

CERTIFICATE OF ACCREDITATION

This is to attest that

INTERTEK ITALIA S.P.A.

VIA PRINCIPE DI UDINE 114 CAMPOFORMIDO (UDINE) 33030, ITALY

Testing Laboratory TL-451

has met the requirements of AC89, *IAS Accreditation Criteria for Testing Laboratories* as well as the *FDA ASCA* 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 April 19, 2024



President

International Accreditation Service, Inc.

3060 Saturn Street, Suite 100, Brea, California 92821, U.S.A. | www.iasonline.org

INTERTEK ITALIA S.P.A.

Contact Name Arianna Fogar

Contact Phone +39 0432 653411

Accredited to ISO/IEC 17025:2017 FDA ASCA Program

Effective Date April 19, 2024

FDA ASCA Program Scope

Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical	
Systems and Laborator	
ANSI AAMI ES 60601- 1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021 [19-46] ANSI AAMI HA 60601- 1-11:2015 [Including	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 MOD) Medical Electrical Equipment Part 1-11: General requirements for basic safety and essential performance Collateral Standard: Requirements for medical
AMD1:2021] [19-47]	electrical equipment and medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC 60601-1-11:2015 MOD)
ANSI AAMI IEC 60601- 1-2:2014 [Including AMD 1:2021] [19-36]	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
ANSI AAMI IEC 60601- 1-8:2006 and A1:2012 [Including AMD 2:2021] [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- 1-12:2016 [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 medical services environment
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
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 [Including: Corrigendum 1 (2012)]
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
ANSI UL 61010-1 3rd Ed, dated May 12, 2012	Standard for Safety for Electrical Equipment For Measurement, Control and Laboratory Use; Part 1: General Requirements





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with revision through	
July 19, 2019	
[19-41]	
IEC 60601-1 Edition 3.2	Medical electrical equipment - Part 1: General requirements for basic safety and
2020-08	essential performance
CONSOLIDATED	
VERSION	
[19-49]	Malia I I I I I I I I I I I I I I I I I I I
IEC 60601-1-2 Edition	Medical electrical equipment – Part 1-2: General requirements for basic safety
4.1 2020-09	and essential performance – Collateral Standard: Electromagnetic disturbances
CONSOLIDATED	– Requirements and tests
VERSION	
[19-36]	
IEC 60601-1-6 Edition	Medical electrical equipment – Part 1-6: General requirements for basic safety
3.2 2020-07	and essential performance – Collateral standard: Usability
CONSOLIDATED	,,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,,
VERSION	
[5-132]	
IEC 60601-1-8 Edition	Medical electrical equipment – Part 1-8: General requirements for basic safety
2.2 2020-07	and essential performance – Collateral Standard: General requirements, tests
CONSOLIDATED	and guidance for alarm systems in medical electrical equipment and medical
VERSION	electrical systems
[5-131]	
IEC 60601-1-11 Edition	Medical electrical equipment – Part 1-11: General requirements for basic safety
2.1 2020-07	and essential performance – Collateral Standard: Requirements for medical
CONSOLIDATED	electrical equipment and medical electrical systems used in the home healthcare
VERSION	environment
[19-38]	
IEC 60601-1-12 Edition	Medical electrical equipment – Part 1-12: General requirements for basic safety
1.1 2020-07	and essential performance – Collateral Standard: Requirements for medical
CONSOLIDATED	electrical equipment and medical electrical systems intended for use in the
VERSION	emergency medical services environment
[19-39]	emergency medical services environment
IEC 60601-2-10 Edition	Madical alastrical aguingant. Dort 2.40: Dorticular requirements for the basis
	Medical electrical equipment – Part 2-10: Particular requirements for the basic
2.1 2016-04	safety and essential performance of nerve and muscle stimulators
[17-16]	M
IEC 60601-2-22 Edition	Medical electrical equipment – Part 2-22: Particular requirements for basic
3.1 2012-10	safety and essential performance of surgical, cosmetic, therapeutic and
[12-268]	diagnostic laser equipment
IEC 60601-2-25 Edition	Medical electrical equipment – Part 2-25: Particular requirements for the basic
2.0 2011-10	safety and essential performance of electrocardiographs
[3-105]	
IEC 60601-2-27 Edition	Medical electrical equipment – Part 2-27: Particular requirements for the basic
3.0 2011-03	safety and essential performance of electrocardiographic monitoring equipment
[3-126]	[Including: Corrigendum 1 (2012)]
IEC 60601-2-35 Edition	Medical electrical equipment – Part 2-35: Particular requirements for the basic
2.0 2020-09	safety and essential performance of heating devices using blankets, pads and
[6-483]	mattresses and intended for heating in medical use
IEC 60601-2-47 Edition	
	Medical electrical equipment – Part 2-47: Particular requirements for the basic
2.0 2012-02	safety and essential performance of ambulatory electrocardiographic systems
[3-155]	





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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
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

Regular Scope

Energy Star		
ENERGY STAR Program	requirements for clothes dryers	
ENERGY STAR Program requirements for clothes washers		
ENERGY STAR Program requirements for commercial dishwashers		
ENERGY STAR Program requirements for commercial ice machines		
ENERGY STAR Program requirements for commercial refrigerators and freezers		
ENERGY STAR Program	requirements for dishwashers	
ENERGY STAR Program requirements for residential refrigerators and freezers		
10 CFR 430 sub B	Uniform Test Method for Measuring the Energy Consumption of Refrigerators,	
appendix A	Refrigerator-Freezers, and Miscellaneous Refrigeration Products	
10 CFR 430 sub B	Uniform Test Method for Measuring the Energy Consumption of Freezers	
appendix B		
10 CFR 430 sub B	Uniform Test Method for Measuring the Energy Consumption of Dishwashers	
appendix C1		
10 CFR 430 sub B	Uniform Test Method for Measuring the Energy Consumption of Clothes Dryers	
appendix D		
10 CFR 430 sub B	Uniform Test Method for Measuring the Energy Consumption of Clothes Dryers	
appendix D1		
10 CFR 430 sub B	Uniform Test Method for Measuring the Energy Consumption of Clothes Dryers	
appendix D2		
10 CFR 430 sub B	Uniform Test Method for Measuring the Energy Consumption of Cooking	
appendix I	Products	
10 CFR 430 sub B	Uniform Test Method for Measuring the Energy Consumption of Automatic and	
appendix J1	Semi-Automatic Clothes Washers	
10 CFR 430 sub B	Uniform Test Method for Measuring the Energy Consumption of Automatic and	
appendix J2	Semi-automatic Clothes Washers	
AHAM HRF-1	Energy and Internal Volume of Refrigerating Appliances	
AHRI 810 (formerly ARI	Performance Rating of Automatic Commercial Ice-Makers	
810)	Mathadat Tarting Organization Defines at the control of the contro	
ASHRAE 72	Method of Testing Commercial Refrigerators and Freezers	
Electrical ANSI/AAMI/ISO 60601-	Madical alastical application with a part O OF, neutral progression was the basis	
2-25	Medical electrical equipment - part 2-25: particular requirements for the basic	
AS/NZS 2040.1	safety and essential performance of electrocardiographs Performance of household electrical appliances - Clothes washing machines	
AS/INZS 2040.1		
AS/NZS 2040.2	Energy consumption and performance (excluded clauses: 4.7, 4.8) Performance of household electrical appliances - Clothes washing machines	
AG/NZG 2040.2	Energy efficiency labelling requirements	
AS/NZS 2442.1	Performance of household electrical appliances - rotary clothes dryers - energy	
AO/1420 2772.1	consumption and performance	
	Concumption and performance	





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AS/NZS 2442.2	Performance of household electrical appliances - rotary clothes dryers - energy labelling requirements
AS/NZS 4474.1	Performance of household electrical appliances - refrigerating appliances - part
	1: energy consumption and performance
AS/NZS 4474.2	Performance of household electrical appliances - refrigerating appliances -
	energy labelling and minimum energy performance standard requirements
CAN/CSA-C22.2 NO. 60079-0	Explosive atmospheres - Part 0: Equipment - General requirements
CAN/CSA-C22.2 NO. 60079-1	Explosive Atmospheres - Part 1: Equipment Protection by Flameproof Enclosures "d"
CAN/CSA-C22.2 NO. 60079-2	Explosive Atmospheres - Part 1: Equipment Protection by Pressurized Enclosure "p"
CAN/CSA-C22.2 NO. 60079-7	Explosive Atmospheres - Part 7: Equipment Protection by Increased Safety "e"
CAN/CSA-C22.2 NO. 60079-11	Explosive atmospheres - Part 11: Equipment protection by intrinsic safety "i"
CAN/CSA-C22.2 NO. 60079-15	Explosive atmospheres - Part 15: Equipment protection by type of protection "n"
CAN/CSA-C22.2 NO. 60079-18	Explosive atmospheres - Part 18: Equipment protection by encapsulation "m"
CAN/CSA-C22.2 NO. 60079-26	Explosive atmospheres - Part 26: Equipment with Equipment Protection Level (EPL) Ga
CAN/CSA-C22.2 NO.	Explosive Atmospheres - Part 31: Equipment Dust Ignition Protection by Enclosure "t"
60079-31 CAN/CSA C300	Enclosure t Energy performance and capacity of household refrigerators, refrigerator-
CAN/COA COU	freezers, freezers, and wine chillers
CAN/CSA C360	Energy Performance, Water Consumption, and Capacity of Household Clothes Washers
CAN/CSA C361	Test Method for Measuring Energy Consumption and Drum Volume of Electrically Heated Household Tumble-Type Clothes Dryers
CAN/CSA C373	Energy consumption test methods and limits for household dishwashers
CSA C22.2 No.30	Explosion-proof enclosures for use in class I hazardous locations (only Clauses 6.2, 6.3, 6.5, 6.6 and 6.7)
CSA C358	Energy consumption test methods for household electric ranges
EN 60456	Clothes washing machines for household use. Methods for measuring the performance (excluded clauses: 8.5, 9.4)
EN ISO 80079-36	Explosive atmospheres. Non-electrical equipment for explosive atmospheres. Basic method and requirements
EN ISO 80079-37	Explosive atmospheres. Non-electrical equipment for explosive atmospheres. Non-electrical type of protection constructional safety "c", control of ignition sources "b", liquid immersion "k"
EN/SANS 50229	Electric clothes washer-dryers for household use. Methods of measuring the performance
IEC 60034-1	Rotating electrical machines - Part 1: Rating and performance
IEC 60034-2-1	Rotating electrical machines - Part 2-1: Standard methods for determining losses and efficiency from tests (excluding machines for traction vehicles)
IEC 60034-30	Rotating electrical machines - Part 30: Efficiency classes of line operated AC motors (IE-code)
IEC 60204-1	Safety of machinery - Electrical equipment of machines - Part 1: General requirements

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IEC 60456	Clothes washing machines for household use - methods for measuring the
	performance (excluded clauses: 8.5, 9.4)
IEC 61010-1 Edition 3.1	Safety requirements for electrical equipment for measurement, control, and
2017-01	laboratory use – Part 1: General requirements
IEC 61010-1-2 Edition	Medical electrical equipment – Part 1-2: General requirements for basic safety
4.1 2020-09	and essential performance – Collateral Standard: Electromagnetic disturbances
CONSOLIDATED	- Requirements and tests
VERSION	
IEC/EN 60335-1	Household and similar electrical appliances - Safety - Part 1: general requirements
IEC/EN 60335-2-2	Household and similar electrical appliances - Safety - Part 2-2: Particular
	requirements for vacuum cleaners and water-suction cleaning appliances
	(excluded clause 21 current-carrying hoses)
IEC/EN 60335-2-3	Household and similar electrical appliances - Safety - Part 2-3: Particular
	requirements for electric irons
IEC/EN 60335-2-5	Household and similar electrical appliances - Safety - Part 2-5: Particular
	requirements for dishwashers
IEC/EN 60335-2-6	Household and similar electrical appliances - Safety - Part 2-6: Particular
	requirements for stationary cooking ranges, hobs, ovens and similar appliances
IEC/EN 60335-2-7	Household and similar electrical appliances - Safety - Part 2-7: Particular
	requirements for washing machines (excluded: aging test for elastomeric parts
	of annex BB)
IEC/EN 60335-2-8	Household and similar electrical appliances – Safety – Part 2-8: Particular
	requirements for shavers, hair clippers and similar appliances
IEC/EN 60335-2-9	Household and similar electrical appliances - Safety - Part 2-9: Particular
	requirements for grills, toasters and similar portable cooking appliances
IEC/EN 60335-2-11	Household and similar electrical appliances - Safety - Part 2-11: Particular
	requirements for tumble dryers
IEC/EN 60335-2-13	Household and similar electrical appliances - Safety - Part 2-13: Particular
	requirements for deep fat fryers, frying pans and similar appliances
IEC/EN 60335-2-14	Household and similar electrical appliances - Safety - Part 2-14: Particular
	requirements for kitchen machines
IEC/EN 60335-2-15	Household and similar electrical appliances - Safety - Part 2-15: Particular
	requirements for appliances for heating liquids
IEC/EN 60335-2-21	Household and similar electrical appliances - Safety - Part 2-21: Particular
	requirements for storage water heaters
IEC/EN 60335-2-23	Household and similar electrical appliances - Safety - Part 2-23: Particular
	requirements for appliances for skin or hair care
IEC/EN 60335-2-24	Household and similar electrical appliances - Safety - Part 2-24: Particular
	requirements for refrigerating appliances, ice-cream appliances and ice makers
IEC/EN 60335-2-27	Household and similar electrical appliances - Safety - Part 2-27: Particular
	requirements for appliances for skin exposure to optical radiation
IEC/EN 60335-2-30	Household and similar electrical appliances - Safety -Part 2-30: Particular
	requirements for room heaters
IEC/EN 60335-2-31	Household and similar electrical appliances - Safety - Part 2-31: Particular
	requirements for range hoods and other cooking fume extractors
IEC/EN 60335-2-32	Household and similar electrical appliances - safety - part 2-32: particular
	requirements for massage appliances
IEC/EN 60335-2-36	Household and similar electrical appliances - Safety - Part 2-36: Particular
	requirements for commercial electric cooking ranges, ovens, hobs and hob
	elements





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IEC/EN 60335-2-37	Household and similar electrical appliances - Safety - Part 2-37: Particular
150/51 0000	requirements for commercial electric doughnut fryers and deep fat fryers
IEC/EN 60335-2-38	Household and similar electrical appliances - Safety - Part 2-38: Particular
	requirements for commercial electric griddles and griddle grills
IEC/EN 60335-2-39	Household and similar electrical appliances - Safety - Part 2-39: Particular
	requirements for commercial electric multi-purpose cooking pans
IEC/EN 60335-2-41	Household and similar electrical appliances - Safety - Part 2-41: Particular requirements for pumps
IEC/EN 60335-2-42	Household and similar electrical appliances - Safety - Part 2-42: Particular
	requirements for commercial electric forced convection ovens, steam cookers
JEC/EN 00005 0 40	and steam-convection ovens
IEC/EN 60335-2-43	Household and similar electrical appliances - Safety - Part 2-43: Particular clothes dryers and towel rails
IEC/EN 60335-2-44	Household and similar electrical appliances - Safety - Part 2-44: Particular
	requirements for ironers
IEC/EN 60335-2-45	Household and similar electrical appliances - Safety - Part 2-45: Particular
	requirements for portable heating tools and similar appliances
IEC/EN 60335-2-47	Household and similar electrical appliances - Safety - Part 2-47: Particular
	requirements for commercial electric boiling pans
IEC/EN 60335-2-48	Household and similar electrical appliances - Safety - Part 2-48: Particular
	requirements for commercial electric grillers and toasters
IEC/EN 60335-2-49	Household and similar electrical appliances - Safety - Part 2-49: Particular
	requirements for commercial electric appliances for keeping food and crockery
	warm
IEC/EN 60335-2-50	Household and similar electrical appliances - Safety - Part 2-50: Particular
	requirements for commercial electric bains-marie
IEC/EN 60335-2-54	Household and similar electrical appliances - Safety - Part 2-54: Particular
	requirements for surface-cleaning appliances for household use employing
	liquids or steam
IEC/EN 60335-2-55	Household and similar electrical appliances - Safety - Part 2-55: Particular
	requirements for electrical appliances for use with aquariums and garden ponds
IEC/EN 60335-2-58	Household and similar electrical appliances - Safety - Part 2-58: Particular
	requirements for commercial electric dishwashing machines
IEC/EN 60335-2-59	Household and similar electrical appliances - Safety - Part 2-59: Particular
	requirements for insect killers
IEC/EN 60335-2-60	Household and similar electrical appliances - Safety - Part 2-60: Particular
	requirements for whirlpool baths
IEC/EN 60335-2-64	Household and similar electrical appliances - Safety - Part 2-64: Particular
	requirements for commercial electric kitchen machines
IEC/EN 60335-2-69	Household and similar electrical appliances - Safety - Part 2-69: Particular
	requirements for wet and dry vacuum cleaners, including power brush, for
	commercial use
IEC/EN 60335-2-72	Household and similar electrical appliances - Safety - Part 2-72: Particular
	requirements for floor treatment machines with or without traction drive, for
	commercial use
IEC/EN 60335-2-75	Household and similar electrical appliances - Safety - Part 2-75: Particular
	requirements for commercial dispensing appliances and vending machines
IEC/EN 60335-2-79	Household and similar electrical appliances - Safety - Part 2-79: Particular
	requirements for high pressure cleaners and steam cleaners
IEC/EN 60335-2-80	Household and similar electrical appliances - Safety - Part 2-80: Particular
	requirements for fans
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JEO/EN 00005 5 55	
IEC/EN 60335-2-89	Household and similar electrical appliances - Safety - Part 2-89: Particular
	requirements for commercial refrigerating appliances with an incorporated or
	remote refrigerant unit or compressor
IEC/EN 60335-2-90	Household and similar electrical appliances - Safety - Part 2-90: Particular
	requirements for commercial microwave ovens
IEC/EN 60335-2-98	Household and similar electrical appliances - Safety - Part 2-98: Particular
	requirements for humidifiers
IEC/EN 60335-2-99	Household and similar electrical appliances – Safety – Part 2-99: Particular
	requirements for commercial electric hoods
IEC/EN 60335-2-102	Household and similar electrical appliances - Safety - Part 2-102: Particular
	requirements for gas, oil and solid-fuel burning appliances having electrical
	connections
IEC/EN 60335-2-105	Household and similar electrical appliances - Safety - Part 2-105: Particular
	requirements for multifunctional shower cabinets
IEC/EN 60529	Degrees of protection provided by enclosures (IP code)
IEC/EN 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and
120/211000011	essential performance
IEC/EN 60601-1-4	Medical electrical equipment - part 1: general requirements for safety – 4 -
120/2110000111	collateral standard: programmable electrical medical systems
IEC/EN 60601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety
123/211 33331 1 3	and essential performance - Collateral standard: Usability
IEC/EN 60601-1-8	Medical electrical equipment - Part 1-8: General requirements for basic safety
120/214 00001-1-0	and essential performance - Collateral Standard: General requirements, tests
	and guidance for alarm systems in medical electrical equipment and medical
	electrical systems
IEC/EN 60601-1-11	Medical electrical equipment - Part 1-11: General requirements for basic safety
120/214 00001-1-11	and essential performance - Collateral Standard: Requirements for medical
	electrical equipment and medical electrical systems used in the home
	healthcare environment
IEC/EN 60601-1-12	Medical electrical equipment - Part 1-12: General requirements for basic safety
120/214 00001 1 12	and essential performance - Collateral Standard: Requirements for medical
	electrical equipment and medical electrical systems intended for use in the
	emergency medical services environment
IEC/EN 60601-2-10	Medical electrical equipment - Part 2-10: Particular requirements for the basic
120/214 00001 2 10	safety and essential performance of nerve and muscle stimulators
IEC/EN 60601-2-22	Medical electrical equipment - Part 2-22: Particular requirements for basic
120/214 0000 1-2-22	safety and essential performance of surgical, cosmetic, therapeutic and
	diagnostic laser equipment
IEC/EN 60601-2-25	Medical electrical equipment - Part 2-25: Particular requirements for the basic
120/214 0000 1-2-20	safety and essential performance of electrocardiographs
IEC/EN 60601-2-27	Medical electrical equipment - Part 2-27: Particular requirements for the basic
120/214 0000 1-2-21	safety and essential performance of electrocardiographic monitoring equipment
IEC/EN 60601-2-41	Medical electrical equipment - Part 2-41: Particular requirements for the basic
120/214 0000 1-2-41	safety and essential performance of surgical luminaires and luminaires for
	diagnosis (excluded: ultraviolet radiation of clause 201.10.7 and characteristics
	of illumination of clause 201.12.1.102)
IEC/EN 60601-2-47	Medical electrical equipment - Part 2-47: Particular requirements for the basic
120/211 00001-2-47	safety and essential performance of ambulatory electrocardiographic systems
IEC/EN 60825-1	Safety of laser products - Part 1: Equipment classification and requirements
	1 1
IEC/EN 60950-1	Information technology equipment - Safety - Part 1: General requirements



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Iaboratory use - Part 1: General requirements		<u></u>
IEC/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 (excluded clause 11.2)	IEC/EN 61010-1	Safety requirements for electrical equipment for measurement, control, and
laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials (excluded clause 11.2) Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials (Excluded clause 13.1 for poisonous and injurious gases) IEC/EN 61010-2-081	IEC/EN 61010 2 010	
the heating of materials (excluded clause 11.2) Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-040; Particular requirements for sterilizers and washer-disinfectors used to treat medical materials (Excluded clause 13.1 for poisonous and injurious gases) IEC/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 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101; Particular requirements for in vitro diagnostic (IVD) medical equipment IEC/EN 61010-2-201 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-201; Particular requirements for in vitro diagnostic (IVD) medical equipment IEC/EN 61121 Tumble dryers for household use - methods for measuring the performance IEC/EN 62364 Medical devices - part 1: application of usability engineering to medical devices liEC/EN 62368-1 Audio/video, information and communication technology equipment - Part 1: Safety requirements (excluded clauses; 5.4.1.0, 5.6.4.1 (overcurrent), 10 (LED, X-ray, UV, acoustic radiations), Annex G7, Annex G15 (Tensile strength test and vibration test), Annex J, Annex M, 8.2, Annex S, 3.2, Annex U) lectric tothes washer-dryers for household use - methods for measuring the performance IEC/EN 80601-2-35 Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use IEC/EN/UL 60079-0 Explosive atmospheres - Part 1: Equipment Protection by Flameproof Enclosures "d" Explosive atmospheres - Part 1: Equipment Protection by Increased Safety "l" Explosive atmospheres - Part 1: Equipment protection by bencylated in medical use in protection by enclosure "d" Explosive atmospheres - P	ILO/EN 01010-2-010	
Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-040: Particular requirements for sterilizers and washerdisinfectors used to treat medical materials (Excluded clause 13.1 for poisonous and injurious gases) 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 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-201: Particular requirements for control equipment IEC/EN 61121		
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IEC/EN/UL 60079-7 Explosive Atmospheres - Part 7: Equipment Protection by Increased Safety "e" IEC/EN/UL 60079-11 Explosive atmospheres - Part 11: Equipment protection by intrinsic safety "i" IEC/EN/UL 60079-15 Explosive atmospheres - Part 15: Equipment protection by type of protection "n" IEC/EN/UL 60079-18 Explosive atmospheres - Part 18: Equipment protection by encapsulation "m" IEC/EN/UL 60079-26 Explosive atmospheres - Part 26: Equipment with Equipment Protection Level (EPL) Ga IEC/EN/UL 60079-31 Explosive Atmospheres - Part 31: Equipment Dust Ignition Protection by Enclosure "t" IEC/EN/UL 60730-1 Automatic electrical controls - Part 1: General requirements IEC/EN/UL 60730-2-5 Automatic electrical controls - Part 2-5: Particular requirements for automatic	IEC/EN/UL 60079-2	Explosive Atmospheres - Part 1: Equipment Protection by Pressurized
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IEC/EN/UL 60079-15 Explosive atmospheres - Part 15: Equipment protection by type of protection "n" IEC/EN/UL 60079-18 Explosive atmospheres - Part 18: Equipment protection by encapsulation "m" IEC/EN/UL 60079-26 Explosive atmospheres - Part 26: Equipment with Equipment Protection Level (EPL) Ga IEC/EN/UL 60079-31 Explosive Atmospheres - Part 31: Equipment Dust Ignition Protection by Enclosure "t" IEC/EN/UL 60730-1 Automatic electrical controls - Part 1: General requirements IEC/EN/UL 60730-2-5 Automatic electrical controls - Part 2-5: Particular requirements for automatic		
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(EPL) Ga IEC/EN/UL 60079-31 Explosive Atmospheres - Part 31: Equipment Dust Ignition Protection by Enclosure "t" IEC/EN/UL 60730-1 Automatic electrical controls - Part 1: General requirements IEC/EN/UL 60730-2-5 Automatic electrical controls - Part 2-5: Particular requirements for automatic	IEC/EN/UL 60079-18	Explosive atmospheres - Part 18: Equipment protection by encapsulation "m"
IEC/EN/UL 60079-31 Explosive Atmospheres - Part 31: Equipment Dust Ignition Protection by Enclosure "t" IEC/EN/UL 60730-1 Automatic electrical controls - Part 1: General requirements IEC/EN/UL 60730-2-5 Automatic electrical controls - Part 2-5: Particular requirements for automatic	IEC/EN/UL 60079-26	Explosive atmospheres - Part 26: Equipment with Equipment Protection Level
Enclosure "t" IEC/EN/UL 60730-1 Automatic electrical controls - Part 1: General requirements IEC/EN/UL 60730-2-5 Automatic electrical controls - Part 2-5: Particular requirements for automatic		(EPL) Ga
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IEC/EN/UL 60730-2-5 Automatic electrical controls - Part 2-5: Particular requirements for automatic		
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electrical hurner control systems	IEC/EN/UL 60730-2-5	·
		electrical burner control systems
IEC/EN/UL 60730-2-9 Automatic electrical controls - Part 2-9: Particular requirements for temperature	IEC/EN/UL 60730-2-9	
sensing control		sensing control





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IEC/EN/UL 60730-2-12	Automatic electrical controls - Part 2-12: Particular requirements for electrically operated door locks
IEC/EN/UL 60730-2-14	Automatic electrical controls - Part 2-14: Particular requirements for electric actuators
ISO 80079-36	Explosive atmospheres. Non-electrical equipment for explosive atmospheres. Basic method and requirements
ISO 80079-37	Explosive atmospheres. Non-electrical equipment for explosive atmospheres. Non-electrical type of protection constructional safety "c", control of ignition sources "b", liquid immersion "k"
KS 2464-1	Performance of household electrical appliances – Refrigeration appliances Part 1: Energy consumption and performance
KS 2464-2	Performance of household electrical appliances – Refrigeration appliances Part 2: Minimum energy performance standard requirements
SANS 1695	Clothes washing machines for household use – methods for measuring the performance
SANS 61121	Tumble dryers for household use - methods for measuring the performance
SANS 62552	Household refrigerating appliances - characteristics and test methods
SASO 2664	Energy Performance and Capacity and Labeling of Household Refrigerators, Refrigerator-Freezers, and Freezers
SASO 2683	Clothes Washing Machines for Household Use – Methods for Measuring the Performance
SASO 2692	Energy Labelling Requirements of Household Electrical Clothes Washing Machines
SASO 2693	Clothes Washing Machines for Household Use – Performance Requirements
SASO 2883	Electric clothes dryers – requirements of energy performance and labels
SASO 2885	Washing machines - requirements of energy performance, water consumption, and labeling
SASO 2892	Refrigerators, Refrigerator- Freezers and Freezers -EnergyPerformance, Testing and Labeling Requirements
SASO 2893:2018	Rotating electrical machines - Part 30: Efficiency classes of line operated AC motors (IE-code)
SASO/IEC 60034-2-1	Rotating electrical machines - Part 2-1: Standard methods for determining losses and efficiency from tests (excluding machines for traction vehicles)
UAE.S IEC 60456	Clothes washing machines for household use – Methods for measuring the performance (excluded clauses: 8.5, 9.4)
UAE.S IEC 61121	Electrical tumble dryers for household use
UAE.S IEC 62512	Electric clothes washer-dryers for household use – Methods for measuring the performance
UAE.S IEC 62552	Household refrigerating appliances – Characteristics and test methods
UL 913	Intrinsically Safe Apparatus and Associated Apparatus for Use in Class I, II and III, Division 1, Hazardous (Classified) Locations
UL 1203	Explosion-Proof and Dust-Ignition-Proof Electrical Equipment for Use in Hazardous (Classified) Locations (only clauses: 20, 21, 22, 25.1, 25.2, 26, 32, 55, 86, 123, and SB1)
EMC	
ANSI C63.4	Methods of measurement of radio-noise emissions from low-voltage electrical and electronic equipment in the range of 9 kHz to 40 GHz (range of 9 kHz to 40 GHz)
CISPR 11	Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement





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CISPR 13	Sound and television broadcast receivers and associated equipment - radio
CIOPIN 13	disturbance characteristics - limits and methods of measurement
CISPR 14-1	Electromagnetic compatibility – Requirements for household appliances, electric
01011(14-1	tools and similar apparatus – Part 1: Emission
CISPR 14-2	Electromagnetic compatibility – Requirements for household appliances, electric
GIOFIX 14-2	tools and similar apparatus – Part 2: Immunity – Product family standard
CISPR 15	Limits and methods of measurement of radio disturbance characteristics of
CIOFICIO	electrical lighting and similar equipment
CISPR 16-2-1	Specification for radio disturbance and immunity measuring apparatus and
	methods - part 2-1: methods of measurement of disturbances and immunity -
	conducted disturbance measurements
CISPR 16-2-2	Specification for radio disturbance and immunity measuring apparatus and
01011110-2-2	methods – Part 2-2: Methods of measurement of disturbances and immunity –
	Measurement of disturbance power
CISPR 16-2-3	Specification for radio disturbance and immunity measuring apparatus and
0101111020	methods – Part 2-3: Methods of measurement of disturbances and immunity –
	Radiated disturbance measurements
CISPR 20	Sound and television broadcast receivers and associated equipment -Immunity
0.020	characteristics - Limits and methods of measurement
CISPR 22	Information technology equipment - Radio disturbance characteristics - Limits
	and methods of measurement
CISPR 24	Information technology equipment - Immunity characteristics – Limits and
	methods of measurement
CISPR 32	Electromagnetic compatibility of multimedia equipment - Emission requirements
CISPR 35	Electromagnetic compatibility of multimedia equipment - Immunity requirements
EN 55011	Industrial, scientific and medical equipment – Radio-frequency disturbance
2.1.00011	characteristics – Limits and methods of measurement
EN 55013	Sound and television broadcast receivers and associated equipment - radio
	disturbance characteristics - limits and methods of measurement
EN 55014-1	Electromagnetic compatibility – Requirements for household appliances, electric
	tools and similar apparatus – Part 1: Emission
EN 55014-2	Electromagnetic compatibility – Requirements for household appliances, electric
	tools and similar apparatus – Part 2: Immunity – Product family standard
EN 55015	Limits and methods of measurement of radio disturbance characteristics of
	electrical lighting and similar equipment
EN 55016-2-1	Specification for radio disturbance and immunity measuring apparatus and
	methods - part 2-1: methods of measurement of disturbances and immunity -
	conducted disturbance measurements
EN 55016-2-2	Specification for radio disturbance and immunity measuring apparatus and
	methods – Part 2-2: Methods of measurement of disturbances and immunity –
	Measurement of disturbance power
EN 55016-2-3	Specification for radio disturbance and immunity measuring apparatus and
	methods – Part 2-3: Methods of measurement of disturbances and immunity –
	Radiated disturbance measurements
EN 55020	Sound and television broadcast receivers and associated equipment -Immunity
	characteristics - Limits and methods of measurement
EN 55022	Information technology equipment - Radio disturbance characteristics - Limits
	and methods of measurement
EN 55024	Information technology equipment - Immunity characteristics – Limits and
	methods of measurement
EN 55032	Electromagnetic compatibility of multimedia equipment - Emission requirements



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EN 55035	Electromagnetic compatibility of multimedia equipment - Immunity requirements
EN 55103-1	Electromagnetic compatibility - Product family standard for audio, video, audiovisual and entertainment lighting control apparatus for professional use - Part 1: Emissions
EN 55103-2	Electromagnetic compatibility - Product family standard for audio, video, audiovisual and entertainment lighting control apparatus for professional use - Part 2: Immunity
IEC/EN 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC/EN 60947-2	Low-voltage switchgear and controlgear - Part 2: Circuit-breakers (EMC part only)
IEC/EN 61000-3-2	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)
IEC/EN 61000-3-3	Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤16 A per phase and not subject to conditional connection
IEC/EN 61000-3-11	Electromagnetic compatibility (EMC) - Part 3-11: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems - equipment with rated current ≤ 75 A and subject to conditional connection
IEC/EN 61000-3-12	Electromagnetic compatibility (EMC) - Part 3-12: Limits - limits for harmonic currents produced by equipment connected to public low-voltage systems with input current >16 A and ≤ 75 A per phase
IEC/EN 61000-4-2	Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test
IEC/EN 61000-4-3	Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test
IEC/EN 61000-4-4	Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test
IEC/EN 61000-4-5	Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test
IEC/EN 61000-4-6	Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields
IEC/EN 61000-4-8	Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test
IEC/EN 61000-4-11	Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests
IEC/EN 61000-4-13	Electromagnetic compatibility (EMC) - Part 4-13: Testing and measurement techniques - Harmonics and interharmonics including mains signalling at A.C. power port, low frequency immunity tests
IEC/EN 61000-4-34	Electromagnetic compatibility (EMC) - Part 4-34: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests for equipment with input current more than 16 A per phase
IEC/EN 61000-6-1	Electromagnetic compatibility (EMC) - Part 6-1: Generic standards - Immunity standard for residential, commercial and light-industrial environments
IEC/EN 61000-6-2	Electromagnetic compatibility (EMC) - Part 6-2: Generic standards - Immunity standard for industrial environment



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IEC/EN 61000-6-3	Electromagnetic compatibility (EMC) - Part 6-3: Generic standards - Emission
120/214 0 1000-0-3	standard for residential, commercial and light-industrial environments
IEC/EN 61000-6-4	Electromagnetic compatibility (EMC) - Part 6-4: Generic standards - Emission
120/2140100001	standard for industrial environments
IEC/EN 61326-1	Electrical equipment for measurement, control and laboratory use - EMC
	requirements - Part 1: General requirements
IEC/EN 61326-2-2	Electrical equipment for measurement, control and laboratory use - EMC
	requirements - Part 2-2: Particular requirements - Test configurations,
	operational conditions and performance criteria for portable test, measuring and
	monitoring equipment used in low-voltage distribution systems
IEC/EN 61326-2-6	Electrical equipment for measurement, control and laboratory use - EMC
	requirements - part 2-6: particular requirements - in vitro diagnostic (IVD)
150/5N 04547	medical equipment
IEC/EN 61547	Equipment for general lighting purposes - EMC immunity requirements
IEC/EN 62233	Measurement methods for electromagnetic fields of household appliances and
1 to be the co	similar apparatus with regard to human exposure
Lighting	Luminairea Part 1. Canaral requirements and tests
IEC/EN 60598-1 IEC/EN 60598-2-1	Luminaires - Part 1: General requirements and tests
IEC/EIN 00398-2-1	Luminaires. Part 2: Particular requirements. Section One: Fixed general purpose luminaires
IEC/EN 60598-2-2	Luminaires - Part 2-2: Particular requirements - Recessed luminaires
IEC/EN 60598-2-3	Luminaires - Part 2-2: Particular requirements - Necessed unimaires Luminaires - Part 2-3: Particular requirements - Luminaires for road and street
IEC/EN 00390-2-3	lighting
IEC/EN 60598-2-4	Luminaires - Part 2-4: Particular requirements - Portable general purpose
120/214 00000-2-4	luminaires
IEC/EN 60598-2-5	Luminaires - Part 2-5: Particular requirements - Floodlights
IEC/EN 60598-2-6	Luminaires - Part 2: Particular requirements - Section 6: Luminaires with built-in
	transformers for filament lamps
IEC/EN 60598-2-7	Luminaires. Part 2: Particular requirements. Section Seven: Portable luminaires
	for garden use
IEC/EN 60598-2-11	Luminaires - Part 2-11: Particular requirements - Aquarium luminaires
IEC/EN 60598-2-13	Luminaires - Part 2-13: Particular requirements - Ground recessed luminaires
IEC/EN 60598-2-17	Luminaires - Part 2-17: Particular requirements - Luminaires for stage lighting,
	television and film studios (outdoor and indoor)
IEC/EN 62031	LED modules for general lighting - Safety specifications
Gas	
EN 30-1-1	Domestic cooking appliances burning gas. Safety. General
EN 30-1-2	Domestic cooking appliances burning gas. Safety. Appliances having forced-
EN 20 1 2	convection ovens and/or grills
EN 30-1-3	Domestic cooking appliances burning gas Safety Appliances having a glass
EN 30-1-4	ceramic hotplate Domestic cooking appliances burning gas. Safety. Appliances having one or
LIN 50-1-4	more burners with an automatic burner control system
EN 30-2-1	Domestic cooking appliances burning gas. Rational use of energy. General
EN 30-2-2	Domestic cooking appliances burning gas. Rational use of energy. Appliances
, 00	having forced-convection ovens and/or grills. Section 2. Forced convection
	ovens/grills
EN 203-1	Gas heated catering equipment. General safety rules
EN 203-2-1	Gas heated catering equipment. Specific requirements. Open burners and wok
	burners
EN 203-2-2	Gas heated catering equipment. Specific requirements. Ovens
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EN 203-2-3	Gas heated catering equipment. Specific requirements. Boiling pans
EN 203-2-4	Gas heated catering equipment. Specific requirements. Fryers
EN 203-2-6	Gas heated catering equipment. Specific requirements. Hot water heaters for
	beverage
EN 203-2-7	Gas heated catering equipment. Specific requirements. Salamanders and
	rotisseries
EN 203-2-8	Gas heated catering equipment. Specific requirements. Brat pans and paella
	cookers
EN 203-2-9	Gas heated catering equipment. Specific requirements. Solid tops, warming
	plates and griddles
EN 203-2-10	Gas heated catering equipment. Specific requirements. Chargrills
EN 203-2-11	Gas heated catering equipment. Specific requirements. Pasta cookers
GSO EN 203-1	Gas heated catering equipment – Part 1: General safety rules
GSO EN 203-2-2	Gas heated catering equipment – Part 2-2: Specific requirements - Ovens
GSO EN 203-2-7	Gas heated catering equipment – Part 2–7: Specific requirements -
	Salamanders and rotisseries
GSO EN 203-2-10	Gas heated catering equipment – Part 2-10: Specific requirements - Chargrills
SASO 167	Methods for Test for Domestic Cookers for Use with Liquefied Petroleum Gases
SASO 168	Domestic Cookers for use with Liquefied Petroleum Gases

ASHRAE: American Society of Heating, Refrigerating and Air-conditioning Engineers

CISPR: The Comité International Spécial des Perturbations Radioélectriques

(International Special Committee on Radio Interference)

CSA: Canadian Standards Association

IEC: International Electrotechnical Commission SASO: Saudi Arabian Standards Organization

UL: Underwriters Laboratories



