



PERRY JOHNSON LABORATORY ACCREDITATION, INC.

Certificate of Accreditation

Perry Johnson Laboratory Accreditation, Inc. has assessed the Organization of:

White Lab S.r.l.

Via del Consorzio 41 - Falconara Marittima, 60015 Italy

*and hereby declares that the Organization is accredited in accordance with
the recognized International Standard:*

ISO/IEC 17025:2017

**& Meets the Requirements of the of the FDA Accreditation Scheme for Conformity
Assessment (ASCA) Program**

Whereby, technical competence has been confirmed for the associated scope supplement, in the fields of:

Electrical, Electromagnetic, Mechanical and Environmental Testing
(As detailed in the supplement)

Accreditation claims for conformity assessment activities shall only be made from the addresses referenced within this certificate and shall apply solely to those activities identified in the related scope. This Accreditation is granted subject to the Accreditation Body rules governing the Accreditation referred to above, and the Organization hereby commits to observing and complying with those rules in their entirety.

For PJLA:

Initial Accreditation Date:

Issue Date:

Expiration Date:

November 13, 2020

January 27, 2025

February 28, 2027

Tracy Szerszen
President

Accreditation No.:

Certificate No.:

111347

L25-83

Perry Johnson Laboratory
Accreditation, Inc. (PJLA)
755 W. Big Beaver, Suite 1325
Troy, Michigan 48084

*The validity of this certificate is maintained through ongoing assessments based
on a continuous accreditation cycle. The validity of this certificate should be
confirmed through the PJLA website: www.pjllabs.com*



Certificate of Accreditation: Supplement

White Lab S.r.l.

Via del Consorzio 41 - Falconara Marittima, 60015 Italy

Contact Name: Massimo Ambrosi Phone: 071-915-6048

Accreditation is granted to the facility to perform the following conformity assessment activities:

FIELD OF TEST	ITEMS, MATERIALS, OR PRODUCTS TESTED	COMPONENT, CHARACTERISTIC, PARAMETER TESTED	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED	FLEX CODE	LOCATION OF ACTIVITY
Electrical	Electrical lighting and similar equipment	Immunity tests to radiofrequency electromagnetic field magnetic fields at mains frequency injected currents bursts, surge, dips, ESD	IEC 61547:1995 / A1:2000, IEC 61547:2009, IEC 61547:2020 EN 61547:1995 / A1:2000, EN 61547:2009	Electromagnetic fields up to 3 V/m from 80 MHz to 2700 MHz Magnetic field with level 3 A/m Burst and fast transient up to 4 KV Surge up to 4 KV ESD up to 15 KV RF currents from 150 kHz to 80 MHz with level 3V Immunity to dips and voltage variations from 10 ms to 5 s	F1	F
	Household appliances, electric tools and similar apparatus	Immunity tests to radiated EM fields, conducted RF currents, burst, surge, ESD and dips	CISPR 14-2:1997 / A1:2001 / A2:2008 CISPR 14-2:2015 CISPR 14-2:2020 EN 55014-2:1997 + EC:1997 / A1:2001 + IS1:2007 / A2:2008 EN 55014-2:2015 EN IEC 55014-2:2021	Electromagnetic fields up to 3 V/m from 80 MHz to 1 000 MHz RF currents from 150 kHz to 230 MHz with level up to 3V Burst and fast transient up to 4 KV Surge up to 4 KV ESD up to 15 KV Immunity to dips and voltage variations from 10 ms to 5 s	F1	F
	Household appliances, electric tools and similar apparatus	Conducted emission tests Power disturbance test Radiated emission test	EN 55014-1:2017 EN IEC 5014-1:2021 CISPR 1-14:2016/ COR1:2016 CISPR 14-1:2020	Conducted emissions in the frequency range 150kHz to 30 MHz Power disturbance test 30 MHz to 300 MHz Radiated emission test 30 MHz to 1 000 MHz	F1	F



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Electrical	Electrical equipment for measurement, control and laboratory use	Immunity to electromagnetic radiated fields, injected RF currents, magnetic fields at mains frequency, burst, surge, ESD and dips Conducted emission tests, Radiated emission test	IEC 61326-1:2005, IEC 61326-1:2012, EN 61326-1:2006, EN 61326-1:2013	Electromagnetic fields up to 10V/m from 80 MHz to 2 700 MHz RF currents from 150kHz to 80MHz with level up to 10V Magnetic field a with level up to 30 A/m Burst and fast transient up to 4 KV Surge up to 4 KV ESD up to 15 KV Conducted emissions in the frequency range 150kHz to 30 MHz Radiated emission test 30 MHz to 18 GHz Immunity to dips and voltage variations from 10ms to 5s	F1	F
Electrical	Medical electrical equipment	Identification, marking and documents (5) Measurements of harmonic and flicker emissions and immunity tests to electromagnetic radiated fields, injected RF currents, magnetic fields at mains frequency, burst, surge, ESD and dips Conducted emission tests, Radiated emission test	IEC 60601-1-2:2001 / A1:2004, IEC 60601-1-2:2007, IEC 60601-1-2:2014/A1:2020, EN 60601-1-2:2001 / A1:2006, EN 60601-1-2:2007, EN 60601-1-2:2015/A1:2021	Electromagnetic fields up to 28 V/m from 80 up to 6 000 MHz RF currents from 150 kHz to 80 MHz with level up to 10 V Magnetic field with level up to 30 A/m Burst and fast transient up to 4 KV Surge up to 4 KV ESD up to 15 KV Conducted emissions in the frequency range 150 kHz to 30 MHz Immunity to dips and voltage variations from 10 ms to 5 s Radiated emission test 30 MHz to 18 GHz Proximity magnetic field up to 65 A/m	F1	F



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Electrical	Multimedia equipment	Conducted emission tests Radiated emission test	EN 55032:2015/AC:2016 /A1:2020/A11:2020 CISPR 32:2015/AMD1:2019	Conducted emissions in the frequency range 150kHz to 30 MHz Radiated emission test 30 MHz to 6000 MHz	F1	F
	Electromedical equipment, industrial equipment, information technology, lighting equipment, household appliances	Immunity to the electromagnetic field radiated with radiofrequency	EN 61000-4-3:2006/A1:2009/A2:2010 IEC 61000-4-3:2006/A1:2007/A2:2010	Electromagnetic fields 10V/m from 80 MHz to 3 GHz	F1	
		Immunity to RF current	EN 61000-4-6:2014/AC:2015 IEC 61000-4-6:2013	RF currents from 150 kHz to 80MHz Voltage level up to 30 V	F1	
		Immunity to ESD	EN 61000-4-2: 2009/ IEC 61000-4-2:2008	Electrostatic air discharge test up to 15kV and electrostatic contact discharge up to ± 8 kV	F1	
		Immunity to Burst/fast transient	IEC 61000-4-4:2012, EN 61000-4-4:2012	Immunity to burst/fast transients up to 4 kV, with frequency repetition 5 or 100 KHz	F1	
		Immunity to Surge	IEC 61000-4-5:2014/A1:2017, EN 61000-4-5:2014/A1:2017	Immunity to surge up to 4kV	F1	
		Immunity to dips and voltage variations	IEC61000-4-11:2004 / A1:2017 IEC 61000-4-11:2020 EN 61000-4-11:2004 / A1:2007 EN 61000-4-11:2020	Immunity to 0% 40% 70% 80% voltage dips and variation	F1	
		Harmonic current emissions	EN 61000-3-2:2019/A1:2021 IEC 61000-3-2:2018/A1:2020	Max current 16 A	F1	
		Flicker measurement (parameters pst, plt, dt, dc, dmax)	EN 61000-3-3:2013/A1:2019/A2:2021/AC:2022 IEC 61000-3-3:2013/A1:2017/A2:2021/COR1:2022	Max current 16A	F1	
		Immunity to magnetic fields	EN 61000-4-8:2010 IEC 61000-4-8:2009	Up to 100 A/m	F1	



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Electrical	Electric and electronic equipment for residential, commercial and light-industrial environments	Conducted emission tests Harmonics Flicker	IEC 61000-6-3:2006/A1:2010 IEC 61000-6-3:2020 EN 61000-6-3:2007/A1:2011+A1:2011/EC:2012 EN 61000-6-3:2021	Conducted emissions in the frequency range 150 kHz to 30 MHz Harmonics on power line Flicker on power line	F1	F
	Electric and electronic equipment for industrial environments	Conducted emission tests Harmonics Flicker	IEC 61000-6-4:2009, IEC 61000-6-4:2018 EN 61000-6-4:2007/A1:2011 EN 61000-6-4:2019	Conducted emissions in the frequency range 150kHz to 30 MHz Harmonics on power line Flicker on power line	F1	F
Electrical and Mechanical	Medical electrical equipment - General requirements for basic safety and essential performance	4 - General Requirements 5 - General Requirements for Testing ME Equipment 6 - Classification of ME Equipment and ME Systems 7 - ME Equipment Identification, Marking and Documents 8 Protection Against Electrical Hazards from ME Equipment 9 - Protection Against Mechanical Hazards of ME Equipment and ME Systems 10 - Protection Against Unwanted and Excessive Radiation Hazards 11 Protection Against Excessive Temperatures and Other Hazards 12 - Accuracy of Controls and Instruments and Protection Against Hazardous Outputs 13 Hazardous Situations and Fault Conditions 14 Programmable Electrical Medical Systems (PEMS) 15 - Construction of ME Equipment 16 ME Systems 17 - Electromagnetic Compatibility of ME Equipment and ME Systems	EN 60601-1:2006/AC:2010/A1:2013 / A12:2014/A2:2021 IEC 60601-1:2005/AMD1:2012/AM D2:2020	Visual examination Power/current absorption up to 16 A Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 32 °C	F1	F



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Electrical and Mechanical	Medical electrical equipment Part 2: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment	201.4 General Requirements 201.5 General Requirements for Testing ME Equipment 201.6 Classification of ME Equipment and ME Systems 201.7 ME Equipment Identification, Marking and Documents 201.8 Protection Against Electrical Hazards from ME Equipment 201.9 Protection Against Mechanical Hazards of ME Equipment and ME Systems 201.10 Protection Against Unwanted and Excessive Radiation Hazards 201.11 Protection Against Excessive Temperatures and Other Hazards: 201.12 Accuracy of Controls and Instruments and Protection Against Hazardous Outputs 201.13 Hazardous Situations and Fault Conditions 201.14 Programmable Electrical Medical Systems (PEMS) 201.15 Construction of ME Equipment 201.16 ME Systems 201.17 Electromagnetic Compatibility of ME Equipment and ME Systems	IEC 60601-2-22:2007/A1:2012 IEC 60601-2-22:2019 EN 60601-2-22:2013 EN IEC 60601-2-22:2020	Visual examination Power/current UP 1 up to 16 A Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 32 °C Fault condition up to 63 A Force up to 200 N Laser power measurements up to 30 W	F1	F



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Electrical and Mechanical	Medical electrical 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	201.4 General Requirements 201.5 General Requirements for Testing ME Equipment 201.6 Classification of ME Equipment and ME Systems 201.7 ME Equipment Identification, Marking and Documents 201.8 Protection Against Electrical Hazards from ME Equipment 201.9 Protection Against Mechanical Hazards of ME Equipment and ME Systems 201.10 Protection Against Unwanted and Excessive Radiation Hazards 201.11 Protection Against Excessive Temperatures and Other Hazards: 201.12 Accuracy of Controls and Instruments and Protection Against Hazardous Outputs 201.13 Hazardous Situations and Fault Conditions 201.14 Programmable Electrical Medical Systems (PEMS) 201.15 Construction of ME Equipment 201.16 ME Systems 201.17 Electromagnetic Compatibility of ME Equipment and ME Systems	CEI EN 60601-2-57:2012, EN 60601-2-57:2011, IEC 60601-2-57:2011	Visual examination Power/current absorption up to 16 A Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test up to 5500 V Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 32 °C Fault condition up to 63 A	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus	4 - General Requirement 5 - General Conditions for the Tests 6 - Classification 7 - Marking and Instructions 8 - Protection Against Access to Live Parts 9 - Starting of Motor-Operated Appliances 10 - Power Input and Current 11 - Heating 13 - Leakage Current and Electric Strength at Operating Temperature 14 - Transient Overvoltages 15 - Moisture Resistance 16 - Leakage Current and Electric Strength 17 - Overload Protection of Transformers and Associated Circuits 18 - Endurance 19 - Abnormal Operation 20 - Stability and Mechanical Hazards 21 - Mechanical Strength 22 - Construction 23 - Internal Wiring 24 - Components 25 - Supply Connection and External Flexible Cords 26 - Terminals for External Conductors 27 - Provision for Earthing 28 - Screws and Connections 29 - Clearances, Creepage Distances and Solid Insulation 30 - Resistance to Heat and Fire 31 - Resistance to Rusting 32 - Radiation, Toxicity and Similar Hazards	EN 60335-1:2012/AC:2014/A11:2014/A13:2017/A1:2019/A2:2019/A14:2019 CEI EN 60335-1:2013/A11:2015/EC:2014/A13:2019/A1/A2/A14:2019 IEC 60335-1:2010/AMD1:2013/AMD2:2016/ISH1:2020 IEC 60335-1:2020	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 32 °C Fault condition up to 63 A Pull force up to 100 N	F1	F



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Electrical and Mechanical	Safety requirements for electrical equipment for measurement, control and laboratory use	4 - Tests 5 - Marking and Documentation 6 - Protection Against Electric Shock 7 - Protection Against Mechanical Hazards 8 - Resistance to Mechanical Stresses 9 - Protection Against the Spread of Fire 10 - Equipment Temperature Limits and Resistance to Heat 11 - Protection Against Hazards from Fluids 14 - Components and Subassemblies 15 - Protection by Interlocks 16 - Hazards Resulting from Application 17 - Risk Assessment	CEI EN 61010-1:2013/EC:2017/A1:2019 EN 61010-1:2010/A1:2019 IEC 61010-1:2010/AMD1:2016	Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test up to 5500 V	F1	F
	Audio/video, information and communication technology equipment	4 - General Requirements 5 - Electrically-Caused Injury 6 - Electrically-Caused Fire 7 - Injury Caused by Hazardous Substances 8 - Mechanically-Caused Injury 9 - Thermal Burn Injury 10 - Radiation	CEI EN 62368-1:2016/EC:2018/A11:2017 EN 62368-1:2014/AC:2015/A11:2017/A C:2017 EN IEC 62368-1:2020/A11:2020/AC:2020 IEC 62368-1:2018	Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5 500 V	F1	F
	Luminaires	2 - Classification of Luminaires 3 - Marking 4 - Construction 5 - External and Internal Wiring 7 - Provision for Earthing 8 - Protection Against Electric Shock 9 - Resistance to Dust, Solid Object and Moisture	CEI EN 60598-1:2015/A1:2019/EC:2015/EC:2016 EN 60598-1:2015/A1:2018/AC:2015/AC:2016/AC:2017 IEC 60598-1:2020 IEC 60598-1:2014/AMD1:2017	Power/current absorption up to 16 A Leakage current up to 5 mA Up to 93 % of relative humidity Dielectric strength test up to 5 500 V	F1	F



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Electrical and Mechanical	Luminaires	10 - Insulation Resistance and Electric Strength, Touch Current and Protective Conductor Current 11 - Creepage Distances and Clearances 12 - Endurance Test and Thermal Test 13 - Resistance to Heat, Fire and Tracking 14 - Screw Terminals 15 - Screwless Terminals and Electrical Connections	CEI EN 60598-1:2015/A1:2019/EC:2015/EC:2016 EN 60598-1:2015/A1:2018/AC:2015/AC:2016/AC:2017 IEC 60598-1:2020 IEC 60598-1:2014/AMD1:2017	Power/current absorption up to 16 A Leakage current up to 5 mA Up to 93 % of relative humidity Dielectric strength test up to 5 500 V	F1	F
	Medical devices	Medical Devices - Application of Risk Management to Medical Devices	EN ISO 14971:2019 EN ISO 14971:2012	Documental Inspection	F1	F
		Medical Electrical Equipment Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability	IEC 60601-1-6:2010+AMD1:2013+AMD2:2020		F1	
		Medical Devices Application of Usability Engineering to Medical Devices	EN 62366-1:2015/AC:2015/A1:2020 IEC 62366 1:2015/A1:2020		F1	
		Medical Device Software Software Life-Cycle Processes	IEC 62304:2006+AMD 1:2015 EN 62304-1:2006/A1:2015		F1	



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus - vacuum cleaners and water-suction cleaning appliances	4 - General Requirement 5 - General Conditions for the Tests 6 -Classification 7 -Marking and Instructions 8 -Protection Against Access to Live Parts 9 -Starting of Motor Operated Appliances 10 -Power Input and Current 11 -Heating 13 -Leakage Current and Electric Strength at Operating Temperature 14- Transient Overvoltages 15 - Moisture Resistance 16 - Leakage Current and Electric Strength 17 -Overload Protection of Transformers and Associated Circuits 18 - Endurance 19 - Abnormal Operation 20 - Stability and Mechanical Hazards 21 - Mechanical Strength 22 -Construction 23 -Internal Wiring 24 -Components 25 -Supply Connection and External Flexible Cords 26 - Terminals for External Conductors 27 -Provision for Earthing 28 - Screws and Connections 29 - Clearances, Creepage Distances and Solid Insulation 30 - Resistance to Heat and Fire 31 - Resistance to Rusting 32 - Radiation, Toxicity and Similar Hazards	IEC 60335-2-2:2009/AMD1:2012/AM D2:2016 IEC 60335-2-2:2019 EN 60335-2-2:2010/A1:2013/A11:2012	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: – 40 °C to 180 °C Fault condition up to 63 A Pull force up to 100 N	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus - electric irons	4 - General Requirement 5 - General Conditions for the Tests 6 -Classification 7 -Marking and Instructions 8 -Protection Against Access to Live Parts 9 -Starting of Motor Operated Appliances 10 -Power Input and Current 11 -Heating 13 -Leakage Current and Electric Strength at Operating Temperature 14- Transient Overvoltages 15 - Moisture Resistance 16 - Leakage Current and Electric Strength 17 -Overload Protection of Transformers and Associated Circuits 18 - Endurance 19 - Abnormal Operation 20 - Stability and Mechanical Hazards 21 - Mechanical Strength 22 -Construction 23 -Internal Wiring 24 -Components 25 -Supply Connection and External Flexible Cords 26 - Terminals for External Conductors 27 -Provision for Earthing 28 - Screws and Connections 29 - Clearances, Creepage Distances and Solid Insulation 30 - Resistance to Heat and Fire 31 - Resistance to Rusting 32 - Radiation, Toxicity and Similar Hazards	IEC 60335-2-3:2012+A1:2015 EN 60335-2-3:2016/A1:2020	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 30 °C Fault condition up to 63 A Pull force up to 100 N	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus - havers, hair clippers and similar appliances	4 - General Requirement 5 - General Conditions for the Tests 6 -Classification 7 -Marking and Instructions 8 -Protection Against Access to Live Parts 9 -Starting of Motor Operated Appliances 10 -Power Input and Current 11 -Heating 13 -Leakage Current and Electric Strength at Operating Temperature 14- Transient Overvoltages 15 - Moisture Resistance 16 - Leakage Current and Electric Strength 17 -Overload Protection of Transformers and Associated Circuits 18 - Endurance 19 - Abnormal Operation 20 - Stability and Mechanical Hazards 21 - Mechanical Strength 22 -Construction 23 -Internal Wiring 24 -Components 25 -Supply Connection and External Flexible Cords 26 - Terminals for External Conductors 27 -Provision for Earthing 28 - Screws and Connections 29 - Clearances, Creepage Distances and Solid Insulation 30 - Resistance to Heat and Fire 31 - Resistance to Rusting 32 - Radiation, Toxicity and Similar Hazards	IEC 60335-2-8:2012+AMD1:2015+AMD2:2018 EN 60335-2-8:2015/A1:2016/A2:2022/A11:2022/A12:2022	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 30 °C Fault condition up to 63 A Pull force up to 100 N	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus - grills, toasters and similar portable cooking appliances	4 - General Requirement 5 - General Conditions for the Tests 6 -Classification 7 -Marking and Instructions 8 -Protection Against Access to Live Parts 9 -Starting of Motor Operated Appliances 10 -Power Input and Current 11 -Heating 13 -Leakage Current and Electric Strength at Operating Temperature 14- Transient Overvoltages 15 - Moisture Resistance 16 - Leakage Current and Electric Strength 17 -Overload Protection of Transformers and Associated Circuits 18 - Endurance 19 - Abnormal Operation 20 - Stability and Mechanical Hazards 21 - Mechanical Strength 22 -Construction 23 -Internal Wiring 24 -Components 25 -Supply Connection and External Flexible Cords 26 - Terminals for External Conductors 27 -Provision for Earthing 28 - Screws and Connections 29 - Clearances, Creepage Distances and Solid Insulation 30 - Resistance to Heat and Fire 31 - Resistance to Rusting 32 - Radiation, Toxicity and Similar Hazards	IEC 60335-2-9:2019, EN 60335-2-9:2003/A12:2007/A13:2010/AC:2011/AC:2012/A1:2004/A2:2006	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 30 °C Fault condition up to 63 A Pull force up to 100 N	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus - warming plates and similar appliances	4 - General Requirement 5 - General Conditions for the Tests 6 -Classification 7 -Marking and Instructions 8 -Protection Against Access to Live Parts 9 -Starting of Motor Operated Appliances 10 -Power Input and Current 11 -Heating 13 -Leakage Current and Electric Strength at Operating Temperature 14- Transient Overvoltages 15 - Moisture Resistance 16 - Leakage Current and Electric Strength 17 -Overload Protection of Transformers and Associated Circuits 18 - Endurance 19 - Abnormal Operation 20 - Stability and Mechanical Hazards 21 - Mechanical Strength 22 -Construction 23 -Internal Wiring 24 -Components 25 -Supply Connection and External Flexible Cords 26 - Terminals for External Conductors 27 -Provision for Earthing 28 - Screws and Connections 29 - Clearances, Creepage Distances and Solid Insulation 30 - Resistance to Heat and Fire 31 - Resistance to Rusting 32 - Radiation, Toxicity and Similar Hazards	IEC 60335-2-12:2002+AMD1:2008 +AMD2:2017, EN 60335-2-12:2003/A1:2008/A2: 2019/A11:2019	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 30 °C Fault condition up to 63 A Pull force up to 100 N	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus - deep fat fryers, frying pans and similar appliances	4 - General Requirement 5 - General Conditions for the Tests 6 -Classification 7 -Marking and Instructions 8 -Protection Against Access to Live Parts 9 -Starting of Motor Operated Appliances 10 -Power Input and Current 11 -Heating 13 -Leakage Current and Electric Strength at Operating Temperature 14- Transient Overvoltages 15 - Moisture Resistance 16 - Leakage Current and Electric Strength 17 -Overload Protection of Transformers and Associated Circuits 18 - Endurance 19 - Abnormal Operation 20 - Stability and Mechanical Hazards 21 - Mechanical Strength 22 -Construction 23 -Internal Wiring 24 -Components 25 -Supply Connection and External Flexible Cords 26 - Terminals for External Conductors 27 -Provision for Earthing 28 - Screws and Connections 29 - Clearances, Creepage Distances and Solid Insulation 30 - Resistance to Heat and Fire 31 - Resistance to Rusting 32 - Radiation, Toxicity and Similar Hazards	IEC 60335-2-13:2021 IEC 60335-2-13:2009+AMD1:2016 EN 60335-2-13:2010/A11:2012/A1:2019	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 30 °C Fault condition up to 63 A Pull force up to 100 N	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus - kitchen machines	4 - General Requirement 5 - General Conditions for the Tests 6 -Classification 7 -Marking and Instructions 8 -Protection Against Access to Live Parts 9 -Starting of Motor Operated Appliances 10 -Power Input and Current 11 -Heating 13 -Leakage Current and Electric Strength at Operating Temperature 14- Transient Overvoltages 15 - Moisture Resistance 16 - Leakage Current and Electric Strength 17 -Overload Protection of Transformers and Associated Circuits 18 - Endurance 19 - Abnormal Operation 20 - Stability and Mechanical Hazards 21 - Mechanical Strength 22 -Construction 23 -Internal Wiring 24 -Components 25 -Supply Connection and External Flexible Cords 26 - Terminals for External Conductors 27 -Provision for Earthing 28 - Screws and Connections 29 - Clearances, Creepage Distances and Solid Insulation 30 - Resistance to Heat and Fire 31 - Resistance to Rusting 32 - Radiation, Toxicity and Similar Hazards	IEC 60335-2-14:2016+AMD1:2019 EN 60335-2-14:2006/A1:2008/A11:2012/AC:2016/A12:2016	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 30 °C Fault condition up to 63 A Pull force up to 100N	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus - heating liquids	4 - General Requirement 5 - General Conditions for the Tests 6 -Classification 7 -Marking and Instructions 8 -Protection Against Access to Live Parts 9 -Starting of Motor Operated Appliances 10 -Power Input and Current 11 -Heating 13 -Leakage Current and Electric Strength at Operating Temperature 14- Transient Overvoltages 15 - Moisture Resistance 16 - Leakage Current and Electric Strength 17 -Overload Protection of Transformers and Associated Circuits 18 - Endurance 19 - Abnormal Operation 20 - Stability and Mechanical Hazards 21 - Mechanical Strength 22 -Construction 23 -Internal Wiring 24 -Components 25 -Supply Connection and External Flexible Cords 26 - Terminals for External Conductors 27 -Provision for Earthing 28 - Screws and Connections 29 - Clearances, Creepage Distances and Solid Insulation 30 - Resistance to Heat and Fire 31 - Resistance to Rusting 32 - Radiation, Toxicity and Similar Hazards	IEC 60335-2-15:2012+AMD1:2016 +AMD2:2018, EN 60335-2-15:2016/A11:2018/A12:2021/A1:2021/A2:2021	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 30 °C Fault condition up to 63 A Pull force up to 100 N	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus - appliances for skin or hair care	4 - General Requirement 5 - General Conditions for the Tests 6 -Classification 7 -Marking and Instructions 8 -Protection Against Access to Live Parts 9 -Starting of Motor Operated Appliances 10 -Power Input and Current 11 -Heating 13 -Leakage Current and Electric Strength at Operating Temperature 14- Transient Overvoltages 15 - Moisture Resistance 16 - Leakage Current and Electric Strength 17 -Overload Protection of Transformers and Associated Circuits 18 - Endurance 19 - Abnormal Operation 20 - Stability and Mechanical Hazards 21 - Mechanical Strength 22 -Construction 23 -Internal Wiring 24 -Components 25 -Supply Connection and External Flexible Cords 26 - Terminals for External Conductors 27 -Provision for Earthing 28 - Screws and Connections 29 - Clearances, Creepage Distances and Solid Insulation 30 - Resistance to Heat and Fire 31 - Resistance to Rusting 32 - Radiation, Toxicity and Similar Hazards	IEC 60335-2-23:2016+AMD1:2019, EN 60335-2-23:2003/A11:2010/AC:2012/A1:2008/A2:2015	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 30 °C Fault condition up to 63 A Pull force up to 100 N	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus - refrigerating appliances, ice-cream appliances and ice makers	4 - General Requirement 5 - General Conditions for the Tests 6 -Classification 7 -Marking and Instructions 8 -Protection Against Access to Live Parts 9 -Starting of Motor Operated Appliances 10 -Power Input and Current 11 -Heating 13 -Leakage Current and Electric Strength at Operating Temperature 14- Transient Overvoltages 15 - Moisture Resistance 16 - Leakage Current and Electric Strength 17 -Overload Protection of Transformers and Associated Circuits 18 - Endurance 19 - Abnormal Operation 20 - Stability and Mechanical Hazards 21 - Mechanical Strength 22 -Construction 23 -Internal Wiring 24 -Components 25 -Supply Connection and External Flexible Cords 26 - Terminals for External Conductors 27 -Provision for Earthing 28 - Screws and Connections 29 - Clearances, Creepage Distances and Solid Insulation 30 - Resistance to Heat and Fire 31 - Resistance to Rusting 32 - Radiation, Toxicity and Similar Hazards	IEC 60335-2-24:2020 EN 60335-2-24:2010 /A1:2019/A2:2019/ A11:2020	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 30 °C Fault condition up to 63 A Pull force up to 100 N	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus - skin exposure to optical radiation	4 - General Requirement 5 - General Conditions for the Tests 6 -Classification 7 -Marking and Instructions 8 -Protection Against Access to Live Parts 9 -Starting of Motor Operated Appliances 10 -Power Input and Current 11 -Heating 13 -Leakage Current and Electric Strength at Operating Temperature 14- Transient Overvoltages 15 - Moisture Resistance 16 - Leakage Current and Electric Strength 17 -Overload Protection of Transformers and Associated Circuits 18 - Endurance 19 - Abnormal Operation 20 - Stability and Mechanical Hazards 21 - Mechanical Strength 22 -Construction 23 -Internal Wiring 24 -Components 25 -Supply Connection and External Flexible Cords 26 - Terminals for External Conductors 27 -Provision for Earthing 28 - Screws and Connections 29 - Clearances, Creepage Distances and Solid Insulation 30 - Resistance to Heat and Fire 31 - Resistance to Rusting 32 - Radiation, Toxicity and Similar Hazards	IEC 60335-2-27:2019, EN 60335-2-27:2013,A1:2020/A2: 2020	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 30 °C Fault condition up to 63 A Pull force up to 100 N	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus - battery chargers	4 - General Requirement 5 - General Conditions for the Tests 6 -Classification 7 -Marking and Instructions 8 -Protection Against Access to Live Parts 9 -Starting of Motor Operated Appliances 10 -Power Input and Current 11 -Heating 13 -Leakage Current and Electric Strength at Operating Temperature 14- Transient Overvoltages 15 - Moisture Resistance 16 - Leakage Current and Electric Strength 17 -Overload Protection of Transformers and Associated Circuits 18 - Endurance 19 - Abnormal Operation 20 - Stability and Mechanical Hazards 21 - Mechanical Strength 22 -Construction 23 -Internal Wiring 24 -Components 25 -Supply Connection and External Flexible Cords 26 - Terminals for External Conductors 27 -Provision for Earthing 28 - Screws and Connections 29 - Clearances, Creepage Distances and Solid Insulation 30 - Resistance to Heat and Fire 31 - Resistance to Rusting 32 - Radiation, Toxicity and Similar Hazards	IEC 60335-2-29:2016+AMD1:2019, EN 60335-2-29:2021/A1:2021	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 30 °C Fault condition up to 63 A Pull force up to 100 N	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus -range hoods and other cooking fume extractors	4 - General Requirement 5 - General Conditions for the Tests 6 -Classification 7 -Marking and Instructions 8 -Protection Against Access to Live Parts 9 -Starting of Motor Operated Appliances 10 -Power Input and Current 11 -Heating 13 -Leakage Current and Electric Strength at Operating Temperature 14- Transient Overvoltages 15 - Moisture Resistance 16 - Leakage Current and Electric Strength 17 -Overload Protection of Transformers and Associated Circuits 18 - Endurance 19 - Abnormal Operation 20 - Stability and Mechanical Hazards 21 - Mechanical Strength 22 -Construction 23 -Internal Wiring 24 -Components 25 -Supply Connection and External Flexible Cords 26 - Terminals for External Conductors 27 -Provision for Earthing 28 - Screws and Connections 29 - Clearances, Creepage Distances and Solid Insulation 30 - Resistance to Heat and Fire 31 - Resistance to Rusting 32 - Radiation, Toxicity and Similar Hazards	IEC 60335-2-31:2012+AMD1:2016 +AMD2:2018, EN 60335-2-31:2014	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 30 °C Fault condition up to 63 A Pull force up to 100 N	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus - massage appliances	4 - General Requirement 5 - General Conditions for the Tests 6 -Classification 7 -Marking and Instructions 8 -Protection Against Access to Live Parts 9 -Starting of Motor Operated Appliances 10 -Power Input and Current 11 -Heating 13 -Leakage Current and Electric Strength at Operating Temperature 14- Transient Overvoltages 15 - Moisture Resistance 16 - Leakage Current and Electric Strength 17 -Overload Protection of Transformers and Associated Circuits 18 - Endurance 19 - Abnormal Operation 20 - Stability and Mechanical Hazards 21 - Mechanical Strength 22 -Construction 23 -Internal Wiring 24 -Components 25 -Supply Connection and External Flexible Cords 26 - Terminals for External Conductors 27 -Provision for Earthing 28 - Screws and Connections 29 - Clearances, Creepage Distances and Solid Insulation 30 - Resistance to Heat and Fire 31 - Resistance to Rusting 32 - Radiation, Toxicity and Similar Hazards	IEC 60335-2:32:2019, EN 60335-2-32:2021	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 30 °C Fault condition up to 63 A Pull force up to 100 N	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus - instantaneous water heaters	4 - General Requirement 5 - General Conditions for the Tests 6 -Classification 7 -Marking and Instructions 8 -Protection Against Access to Live Parts 9 -Starting of Motor Operated Appliances 10 -Power Input and Current 11 -Heating 13 -Leakage Current and Electric Strength at Operating Temperature 14- Transient Overvoltages 15 - Moisture Resistance 16 - Leakage Current and Electric Strength 17 -Overload Protection of Transformers and Associated Circuits 18 - Endurance 19 - Abnormal Operation 20 - Stability and Mechanical Hazards 21 - Mechanical Strength 22 -Construction 23 -Internal Wiring 24 -Components 25 -Supply Connection and External Flexible Cords 26 - Terminals for External Conductors 27 -Provision for Earthing 28 - Screws and Connections 29 - Clearances, Creepage Distances and Solid Insulation 30 - Resistance to Heat and Fire 31 - Resistance to Rusting 32 - Radiation, Toxicity and Similar Hazards	IEC 60335-2-35:2012+AMD1:2016 +AMD2:2020, EN 60335-2-35:2016/A1:2019/A2: 2021	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 30 °C Fault condition up to 63 A Pull force up to 100 N	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus - insect killers	4 - General Requirement 5 - General Conditions for the Tests 6 -Classification 7 -Marking and Instructions 8 -Protection Against Access to Live Parts 9 -Starting of Motor Operated Appliances 10 -Power Input and Current 11 -Heating 13 -Leakage Current and Electric Strength at Operating Temperature 14- Transient Overvoltages 15 - Moisture Resistance 16 - Leakage Current and Electric Strength 17 -Overload Protection of Transformers and Associated Circuits 18 - Endurance 19 - Abnormal Operation 20 - Stability and Mechanical Hazards 21 - Mechanical Strength 22 -Construction 23 -Internal Wiring 24 -Components 25 -Supply Connection and External Flexible Cords 26 - Terminals for External Conductors 27 -Provision for Earthing 28 - Screws and Connections 29 - Clearances, Creepage Distances and Solid Insulation 30 - Resistance to Heat and Fire 31 - Resistance to Rusting 32 - Radiation, Toxicity and Similar Hazards	IEC 60335-2-59:2002/A1:2006/A2: 2009, IEC 60335-2-59:2021 EN 60335-2-59:2003/A1:2006/A2: 2009/A11:2018	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 30 °C Fault condition up to 63 A Pull force up to 100 N	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus - air-cleaning appliances	4 - General requirement 5 - General Conditions for the Tests 6 -Classification 7 -Marking and Instructions 8 -Protection Against Access to Live Parts 9 -Starting of Motor Operated Appliances 10 -Power Input and Current 11 -Heating 13 -Leakage Current and Electric Strength at Operating Temperature 14- Transient Overvoltages 15 - Moisture Resistance 16 - Leakage Current and Electric Strength 17 -Overload Protection of Transformers and Associated Circuits 18 - Endurance 19 - Abnormal Operation 20 - Stability and Mechanical Hazards 21 - Mechanical Strength 22 -Construction 23 -Internal Wiring 24 -Components 25 -Supply Connection and External Flexible Cords 26 - Terminals for External Conductors 27 -Provision for Earthing 28 - Screws and Connections 29 - Clearances, Creepage Distances and Solid Insulation 30 - Resistance to Heat and Fire 31 - Resistance to Rusting 32 - Radiation, Toxicity and Similar Hazards	IEC 60335-2-65:2002/Ec1:2004/A1:2008 EN 60335-2-65:2003/A1:2008/A11:2012/A12:2022/A2:2022	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 30 °C Fault condition up to 63 A Pull force up to 100 N	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus - commercial dispensing appliances and vending machines	4 - General Requirement 5 - General Conditions for the Tests 6 -Classification 7 -Marking and Instructions 8 -Protection Against Access to Live Parts 9 -Starting of Motor Operated Appliances 10 -Power Input and Current 11 -Heating 13 -Leakage Current and Electric Strength at Operating Temperature 14- Transient Overvoltages 15 - Moisture Resistance 16 - Leakage Current and Electric Strength 17 -Overload Protection of Transformers and Associated Circuits 18 - Endurance 19 - Abnormal Operation 20 - Stability and Mechanical Hazards 21 - Mechanical Strength 22 -Construction 23 -Internal Wiring 24 -Components 25 -Supply Connection and External Flexible Cords 26 - Terminals for External Conductors 27 -Provision for Earthing 28 - Screws and Connections 29 - Clearances, Creepage Distances and Solid Insulation 30 - Resistance to Heat and Fire 31 - Resistance to Rusting 32 - Radiation, Toxicity and Similar Hazards	IEC 60335-2-75:2012+AMD1:2015 +AMD2:2018, EN 60335-2-75:2004/A1:2005/A11 :2006/A2:2008/A12:2010	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 30 °C Fault condition up to 63 A Pull force up to 100 N	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus - fans	4 - General Requirement 5 - General Conditions for the Tests 6 -Classification 7 -Marking and Instructions 8 -Protection Against Access to Live Parts 9 -Starting of Motor Operated Appliances 10 -Power Input and Current 11 -Heating 13 -Leakage Current and Electric Strength at Operating Temperature 14- Transient Overvoltages 15 - Moisture Resistance 16 - Leakage Current and Electric Strength 17 -Overload Protection of Transformers and Associated Circuits 18 - Endurance 19 - Abnormal Operation 20 - Stability and Mechanical Hazards 21 - Mechanical Strength 22 -Construction 23 -Internal Wiring 24 -Components 25 -Supply Connection and External Flexible Cords 26 - Terminals for External Conductors 27 -Provision for Earthing 28 - Screws and Connections 29 - Clearances, Creepage Distances and Solid Insulation 30 - Resistance to Heat and Fire 31 - Resistance to Rusting 32 - Radiation, Toxicity and Similar Hazards	EN 60335-2-80:2003/A1:2004/A2: 2009, IEC 60335-2-80:2015	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 30 °C Fault condition up to 63 A Pull force up to 100 N	F1	F



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Electrical and Mechanical	Medical electrical equipment - high frequency surgical equipment and high frequency surgical accessories	4 - General Requirements 5 - General Requirements for Testing ME Equipment 6 - Classification of ME Equipment and ME Systems 7 - ME Equipment Identification, Marking and Documents 8 Protection Against Electrical Hazards from ME Equipment 9 - Protection Against Mechanical Hazards of ME Equipment and ME Systems 10 - Protection Against Unwanted and Excessive Radiation Hazards 11 Protection Against Excessive Temperatures and Other Hazards 12 - Accuracy of Controls and Instruments and Protection Against Hazardous Outputs 13 Hazardous Situations and Fault Conditions 14 Programmable Electrical Medical Systems (PEMS) 15 - Construction of ME Equipment 16 ME Systems 17 - Electromagnetic Compatibility of ME Equipment and ME Systems	IEC 60601-2-2:2017 EN 60601-2-2:2018	Visual examination Power/current absorption up to 16 A Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 °C to 30 °C	F1	F



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Electrical and Mechanical	Medical electrical equipment - endoscopic equipment	4 - General Requirements 5 - General Requirements for Testing ME Equipment 6 - Classification of ME Equipment and ME Systems 7 - ME Equipment Identification, Marking and Documents 8 Protection Against Electrical Hazards from ME Equipment 9 - Protection Against Mechanical Hazards of ME Equipment and ME Systems 10 - Protection Against Unwanted and Excessive Radiation Hazards 11 Protection Against Excessive Temperatures and Other Hazards 12 - Accuracy of Controls and Instruments and Protection Against Hazardous Outputs 13 Hazardous Situations and Fault Conditions 14 Programmable Electrical Medical Systems (PEMS) 15 - Construction of ME Equipment 16 ME Systems 17 - Electromagnetic Compatibility of ME Equipment and ME Systems	EN 60601-2-18:2015 IEC 60601-2-18:2009	Visual examination Power/current absorption up to 16 A Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 °C to 32 °C	F1	F



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Contact Name: Massimo Ambrosi Phone: 071-915-6048

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Electrical and Mechanical	Medical electrical equipment - infant phototherapy equipment	4 - General Requirements 5 - General Requirements for Testing ME Equipment 6 - Classification of ME Equipment and ME Systems 7 - ME Equipment Identification, Marking and Documents 8 Protection Against Electrical Hazards from ME Equipment 9 - Protection Against Mechanical Hazards of ME Equipment and ME Systems 10 - Protection Against Unwanted and Excessive Radiation Hazards 11 Protection Against Excessive Temperatures and Other Hazards 12 - Accuracy of Controls and Instruments and Protection Against Hazardous Outputs 13 Hazardous Situations and Fault Conditions 14 Programmable Electrical Medical Systems (PEMS) 15 - Construction of ME Equipment 16 ME Systems 17 - Electromagnetic Compatibility of ME Equipment and ME Systems	EN 60601-2-50:2021 IEC 60601-2-50:2020	Visual examination Power/current absorption up to 16 A Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 °C to 32 °C	F1	F



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Electrical and Mechanical	Medical electrical equipment - infant transport incubators	4 - General Requirements 5 - General Requirements for Testing ME Equipment 6 - Classification of ME Equipment and ME Systems 7 - ME Equipment Identification, Marking and Documents 8 Protection Against Electrical Hazards from ME Equipment 9 - Protection Against Mechanical Hazards of ME Equipment and ME Systems 10 - Protection Against Unwanted and Excessive Radiation Hazards 11 Protection Against Excessive Temperatures and Other Hazards 12 - Accuracy of Controls and Instruments and Protection Against Hazardous Outputs 13 Hazardous Situations and Fault Conditions 14 Programmable Electrical Medical Systems (PEMS) 15 - Construction of ME Equipment 16 ME Systems 17 - Electromagnetic Compatibility of ME Equipment and ME Systems	EN IEC 60601-2-20:2020 , IEC 60601-2-20:2020	Visual examination Power/current absorption up to 16 A Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 °C to 32 °C	F1	F



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Electrical and Mechanical	Medical electrical equipment - medical beds	4 - General Requirements 5 - General Requirements for Testing ME Equipment 6 - Classification of ME Equipment and ME Systems 7 - ME Equipment Identification, Marking and Documents 8 Protection Against Electrical Hazards from ME Equipment 9 - Protection Against Mechanical Hazards of ME Equipment and ME Systems 10 - Protection Against Unwanted and Excessive Radiation Hazards 11 Protection Against Excessive Temperatures and Other Hazards 12 - Accuracy of Controls and Instruments and Protection Against Hazardous Outputs 13 Hazardous Situations and Fault Conditions 14 Programmable Electrical Medical Systems (PEMS) 15 - Construction of ME Equipment 16 ME Systems 17 - Electromagnetic Compatibility of ME Equipment and ME Systems	EN 60601-2-52:2010/A1:2015/AC: 2011, IEC 60601-2-52:2009/A1:2015	Visual examination Power/current absorption up to 16 A Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 °C to 32 °C	F1	F



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Electrical and Mechanical	Medical electrical equipment - infant radiant warmers	4 - General Requirements 5 - General Requirements for Testing ME Equipment 6 - Classification of ME Equipment and ME Systems 7 - ME Equipment Identification, Marking and Documents 8 Protection Against Electrical Hazards from ME Equipment 9 - Protection Against Mechanical Hazards of ME Equipment and ME Systems 10 - Protection Against Unwanted and Excessive Radiation Hazards 11 Protection Against Excessive Temperatures and Other Hazards 12 - Accuracy of Controls and Instruments and Protection Against Hazardous Outputs 13 Hazardous Situations and Fault Conditions 14 Programmable Electrical Medical Systems (PEMS) 15 - Construction of ME Equipment 16 ME Systems 17 - Electromagnetic Compatibility of ME Equipment and ME Systems	EN 60601-2-21:2021, IEC 60601-2-21:2020	Visual examination Power/current absorption up to 16 A Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 °C to 32 °C	F1	F



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Electrical and Mechanical	Medical electrical equipment – haemodialysis, haemodiafiltration and haemofiltration equipment	4 - General Requirements 5 - General Requirements for Testing ME Equipment 6 - Classification of ME Equipment and ME Systems 7 - ME Equipment Identification, Marking and Documents 8 Protection Against Electrical Hazards from ME Equipment 9 - Protection Against Mechanical Hazards of ME Equipment and ME Systems 10 - Protection Against Unwanted and Excessive Radiation Hazards 11 Protection Against Excessive Temperatures and Other Hazards 12 - Accuracy of Controls and Instruments and Protection Against Hazardous Outputs 13 Hazardous Situations and Fault Conditions 14 Programmable Electrical Medical Systems (PEMS) 15 - Construction of ME Equipment 16 ME Systems 17 - Electromagnetic Compatibility of ME Equipment and ME Systems	EN 60601-2-16:2019 IEC 60601-2-16:2018	Visual examination Power/current absorption up to 16 A Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 °C to 32 °C	F1	F



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Electrical and Mechanical	Medical electrical equipment - nerve and musclestimulators	4 - General Requirements 5 - General Requirements for Testing ME Equipment 6 - Classification of ME Equipment and ME Systems 7 - ME Equipment Identification, Marking and Documents 8 Protection Against Electrical Hazards from ME Equipment 9 - Protection Against Mechanical Hazards of ME Equipment and ME Systems 10 - Protection Against Unwanted and Excessive Radiation Hazards 11 Protection Against Excessive Temperatures and Other Hazards 12 - Accuracy of Controls and Instruments and Protection Against Hazardous Outputs 13 Hazardous Situations and Fault Conditions 14 Programmable Electrical Medical Systems (PEMS) 15 - Construction of ME Equipment 16 ME Systems 17 - Electromagnetic Compatibility of ME Equipment and ME Systems	EN 60601-2-10:2015/A1:2016, IEC 60601-2-10:2012/A1:2016	Visual examination Power/current absorption up to 16 A Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 °C to 32 °C	F1	F



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Electrical and Mechanical	Medical electrical equipment - ultrasonic physiotherapy equipment	4 - General Requirements 5 - General Requirements for Testing ME Equipment 6 - Classification of ME Equipment and ME Systems 7 - ME Equipment Identification, Marking and Documents 8 Protection Against Electrical Hazards from ME Equipment 9 - Protection Against Mechanical Hazards of ME Equipment and ME Systems 10 - Protection Against Unwanted and Excessive Radiation Hazards 11 Protection Against Excessive Temperatures and Other Hazards 12 - Accuracy of Controls and Instruments and Protection Against Hazardous Outputs 13 Hazardous Situations and Fault Conditions 14 Programmable Electrical Medical Systems (PEMS) 15 - Construction of ME Equipment 16 ME Systems 17 - Electromagnetic Compatibility of ME Equipment and ME Systems	EN 60601-2-5:2015 , IEC 60601-2-5:2009	Visual examination Power/current absorption up to 16 A Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 °C to 32 °C	F1	F



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Environmental	Medical electrical equipment -	4.1 Identification of Environmental Aspects 4.2 Determination of Significant Environmental Aspects 4.3 Information from the Supply Chain 4.4 Reduction of Adverse Environmental Impacts 4.5 environmental Information	IEC 60601-1-9:2007+AMD1:2013+AMD2:2020, EN 60601-1-9:2008/A1:2013/A2:2020	Requirements for environmentally conscious design	F1	F
Electrical	Electrical equipment for measurement, control and laboratory use	Immunity to Electromagnetic Radiated Fields, Injected RF Currents, Magnetic Fields at Mains Frequency, Burst, Surge, ESD and Dips Conducted Emission Tests, Radiated Emission Test	EN IEC 61326-1:2021, IEC 61326-1:2020	Visual examination Electromagnetic fields up to 10V/m from 80 MHz to 2 700 MHz RF currents from 150kHz to 80MHz with level up to 10V Magnetic field a with level up to 30 A/m Burst and fast transient up to 4 KV Surge up to 4 KV ESD up to 15 KV Conducted emissions in the frequency range 150kHz to 30 MHz Radiated emission test 30 MHz to 1 GHz Immunity to dips and voltage variations from 10ms to 5s	F1	F



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Electrical	Electrical equipment	4 Designation 5 Degrees of Protection Against Access to Hazardous Parts and Against Solid Foreign Objects Indicated by the First Characteristic Numeral 6 Degrees of Protection Against Ingress of Water Indicated by the Second Characteristic Numeral 7 Degrees of Protection Against Access to Hazardous Parts Indicated by the Additional Letter 8 Supplementary Letters 9 Examples of Designations with the Ip Code 10 Marking 11 Examples of Designations with the Ip Code 12 Tests for Protection Against Access to Hazardous Parts Indicated by the First Characteristic Numeral 13 Tests for Protection Against Solid Foreign Objects Indicated by the First Characteristic Numeral 14 Tests for Protection Against Water Indicated by the Second Characteristic Numeral 15 Tests for Protection Against Access to Hazardous Parts Indicated by the Additional Letter	EN 60529:1991/corr:1993/A1:2000/A2:2013/EC:2016/A2AC:2019 IEC 529:1989/IEC 60529/A1:1999/A2:2013/COR2:2015/A2/COR1:2019	All IP degrees	F1	F
Environmental	Components or equipment	4 General Test Procedure 5 Measurements 6 Information to be Given in the Relevant Specification 7 Information to be Given in the Test Report	IEC 60068-2-78:2012 EN 60068-2-78:2013	UP TO 40°C Up to 93% RH		



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Electrical and mechanical	Medical electrical equipment- short-wave therapy equipment	4 - General Requirements 5 - General Requirements for Testing ME Equipment 6 - Classification of ME Equipment and ME Systems 7 - ME Equipment Identification, Marking and Documents 8 Protection Against Electrical Hazards from ME Equipment 9 - Protection Against Mechanical Hazards of ME Equipment and ME Systems 10 - Protection Against Unwanted and Excessive Radiation Hazards 11 Protection Against Excessive Temperatures and Other Hazards 12 - Accuracy of Controls and Instruments and Protection Against Hazardous Outputs 13 Hazardous Situations and Fault Conditions 14 Programmable Electrical Medical Systems (PEMS) 15 - Construction of ME Equipment 16 ME Systems 17 - Electromagnetic Compatibility of ME Equipment and ME Systems	IEC 60601-2-3:2012/AMD1:2016 EN 60601-2-3:2015/A1:2016	Visual examination Power/current absorption up to 16 A Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 °C to 32 °C	F1	F



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Electrical and Mechanical	Machinery	4- General Requirements 5 Incoming Supply Conductor Terminations and Devices for Disconnecting and Switching Off 6 Protection Against Electric Shock 7 Protection of Equipment 8 Equipotential Bonding 9 Control Circuits and Control Functions 10 Operator InterFace and Machine-Mounted Control Devices 11 Controlgear: Location, Mounting, and Enclosures 12 Conductors and Cables 13 Wiring Practices 14 Electric Motors and Associated Equipment 15 Socket-Outlets and Lighting 16 Marking, Warning Signs and Reference Designations 17 Technical Documentation 18 Verification	IEC 60204-1:2016/AMD1:2021 EN 60204-1:2018	Visual examination Documental examination Clearance, creepage 0.01 mm to 1 m IP grade Mechanical inspection Marking inspection	F1	F



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Electrical and Mechanical	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs	4 - General Requirements 5 - General Requirements for Testing ME Equipment 6 - Classification of ME Equipment and ME Systems 7 - ME Equipment Identification, Marking and Documents 8 Protection Against Electrical Hazards from ME Equipment 9 - Protection Against Mechanical Hazards of ME Equipment and ME Systems 10 - Protection Against Unwanted and Excessive Radiation Hazards 11 Protection Against Excessive Temperatures and Other Hazards 12 - Accuracy of Controls and Instruments and Protection Against Hazardous Outputs 13 Hazardous Situations and Fault Conditions 14 Programmable Electrical Medical Systems (PEMS) 15 - Construction of ME Equipment 16 ME Systems 17 - Electromagnetic Compatibility of ME Equipment and ME Systems	EN 60601-2-25:2015 IEC 60601-2-25:2011	Visual examination Power/current absorption up to 16 A Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 °C to 32 °C	F1	F



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Electrical and Mechanical	Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems	4 - General Requirements 5 - General Requirements for Testing ME Equipment 6 - Classification of ME Equipment and ME Systems 7 - ME Equipment Identification, Marking and Documents 8 Protection Against Electrical Hazards from ME Equipment 9 - Protection Against Mechanical Hazards of ME Equipment and ME Systems 10 - Protection Against Unwanted and Excessive Radiation Hazards 11 Protection Against Excessive Temperatures and Other Hazards 12 - Accuracy of Controls and Instruments and Protection Against Hazardous Outputs 13 Hazardous Situations and Fault Conditions 14 Programmable Electrical Medical Systems (PEMS) 15 - Construction of ME Equipment 16 ME Systems 17 - Electromagnetic Compatibility of ME Equipment and ME Systems	EN 60601-2-47:2015 IEC 60601-2-47:2012	Visual examination Power/current absorption up to 16 A Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 °C to 32 °C	F1	F



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Electrical and Mechanical	Medical electrical equipment and medical electrical systems used in the home healthcare environment	4 - General Requirements 5 - General Requirements for Testing ME Equipment 6 - Classification of ME Equipment and ME Systems 7 - ME Equipment Identification, Marking and Documents 8 Protection Against Electrical Hazards from ME Equipment 9 - Protection Against Mechanical Hazards of ME Equipment and ME Systems 10 - Protection Against Unwanted and Excessive Radiation Hazards 11 Protection Against Excessive Temperatures and Other Hazards 12 - Accuracy of Controls and Instruments and Protection Against Hazardous Outputs 13 Hazardous Situations and Fault Conditions 14 Programmable Electrical Medical Systems (PEMS) 15 - Construction of ME Equipment 16 ME Systems 17 - Electromagnetic Compatibility of ME Equipment and ME Systems	EN 60601-1-11:2015/A1:2021 IEC 60601-11:2015+AMD1:2020	Visual examination Power/current absorption up to 16 A Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 °C to 32 °C	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus - commercial electric cooking ranges, ovens, hobs and hob elements	4 General Requirements, 5 General Conditions for the Tests 6 Classification 7 Marking and Instructions 8 Protection Against Access to Live Parts 9 Starting of Omoto Operated Appliances 10 Power Input and Current 11 Heating 13 Leakage Current and Electric Strength at Operating Temperature 14 Transient Voltage 15 Moisture Resistance 16 Leakage Current and Electric Strength 17 Overload Protection of Transformers and Associated Circuits 18 Endurance 19 Abnormal Operations 20. -Stability and Mechanical Hazards 21 Mechanical Strength 22 Construction 23 Internal Wiring 24 Componens 25 Supply Connectin and External Flexible Cords 26 Terminal for External Conductors 27 Provision for Hearthing 28 Screws and Connections 29 Clearances, Creepage Distances and Solid Insulation 30 Resistance to Heath and Fire 31 Resistance to Rusting 32 Radiation, Toxicity and Similar Hazards	IEC 60335-2-36:2021 EN 60335-2-36:2002/A11:2012	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle: up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 32 °C Fault condition up to 63 A Pull force up to 100 N	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus- commercial refrigerating appliances and ice-makers with an incorporated or remote refrigerant unit or motor-compressor	4 General Requirement 5 General Conditions for the Tests 6 Classification 7 Marking and Instructions 8 Protection Against Access to Live Parts 9 Starting of Motor-Operated Appliances 10 Power Input and Current 11 heating 13 Leakage Current and Electric Strength at Operating Temperature 14 Transient Overvoltages 15 Moisture Resistance 16 Leakage Current and Electric Strength 17 Overload Protection of Transformers and Associated Circuits 18 Endurance 19 Abnormal Operation 20 Stability and Mechanical Hazards 21 Mechanical Strength 22 Construction 23 Internal Wiring 24 Components 25 Supply Connection and External Flexible Cords 26 Terminals for External Conductors 27 Provision for Earthing 28 Screws and Connections 29 Clearances, Creepage Distances and Solid Insulation 30 Resistance to Heat and Fire 31 Resistance to Rusting 32 Radiation, Toxicity and Similar Hazards	EN IEC 60335-2-89:2022/A11:2022/AC:2023-11 IEC 60335-2-89:2019	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle: up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 32 °C Fault condition up to 63 A Pull force up to 100 N	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus - commercial electric cooking ranges, ovens, hobs and hob elements	4 General Requirements, 5 General Conditions for the Tests 6 Classification 7 Marking and Instructions 8 Protection Against Access to Live Parts 9 Starting of Omoto Operated Appliances 10 Power Input and Current 11 Heating 13 Leakage Current and Electric Strength at Operating Temperature 14 Transient Voltage 15 Moisture Resistance 16 Leakage Current and Electric Strength 17 Overload Protection of Transformers and Associated Circuits 18 Endurance 19 Abnormal Operations 20. -Stability and Mechanical Hazards 21 Mechanical Strength 22 Construction 23 Internal Wiring 24 Componens 25 Supply Connectin and External Flexible Cords 26 Terminal for External Conductors 27 Provision for Hearthing 28 Screws and Connections 29 Clearances, Creepage Distances and Solid Insulation 30 Resistance to Heath and Fire 31 Resistance to Rusting 32 Radiation, Toxicity and Similar Hazards	IEC 60335-2-36:2021 EN 60335-2-36:2002/A11:2012	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle: up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 32 °C Fault condition up to 63 A Pull force up to 100 N	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus- commercial refrigerating appliances and ice-makers with an incorporated or remote refrigerant unit or motor-compressor Commercial kitchen machines such as mixers, liquid or food blenders, kneaders, beaters, shredders, graters, mincers, slicers, peelers, tin openers, coffee grinders, washing and/or drying of food, portioning machines, pastry rollers, noodle strip cutters, food processors, beam mixers.	4 General Requirement 5 General Conditions for the Tests 6 Classification 7 Marking and Instructions 8 Protection Against Access to Live Parts 9 Starting of Motor-Operated Appliances 10 Power Input and Current 11 heating 13 Leakage Current and Electric Strength at Operating Temperature 14 Transient Overvoltage 15 Moisture Resistance 16 Leakage Current and Electric Strength 17 Overload Protection of Transformers and Associated Circuits 18 Endurance 19 Abnormal Operation 20 Stability and Mechanical Hazards 21 Mechanical Strength 22 Construction 23 Internal Wiring 24 Components 25 Supply Connection and External Flexible Cords 26 Terminals for External Conductors 27 Provision for Earthing 28 Screws and Connections 29 Clearances, Creepage Distances and Solid Insulation 30 Resistance to Heat and Fire 31 Resistance to Rusting 32 Radiation, Toxicity and Similar Hazards	EN IEC 60335-2-89:2022/A11:2022/AC:2023-11 IEC 60335-2-89:2019 IEC 60335-2-64:2021	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle: up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 32 °C Fault condition up to 63 A Pull force up to 100 N	F1	F



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FIELD OF TEST	ITEMS, MATERIALS, OR PRODUCTS TESTED	COMPONENT, CHARACTERISTIC, PARAMETER TESTED	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED	FLEX CODE	LOCATION OF ACTIVITY
Electrical	Multimedia equipment	Immunity Tests to Continuous RF Disturbances Power Frequency Magnetic Fields Broadband Impulsive Conducted Disturbances Immunity to Burst, Surge, ESD and Dips	EN 55035:2017/A11:2020 CISPR 35:2016	Electromagnetic fields from 80 up to 3 000 MHz field up to 3 V/m RF currents from 150 kHz to 80 MHz with level up to 3 V Magnetic field with level up to 3A/m Burst and fast transient up to 4 KV Surge up to 4 KV ESD up to 8 KV Immunity to dips and voltage variations from 10 ms to 5s	F1	F



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Electrical and Mechanical	Medical electrical equipment- Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment	§ 4 General requirements §5 General requirements for testing ME EQUIPMENT §6 Classification of ME EQUIPMENT and ME SYSTEMS §7 - ME EQUIPMENT identification, marking and documents §8 Protection against electrical HAZARDS from ME EQUIPMENT § 9 - Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS §10 - Protection against unwanted and excessive radiation HAZARDS §11 Protection against excessive temperatures and other HAZARDS §12 - Accuracy of controls and instruments and protection against hazardous outputs §13HAZARDOUS SITUATIONS and fault conditions §14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) §15 - Construction of ME EQUIPMENT §16 ME SYSTEMS §17 - Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	EN 60601-2-6:2015/A1:2016 IEC 60601-2-6:2015/A1:2016	Visual examination Power/current absorption up to 16 A Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle: up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 32 °C	F1	F



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Electrical and Mechanical	Household and similar electrical appliances - Safety - Part 2-64: Particular requirements for commercial electric kitchen machines	4 General requirements, 5 General conditions for the tests 6 Classification 7 Marking and instructions 8 Protection against access to live parts 9 Starting of omoto operated appliances 10 Power input and current 11 Heating 13 Leakage current and electric strength at operating temperature 14 Transient Voltage 15 Moisture resistance 16 Leakage current and electric strength 17 Overload protection of transformers and associated circuits 18 Endurance 19 Abnormal operations 20. -Stability and mechanical hazards 21 Mechanical Strength 22 Construction 23 Internal wiring 24 Componens 25 Supply connectin and external flexible cords 26 Terminal for external conductors 27 Provision for hearting 28 Screws and connections 29 Clearances, creepage distances and solid insulation 30 Resistance to heath and fire 31 Resistance to rusting 32 Radiation, toxicity and similar hazards	EN 60335-2-64:2000/A1:2002 IEC 60335-2-64:1997/A1:2000 IEC 60335-2-64:2021+AMD1:2024	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5 500 V Clearance, creepage 0.01 mm to 1 m Angle: up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 32 °C Fault condition up to 63 A Pull force up to 100 N	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus	4 General requirements, 5 General conditions for the tests 6 Classification 7 Marking and instructions 8 Protection against access to live parts 9 Starting of omoto operated appliances 10 Power input and current 11 Heating 13 Leakage current and electric strength at operating temperature 14 Transient Voltage 15 Moisture resistance 16 Leakage current and electric strength 17 Overload protection of transformers and associated circuits 18 Endurance 19 Abnormal operations 20. -Stability and mechanical hazards 21 Mechanical Strength 22 Construction 23 Internal wiring 24 Componens 25 Supply connectin and external flexible cords 26 Terminal for external conductors 27 Provision for hearting 28 Screws and connections 29 Clearances, creepage distances and solid insulation 30 Resistance to heath and fire 31 Resistance to rusting 32 Radiation, toxicity and similar hazards	EN IEC 60335-1: 2023/A11:2023 CEI EN IEC 60335-1: 2024/A11:2024	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle: up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 32 °C Fault condition up to 63 A Pull force up to 100 N	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus- electric irons	4 General requirement 5 General conditions for the tests 6 Classification 7 Marking and instructions 8 Protection against access to live parts 9 Starting of motor-operated appliances 10 Power input and current 11 Heating 13 Leakage current and electric strength at operating temperature 14 Transient overvoltages 15 Moisture resistance 16 Leakage current and electric strength 17 Overload protection of transformers and associated circuits 18 Endurance 19 Abnormal operation 20 Stability and mechanical hazards 21 Mechanical strength 22 Construction 23 Internal wiring 24 Components 25 Supply connection and external flexible cords 26 Terminals for external conductors 27 Provision for earthing 28 Screws and connections 29 Clearances, creepage distances and solid insulation 30 Resistance to heat and fire 31 Resistance to rusting 32 Radiation, toxicity and similar hazards	IEC 60335-2-3:2022	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle: up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 32 °C Fault condition up to 63 A Pull force up to 100 N	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus- vacuum cleaners and water-suction cleaning appliances	4 General requirement 5 General conditions for the tests 6 Classification 7 Marking and instructions 8 Protection against access to live parts 9 Starting of motor-operated appliances 10 Power input and current 11 Heating 13 Leakage current and electric strength at operating temperature 14 Transient overvoltages 15 Moisture resistance 16 Leakage current and electric strength 17 Overload protection of transformers and associated circuits 18 Endurance 19 Abnormal operation 20 Stability and mechanical hazards 21 Mechanical strength 22 Construction 23 Internal wiring 24 Components 25 Supply connection and external flexible cords 26 Terminals for external conductors 27 Provision for earthing 28 Screws and connections 29 Clearances, creepage distances and solid insulation 30 Resistance to heat and fire 31 Resistance to rusting 32 Radiation, toxicity and similar hazards	EN IEC 60335-2-2:2023/A11:2023	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle: up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 32 °C Fault condition up to 63 A Pull force up to 100 N	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus- refrigerating appliances, ice-cream appliances and ice makers	4 General requirement 5 General conditions for the tests 6 Classification 7 Marking and instructions 8 Protection against access to live parts 9 Starting of motor-operated appliances 10 Power input and current 11 Heating 13 Leakage current and electric strength at operating temperature 14 Transient overvoltages 15 Moisture resistance 16 Leakage current and electric strength 17 Overload protection of transformers and associated circuits 18 Endurance 19 Abnormal operation 20 Stability and mechanical hazards 21 Mechanical strength 22 Construction 23 Internal wiring 24 Components 25 Supply connection and external flexible cords 26 Terminals for external conductors 27 Provision for earthing 28 Screws and connections 29 Clearances, creepage distances and solid insulation 30 Resistance to heat and fire 31 Resistance to rusting 32 Radiation, toxicity and similar hazards	EN IEC 60335-2-24:2022/A11:2022	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle: up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 32 °C Fault condition up to 63 A Pull force up to 100 N	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus- skin exposure to optical radiation	4 General requirement 5 General conditions for the tests 6 Classification 7 Marking and instructions 8 Protection against access to live parts 9 Starting of motor-operated appliances 10 Power input and current 11 Heating 13 Leakage current and electric strength at operating temperature 14 Transient overvoltages 15 Moisture resistance 16 Leakage current and electric strength 17 Overload protection of transformers and associated circuits 18 Endurance 19 Abnormal operation 20 Stability and mechanical hazards 21 Mechanical strength 22 Construction 23 Internal wiring 24 Components 25 Supply connection and external flexible cords 26 Terminals for external conductors 27 Provision for earthing 28 Screws and connections 29 Clearances, creepage distances and solid insulation 30 Resistance to heat and fire 31 Resistance to rusting 32 Radiation, toxicity and similar hazards	IEC 60335-2-27:2024	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle: up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 32 °C Fault condition up to 63 A Pull force up to 100 N	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus- range hoods and other cooking fume extractors	4 General requirement 5 General conditions for the tests 6 Classification 7 Marking and instructions 8 Protection against access to live parts 9 Starting of motor-operated appliances 10 Power input and current 11 Heating 13 Leakage current and electric strength at operating temperature 14 Transient overvoltages 15 Moisture resistance 16 Leakage current and electric strength 17 Overload protection of transformers and associated circuits 18 Endurance 19 Abnormal operation 20 Stability and mechanical hazards 21 Mechanical strength 22 Construction 23 Internal wiring 24 Components 25 Supply connection and external flexible cords 26 Terminals for external conductors 27 Provision for earthing 28 Screws and connections 29 Clearances, creepage distances and solid insulation 30 Resistance to heat and fire 31 Resistance to rusting 32 Radiation, toxicity and similar hazards	IEC 60335-2-31:2024 EN 60335-2-31:2014/A1:2023/A2:2023	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle: up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 32 °C Fault condition up to 63 A Pull force up to 100 N	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus- havers, hair clippers and similar appliances	4 General requirement 5 General conditions for the tests 6 Classification 7 Marking and instructions 8 Protection against access to live parts 9 Starting of motor-operated appliances 10 Power input and current 11 Heating 13 Leakage current and electric strength at operating temperature 14 Transient overvoltages 15 Moisture resistance 16 Leakage current and electric strength 17 Overload protection of transformers and associated circuits 18 Endurance 19 Abnormal operation 20 Stability and mechanical hazards 21 Mechanical strength 22 Construction 23 Internal wiring 24 Components 25 Supply connection and external flexible cords 26 Terminals for external conductors 27 Provision for earthing 28 Screws and connections 29 Clearances, creepage distances and solid insulation 30 Resistance to heat and fire 31 Resistance to rusting 32 Radiation, toxicity and similar hazards	IEC 60335-2-8:2022	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle: up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 32 °C Fault condition up to 63 A Pull force up to 100 N	F1	F



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Electrical and Mechanical	Luminaires	2 Classification of luminaires 3 Marking 4 Construction 5 External and internal wiring 7 Provision for earthing 8 Protection against electric shock 9 Resistance to dust, solid object and moisture 10 Insulation resistance and electric strength, touch current and protective conductor current 11 Creepage distances and clearances 12 Endurance test and thermal test 13 Resistance to heat, fire and tracking 14 Screw terminals 15 Screwless terminals and electrical connections	EN 60598-1:2015/A1:2018/A11:2022	Power/current absorption up to 16 A 3 kW Leakage current <4uA ÷ 5 mA Up to 93% of relative humidity Dielectric strength test: 500V ÷ 5500 V kV/50 Hz	F1	F
Electrical and Mechanical	Medical electrical equipment infant transport incubators	§ 4 General requirements §5 General requirements for testing ME equipment §6 Classification of ME Equipment and ME Systems §7 ME Equipment identification, marking and documents §8 Protection against electrical hazards from ME equipment § 9 Protection against mechanical hazards of ME equipment and ME systems §10 Protection against unwanted and excessive radiation hazards §11 Protection against excessive temperatures and other hazards §12 Accuracy of controls and instruments and protection against hazardous outputs §13 Hazardous situations and fault conditions §14 Programmable electrical medical systems (PEMs) §15 - Construction of ME Equipment §16 ME Systems §17 Electromagnetic Compatibility of ME Equipment and ME Systems	EN IEC 60601-2-20: 2020/A1:2023, IEC 60601-2-20: 2020+AMD1:2023	Visual examination Power/current absorption up to 16 A Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle: up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 32 °C	F1	



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Electrical and Mechanical-	Medical electrical equipment infant radiant warmers	§ 4 General requirements §5 General requirements for testing ME equipment §6 Classification of ME Equipment and ME Systems §7 ME Equipment identification, marking and documents §8 Protection against electrical hazards from ME equipment § 9 Protection against mechanical hazards of ME equipment and ME systems §10 Protection against unwanted and excessive radiation hazards §11 Protection against excessive temperatures and other hazards §12 Accuracy of controls and instruments and protection against hazardous outputs §13 Hazardous situations and fault conditions §14 Programmable electrical medical systems (PEMs) §15 - Construction of ME Equipment §16 ME Systems §17 Electromagnetic Compatibility of ME Equipment and ME Systems	EN 60601-2-21:2021/A1:2023, IEC 60601-2-21:2020+AMD1:2023	Visual examination Power/current absorption up to 16 A Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle: up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 32 °C	F1	F



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Electrical and Mechanical	Medical electrical equipment infant phototherapy equipment	§ 4 General requirements §5 General requirements for testing ME equipment §6 Classification of ME Equipment and ME Systems §7 ME Equipment identification, marking and documents §8 Protection against electrical hazards from ME equipment § 9 Protection against mechanical hazards of ME equipment and ME systems §10 Protection against unwanted and excessive radiation hazards §11 Protection against excessive temperatures and other hazards §12 Accuracy of controls and instruments and protection against hazardous outputs §13 Hazardous situations and fault conditions §14 Programmable electrical medical systems (PEMs) §15 - Construction of ME Equipment §16 ME Systems §17 Electromagnetic Compatibility of ME Equipment and ME Systems	EN 60601-2-50:2021/A1:2023 IEC 60601-2-50:2020+AMD1:2023	Visual examination Power/current absorption up to 16 A Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle: up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 32 °C	F1	F



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Electrical and Mechanical	Medical electrical equipment infant phototherapy equipment	§ 4 General requirements §5 General requirements for testing ME equipment §6 Classification of ME Equipment and ME Systems §7 ME Equipment identification, marking and documents §8 Protection against electrical hazards from ME equipment § 9 Protection against mechanical hazards of ME equipment and ME systems §10 Protection against unwanted and excessive radiation hazards §11 Protection against excessive temperatures and other hazards §12 Accuracy of controls and instruments and protection against hazardous outputs §13 Hazardous situations and fault conditions §14 Programmable electrical medical systems (PEMs) §15 - Construction of ME Equipment §16 ME Systems §17 Electromagnetic Compatibility of ME Equipment and ME Systems	EN 60601-2-50:2021/A1:2023 IEC 60601-2-50:2020+AMD1:2023	Visual examination Power/current absorption up to 16 A Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle: up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 32 °C	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus	4 – General requirements; 5 General conditions for the tests; 6 – Classification; 7 – Marking and instructions; 8 – Protection against access to live parts; 9 – Starting of omoto operated appliances 10 – Power input and current 11 – Heating 13 – Leakage current and electric strength at operating temperature 14 – Transient Voltage;; 15 – Moisture resistance; 16 Leakage current and electric strength; 17 – Overload protection of transformers and associated circuits; 18 – Endurance; 19 – Abnormal operations; 20. -Stability and mechanical hazards; 21 – Mechanical Strength; 22 – Construction; 23 – Internal wiring; 24 – Componens; 25 – Supply connectin and external flexible cords; 26 – Terminal for external conductors; 27 – Provision for hearting; 28 – Screws and connections; 29 – Clearances, creepage distances and solid insulation; 30 – Resistance to heath and fire; 31 – Resistance to rusting; 32 – Radiation, toxicity and similar hazards	EN IEC 60335-1: 2023/A11:2023 CEI EN IEC 60335-1: 2024/A11:2024	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle: up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 32 °C Fault condition up to 63 A Pull force up to 100 N;	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus- electric irons	4 General requirement 5 General conditions for the tests 6 Classification 7 Marking and instructions 8 Protection against access to live parts 9 Starting of motor-operated appliances 10 Power input and current 11 Heating 13 Leakage current and electric strength at operating temperature 14 Transient overvoltages 15 Moisture resistance 16 Leakage current and electric strength 17 Overload protection of transformers and associated circuits 18 Endurance 19 Abnormal operation 20 Stability and mechanical hazards 21 Mechanical strength 22 Construction 23 Internal wiring 24 Components 25 Supply connection and external flexible cords 26 Terminals for external conductors 27 Provision for earthing 28 Screws and connections 29 Clearances, creepage distances and solid insulation 30 Resistance to heat and fire 31 Resistance to rusting 32 Radiation, toxicity and similar hazards	IEC 60335-2-3:2022	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle: up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 32 °C Fault condition up to 63 A Pull force up to 100 N;	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus- vacuum cleaners and water-suction cleaning appliances	4 General requirement 5 General conditions for the tests 6 Classification 7 Marking and instructions 8 Protection against access to live parts 9 Starting of motor-operated appliances 10 Power input and current 11 Heating 13 Leakage current and electric strength at operating temperature 14 Transient overvoltages 15 Moisture resistance 16 Leakage current and electric strength 17 Overload protection of transformers and associated circuits 18 Endurance 19 Abnormal operation 20 Stability and mechanical hazards 21 Mechanical strength 22 Construction 23 Internal wiring 24 Components 25 Supply connection and external flexible cords 26 Terminals for external conductors 27 Provision for earthing 28 Screws and connections 29 Clearances, creepage distances and solid insulation 30 Resistance to heat and fire 31 Resistance to rusting 32 Radiation, toxicity and similar hazards	EN IEC 60335-2-2:2023/A11:2023	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle: up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 32 °C Fault condition up to 63 A Pull force up to 100 N;	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus- refrigerating appliances, ice-cream appliances and ice makers	4 General requirement 5 General conditions for the tests 6 Classification 7 Marking and instructions 8 Protection against access to live parts 9 Starting of motor-operated appliances 10 Power input and current 11 Heating 13 Leakage current and electric strength at operating temperature 14 Transient overvoltages 15 Moisture resistance 16 Leakage current and electric strength 17 Overload protection of transformers and associated circuits 18 Endurance 19 Abnormal operation 20 Stability and mechanical hazards 21 Mechanical strength 22 Construction 23 Internal wiring 24 Components 25 Supply connection and external flexible cords 26 Terminals for external conductors 27 Provision for earthing 28 Screws and connections 29 Clearances, creepage distances and solid insulation 30 Resistance to heat and fire 31 Resistance to rusting 32 Radiation, toxicity and similar hazards	EN IEC 60335-2-24:2022/A11:2022	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle: up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 32 °C Fault condition up to 63 A Pull force up to 100 N;	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus- skin exposure to optical radiation	4 General requirement 5 General conditions for the tests 6 Classification 7 Marking and instructions 8 Protection against access to live parts 9 Starting of motor-operated appliances 10 Power input and current 11 Heating 13 Leakage current and electric strength at operating temperature 14 Transient overvoltages 15 Moisture resistance 16 Leakage current and electric strength 17 Overload protection of transformers and associated circuits 18 Endurance 19 Abnormal operation 20 Stability and mechanical hazards 21 Mechanical strength 22 Construction 23 Internal wiring 24 Components 25 Supply connection and external flexible cords 26 Terminals for external conductors 27 Provision for earthing 28 Screws and connections 29 Clearances, creepage distances and solid insulation 30 Resistance to heat and fire 31 Resistance to rusting 32 Radiation, toxicity and similar hazards	IEC 60335-2-27:2024	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle: up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 32 °C Fault condition up to 63 A Pull force up to 100 N;	F1	F



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White Lab S.r.l.

Via del Consorzio 41 - Falconara Marittima, 60015 Italy
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Electrical and Mechanical	Household appliances, electric tools and similar apparatus- range hoods and other cooking fume extractors	4 General requirement 5 General conditions for the tests 6 Classification 7 Marking and instructions 8 Protection against access to live parts 9 Starting of motor-operated appliances 10 Power input and current 11 Heating 13 Leakage current and electric strength at operating temperature 14 Transient overvoltages 15 Moisture resistance 16 Leakage current and electric strength 17 Overload protection of transformers and associated circuits 18 Endurance 19 Abnormal operation 20 Stability and mechanical hazards 21 Mechanical strength 22 Construction 23 Internal wiring 24 Components 25 Supply connection and external flexible cords 26 Terminals for external conductors 27 Provision for earthing 28 Screws and connections 29 Clearances, creepage distances and solid insulation 30 Resistance to heat and fire 31 Resistance to rusting 32 Radiation, toxicity and similar hazards	IEC 60335-2-31:2024 EN 60335-2-31:2014/A1:2023/A2: 2023	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle: up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 32 °C Fault condition up to 63 A Pull force up to 100 N;	F1	F



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Electrical and Mechanical	Household appliances, electric tools and similar apparatus- havers, hair clippers and similar appliances	4 General requirement 5 General conditions for the tests 6 Classification 7 Marking and instructions 8 Protection against access to live parts 9 Starting of motor-operated appliances 10 Power input and current 11 Heating 13 Leakage current and electric strength at operating temperature 14 Transient overvoltages 15 Moisture resistance 16 Leakage current and electric strength 17 Overload protection of transformers and associated circuits 18 Endurance 19 Abnormal operation 20 Stability and mechanical hazards 21 Mechanical strength 22 Construction 23 Internal wiring 24 Components 25 Supply connection and external flexible cords 26 Terminals for external conductors 27 Provision for earthing 28 Screws and connections 29 Clearances, creepage distances and solid insulation 30 Resistance to heat and fire 31 Resistance to rusting 32 Radiation, toxicity and similar hazards	IEC 60335-2-8:2022	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle: up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 32 °C Fault condition up to 63 A Pull force up to 100 N;	F1	F



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Electrical and Mechanical	Luminaires	2 – CLASSIFICATION OF LUMINAIRES; 3 – MARKING; 4 – CONSTRUCTION; 5 – EXTERNAL AND INTERNAL WIRING; 7 – PROVISION FOR EARTHING; 8 – PROTECTION AGAINST ELECTRIC SHOCK; 9 – RESISTANCE TO DUST, SOLID OBJECT AND MOISTURE; 10 – INSULATION RESISTANCE AND ELECTRIC STRENGTH, TOCUH CURRENT AND PROTECTIVE CONDUCTOR CURRENT; 11 – CREEPAGE DISTANCES AND CLEARANCES; 12 – ENDURANCE TEST AND THERMAL TEST; 13 – RESISTANCE TO HEAT, FIRE AND TRACKING; 14 – SCREW TERMINALS; 15 – SCREWLESS TERMINALS AND ELECTRICAL CONNECTIONS	EN 60598-1:2015/A1:2018/A11:2022	Power/current absorption up to 16 A 3 kW Leakage current <4uA ÷ 5 mA Up to 93% of relative humidity Dielectric strength test: 500V ÷ 5500 V kV/50 Hz	F1	F



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Electrical and Mechanical	Medical electrical equipment – infant transport incubators	§ 4 – General requirements; § 5 – General requirements for testing ME EQUIPMENT § 6 – Classification of ME EQUIPMENT and ME SYSTEMS; § 7 – ME EQUIPMENT identification, marking and documents; § 8 Protection against electrical HAZARDS from ME EQUIPMENT § 9 - Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS; § 10 -Protection against unwanted and excessive radiation HAZARDS; § 11 Protection against excessive temperatures and other HAZARDS; § 12 - Accuracy of controls and instruments and protection against hazardous outputs; § 13 HAZARDOUS SITUATIONS and fault conditions; § 14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) ; § 15 - Construction of ME EQUIPMENT; § 16 ME SYSTEMS; § 17 – Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	EN IEC 60601-2-20: 2020/A1:2023, IEC 60601-2-20:	Visual examination Power/current absorption up to 16 A Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle: up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 32 °C	F1	F



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Electrical and Mechanical-	Medical electrical equipment – infant radiant warmers	§ 4 – General requirements; §5 – General requirements for testing ME EQUIPMENT §6 – Classification of ME EQUIPMENT and ME SYSTEMS; §7 – ME EQUIPMENT identification, marking and documents; §8 Protection against electrical HAZARDS from ME EQUIPMENT § 9 - Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS; §10 - Protection against unwanted and excessive radiation HAZARDS; §11 Protection against excessive temperatures and other HAZARDS; §12 - Accuracy of controls and instruments and protection against hazardous outputs; §13HAZARDOUS SITUATIONS and fault conditions; §14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) ; §15 - Construction of ME EQUIPMENT; §16 ME SYSTEMS; §17 – Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	EN 60601-21:2021/A1:2023, IEC 60601-2-21:2020+AMD1:2023	Visual examination Power/current absorption up to 16 A Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle: up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 32 °C	F1	F



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Electrical and Mechanical	Medical electrical equipment – infant phototherapy equipment	§ 4 – General requirements; §5 – General requirements for testing ME EQUIPMENT §6 – Classification of ME EQUIPMENT and ME SYSTEMS; §7 – ME EQUIPMENT identification, marking and documents; §8 Protection against electrical HAZARDS from ME EQUIPMENT § 9 - Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS; §10 - Protection against unwanted and excessive radiation HAZARDS; §11 Protection against excessive temperatures and other HAZARDS; §12 - Accuracy of controls and instruments and protection against hazardous outputs; §13HAZARDOUS SITUATIONS and fault conditions; §14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) ; §15 - Construction of ME EQUIPMENT; §16 ME SYSTEMS; §17 – Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	EN 60601-2-50:2021/A1:2023; IEC 60601-2-50:2020+AMD1:2023	Visual examination Power/current absorption up to 16 A Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle: up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 32 °C	F1	F
Electrical and Mechanical	Electro medical equipment, industrial equipment, information technology, lighting equipment, household appliances	Immunity to RF current	EN IEC 61000-4-6:2023, IEC 61000-4-6:2023	RF currents from 150 kHz to 80 MHz Voltage level up to 30 V	F1	F



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Electrical and Mechanical	Audio/video, information and communication technology equipment	4 – General requirements; 5 – Electrically-caused injury; 6 – Electrically-caused fire; 7 – Injury caused by hazardous substances; 8 – Mechanically-caused injury; 9 - Thermal burn injury; 10 - Radiation	IEC 62368-1:2023 EN IEC 62368-1:2024	Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V	F1	F
Electrical and Mechanical	Medical electrical equipment – high frequency surgical equipment and high frequency surgical accessories	§ 4 – General requirements; §5 – General requirements for testing ME EQUIPMENT §6 – Classification of ME EQUIPMENT and ME SYSTEMS; §7 – ME EQUIPMENT identification, marking and documents; §8 Protection against electrical HAZARDS from ME EQUIPMENT § 9 - Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS; §10 -Protection against unwanted and excessive radiation HAZARDS; §11 Protection against excessive temperatures and other HAZARDS; §12 - Accuracy of controls and instruments and protection against hazardous outputs; §13HAZARDOUS SITUATIONS and fault conditions; §14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) ; §15 -Construction of ME QUIPMENT; §16 ME SYSTEMS; §17 –Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	IEC 60601-2-2:2017+ AMD1 :2023; EN 60601-2-2:2018/A1:2024	Visual examination Power/current absorption up to 16 A Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle: up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 30 °C	F1	F



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Electrical and Mechanical	Medical electrical 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	201.4 General requirements ; 201.5 General requirements for testing ME EQUIPMENT; 201.6 Classification of ME EQUIPMENT and ME SYSTEMS; 201.7 ME EQUIPMENT identification, marking and documents ; 201.8 Protection against electrical HAZARDS from ME EQUIPMENT; 201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS; 201.10 Protection against unwanted and excessive radiation HAZARDS; 201.11 Protection against excessive temperatures and other HAZARDS; 201.12 Accuracy of controls and instruments and protection against hazardous outputs; 201.13 HAZARDOUS SITUATIONS and fault conditions; 201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS); 201.15 Construction of ME EQUIPMENT; 201.16 ME SYSTEMS; 201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	IEC 60601-2-57:2023	Visual examination Power/current absorption up to 16 A Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Angle: up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 – 32 °C Fault condition up to 63 A	F1	F



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Electromagnetic compatibility tests	Medical electrical equipment	Immunity tests to electromagnetic radiated fields, injected RF currents, magnetic fields at mains frequency, burst, surge, ESD and dips	IEC TR 60601-4-2: 2016	Electromagnetic fields up to 28 V/m from 80 up to 6 000 MHz RF currents from 150 kHz to 80 MHz with level up to 10 V Magnetic field with level up to 30 A/m Burst and fast transient up to 4 KV Surge up to 4 KV ESD up to 15 KV Conducted emissions in the frequency range 150 kHz to 30 MHz Immunity to dips and voltage variations from 10 ms to 5 s	F1	F
Electromagnetic compatibility tests	Medical electrical equipment	Radiated fields in close proximity - Immunity test	IEC 61000-4-39:2017	Proximity magnetic field up to 65 A/m	F1	F



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Electrical and Mechanical	Medical electrical equipment – microwave therapy equipment	§ 4 – General requirements; §5 – General requirements for testing ME EQUIPMENT §6 – Classification of ME EQUIPMENT and ME SYSTEMS; §7 – ME EQUIPMENT identification, marking and documents; §8 Protection against electrical HAZARDS from ME EQUIPMENT § 9 - Protection against ECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS; §10 -Protection against unwanted and excessive radiation HAZARDS; §11 Protection against excessive temperatures and other HAZARDS; §12 - Accuracy of controls and instruments and protection against hazardous outputs; §13HAZARDOUS SITUATIONS and fault conditions; §14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) ; §15 - Construction of ME EQUIPMENT; §16 ME SYSTEMS; §17 - Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	IEC 60601-2-6:2015+ AMD1 :2016 +AMD2:2022; EN 60601-2-6:2015/A1:2016/A2: 2024	Visual examination Power/current absorption up to 16 A Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle: up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 30 °C	F1	F



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FDA ASCA Basic Safety and Essential Performance

Scope of Accreditation

METHOD USED	FDA Number
IEC 60601-1:2005/AMD1:2012/AMD2:2020	19-49
IEC 61010-1:2010/AMD1:2016	19-34
IEC 60601-1-2:2014/A1:2020	19-36
IEC 60601-1-6:2010+AMD1:2013+AMD2:2020	5-132
IEC 60601-1-11:2015+AMD1:2020	19-38
IEC 60601-2-2:2017+ AMD1:2023	6-389
IEC 60601-2-6:2015/A1:2016	6-423
IEC 60601-2-10:2012/A1:2016	17-16
IEC 60601-2-20:2020+AMD1:2023	6-462
IEC 60601-2-21:2020+AMD1:2023	6-463
IEC 60601-2-50:2020+AMD1:2023	6-450
IEC 60601-2-57:2023	12-355

1. Location of activity:

**Location
Code**

F

Location

Conformity assessment activity is performed at the CABs fixed facility

2. Flex Code:

- F0- Fixed scope item. No deviations allowed to the line item as identified, except for updating to the most recent version of an accredited standard method after verification.
- F1- Laboratory has the capability to test a new item, material, matrix, or product similar in composition to item, material, matrix, or product identified on the scope
- F2- Laboratory has the capability to introduce the newest revision of an accredited authoritative standard method (with no modifications) identified on the scope
- F3- Laboratory has the capability to introduce a parameter/component/analyte to an accredited test method identified on the scope
- F4- Laboratory has the capability to introduce a new revision of an accredited non-standard method using the same technology or technique identified on the scope
- F5- Laboratory has the capability to introduce a validated method that is equivalent to an accredited method (using same technology or technique) identified on the scope