.2 No. 80601-2-78	Medical electrical equipment - Part 2-78: Particular requirements for the basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation
CAN/CSA C300	Energy performance and capacity of household refrigerators, refrigerator-freezers, freezers, and wine chillers
CAN/CSA-C388-15	Energy performance and capacity measurement of household microwave ovens
CAN/CSA-C657-15	Energy performance standard for commercial refrigeration equipment
CAN/CSA-C62301:07	Household electrical appliances – Measurement of standby power
CAN/CSA-C62301:11	Household electrical appliances – Measurement of standby power
CAN/CSA-E60730-1:13	Automatic electrical controls – Part 1: General requirements (Only Clauses 15, 17. H17, H27, H28)
CAN/CSA-E60730-1:15	Automatic electrical controls – Part 1: General requirements (Only Clauses 15, 17. H17, H27, H28)
CAN/CSA-CEI/IEC 62304	Medical device software – Software life-cycle processes
CAN/CSA/IEC 62366	Medical Devices–Application of usability engineering to medical devices
CAN/CSA/IEC 62366-1	Medical devices – Part 1: Application of usability engineering to medical devices
CSA-C22.2 No. 62368-1	Audio/video, information and communication technology equipment – Part 1: Safety requirements
CSA-C22.2 No. 80601-2-61	Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
DGNTI-COPANIT 511: 2017	LIMITS, TEST METHODS AND LABELING
EN 60065	Audio, video and similar electronic apparatus – Safety requirements
EN 60601-1	Medical electrical equipment Part 1: General requirements for basic safety and essential performance
EN 60601-1-3	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral standard: Radiation protection in diagnostic X-ray equipment
EN 60601-1-8	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
EN 60601-1-9	Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral standard: Requirements for environmentally conscious design
EN 60601-1-10	Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral standard: Requirements for the development of physiologic closed-loop controllers
EN 606001-1-11	Medical electrical equipment – Part 1: 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
EN 60601-1-12	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
EN 60601-2-2	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
EN 60601-2-4	Medical electrical equipment – Part 2: Particular requirements for basic safety and essential performance of cardiac defibrillators
EN 60601-2-5	Medical electrical equipment – Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment
EN 60601-2-10	Medical electrical equipment – Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
EN 60601-2-18	Medical electrical equipment – Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
EN 60601-2-22	Medical electrical equipment – Part 2: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
EN 60601-2-24	Medical electrical equipment – Part 2: Particular requirements for the safety of infusion pumps and controllers
EN 60601-2-25	Medical electrical equipment – Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
EN 60601-2-27	Medical electrical equipment – Part 2: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment

EN 60601-2-28	Medical electrical equipment – Particular requirements for basic safety and essential performance of X-ray tube assemblies for medical diagnosis
EN 80601-2-30	Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
EN 60601-2-34	Medical electrical equipment – Part 2: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment
EN 60601-2-37	Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
EN 60601-2-43	Medical electrical equipment – Part 2-43: Particular requirements for basic safety and essential performance of X-ray equipment for interventional procedures
EN 60601-2-44	Medical electrical equipment – Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography
EN 60601-2-45	Medical electrical equipment – Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices
EN 60601-2-47	Medical electrical equipment – Part 2: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
EN 60601-2-49	Medical electrical equipment – Part 2: Particular requirements for the safety of multifunction patient monitoring equipment
EN 60601-2-54	Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
EN 60601-2-57	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
EN 60601-2-63	Medical electrical equipment – Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment
EN 60601-2-65	Medial electrical equipment Part 2: Particular requirements for basic safety and essential performance of dental intra-oral X-ray equipment
EN 60950-1	Information technology equipment – Safety – Part 1: General requirements
EN 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements

EN 61010-2-010	Safety requirements for electrical equipment for measurement, control and laboratory use –Part 2-010: Particular requirements for laboratory equipment for the heating of materials
EN 61010-2-051	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-051: Particular requirements for laboratory equipment for mixing and stirring
EN 61010-2-081	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
EN 61010-2-091	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-091: Particular requirements for cabinet X-ray systems
EN 61010-2-101	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
EN 62366	Medical devices Part 1: Application of usability engineering to medical devices
EN 62366-1	Medical devices Part 1: Application of usability engineering to medical devices
EN 62368-1	Audio/video, information and communication technology equipment – Part 1: Safety requirements
EN 80601-2-60	Medical electrical equipment – Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment
EN ISO 80601-2-61	Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
IEC 60065	Audio, video and similar electronic apparatus – Safety requirements (Eighth Edition)
IEC 60335-1	Household and similar electrical appliances, Part 1: General requirements [Excluded: Clauses 15.1, 29.1, and Annex B]
IEC 60335-1:2010+ AMD1:2013+ AMD2:2016	Household and similar electrical appliances, Part 1: General requirements [Excluded: Clauses 15.1, 29.1, and Annex B]
IEC 60335-2-24	Household and similar electrical appliances, Part 2: Particular requirements for refrigerating appliances, ice-cream appliances, and ice-makers [Excluded: Clauses 22.103, 22.104, 22.109, 24.101, 24.102, and 30.101]
IEC 60335-2-24:2010+ AMD1:2012+ AMD2:2017	Household and similar electrical appliances, Part 2: Particular requirements for refrigerating appliances, ice-cream appliances, and ice-makers

	[Excluded: Clauses 22.103, 22.104, 22.109, 24.101, 24.102, and 30.101]
IEC 60601-1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-3	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-1-6	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
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