



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

Accreditation No.: 111347

Certificate No.: L25-83

Tracy Szerszen

President

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.pjlabs.com





White Lab S.r.l.

Via del Consorzio 41 - Falconara Marittima, 60015 Italy Contact Name: Massimo Ambrosi Phone: 071-915-6048

ITEMS, MATERIALS, OR PRODUCTS TESTED	COMPONENT, CHARACTERISTIC, PARAMETER TESTED	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED	FLEX CODE	LOCATION OF ACTIVITY
Electrical lighting	Immunity tests to	IEC 61547:1995 / A1:2000,	Electromagnetic fields up to 3 V/m from	F1	F
		IEC 61547:2009,	1 7 7		
1 1	magnetic fields at mains	IEC 61547:2020			
		EN 61547-1005 / A1-2000	Burst and fast transient up to 4 KV		
		EN 01347.19937 A1.2000,	Surge up to 4 KV		
	1 /	EN 61547:2009			
			ESD up to 15 KV		
		9	RF currents from 150 kHz to 80 MHz with level 3V		
			Immunity to dips and voltage variations		
II	I	CISDD 14 2:1007 / A1:2001 /		E1	F
				Γ1	Г
	conducted RF currents,	CISPR 14-2:2015			
apparatus		CIGRD 14 2 2020			
	dips	CISPR 14-2:2020	with level up to 3 V		
		EN 55014-2:1997 + EC:1997 /	Burst and fast transient up to 4 KV		
		A1:2001 + IS1:2007 / A2:2008	Surge up to 4 KV		
		EN 55014-2:2015	ESD up to 15 KV		
		EN IEC 55014-2:2021	Immunity to dips and voltage variations		
TT 1 11		TN 55014 1 0015		. D.1	-
		EN 55014-1:2017		FI	F
	Radiated emission test	EN IEC 5014-1:2021	Power disturbance test 30 MHz to 300		
apparatus			MHz		
			D 1: 4 1 . : : 4 420 MH-: 1000		
	OR PRODUCTS TESTED	Electrical lighting and similar equipment Household appliances, electric tools and similar apparatus Conducted emission tests Power disturbance test Radiated emission test	OR PRODUCTS TESTED PARAMETER TESTED Electrical lighting and similar equipment Household appliances, electric tools and similar apparatus Household appliances, electric tools and similar apparatus Household appliances, electric tools and similar apparatus Household appliances, electric tools and similar appliances, electric tools and similar Household appliances, electric tools and similar Conducted emission tests Radiated emission test Radiated emission test EN STANDARD METHOD IEC 61547:1995 / A1:2000, EN 61547:2020 EN 61547:2029 EN 61547:2029 EN 61547:2009 EN 61547:2009 EN 61547:2009 EN 61547:2009 EN 61547:2009 CISPR 14-2:2015 CISPR 14-2:2015 EN 55014-2:2015 EN 1EC 55014-2:2021 EN 55014-2:2021	CHARACTERISTIC PARAMETER TESTED PARAMETER TES	CHARACTERISTIC, TESTED PARAMETER TISTED PARAMETER TISTED TIST





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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	Conducted emissions in the frequency range 150kHz to 30 MHz	F1	F
			CISPR 32:2015/AMD1:2019	Radiated emission test 30 MHz to 6000 MHz		
	Electromedical equipment, industrial equipment, information	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	
	technology, lighting equipment,	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	
	household appliances	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 - Clearences, 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/A14:20 19 CEI EN 60335- 1:2013/A11:2015/EC:2014/A13:2019/A1/A 2/A14:2019 IEC 60335- 1:2010/AMD1:2013/ AMD2:2016/ISH1:20 20 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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Of TEST	TESTED	TAKKINETEK TESTED		TECHNIQUE COLD		ACTIVITY
Electrical and	Safety requirements	4 - Tests	CEI EN 61010-	Power/current absorption	F1	F
Mechanical	for electrical	5 - Marking and Documentation	1:2013/EC:2017/A1:2019	up to 16 A 3 kW		
	equipment for	6 - Protection Against Electric Shock	EN 61010-1:2010/A1:2019	Leakage current up to 5		
	measurement,	7 -Protection Against Mechanical Hazards	IEC 61010-	mA		
	control and	8 - Resistance to Mechanical Stresses	1:2010/AMD1:2016	Up to 93% of relative		
	laboratory use	9 - Protection Against the Spread of Fire		humidity		
		10 - Equipment Temperature Limits and		Dielectric strength test		
		Resistance to Heat		up to 5500 V		
		11 - Protection Against Hazards from Fluids				
		14 - Components and Subassemblies				
		15 - Protection by Interlocks				
		16 - Hazards Resulting from Application				
		17 - Risk Assessment				
	Audio/video,	4 - General Requirements 5 - Electrically-	CEI EN 62368-	Power/current absorption	F1	F
	information and	Caused Injury	1:2016/EC:2018/A11:2017	up to 16 A 3 kW		
	communication	6 - Electrically-Caused Fire	EN 62368-	Leakage current up to 5		
	technology	7 - Injury Caused by Hazardous Substances	1:2014/AC:2015/A11:2017/A	mA		
	equipment	8 - Mechanically-Caused Injury	C:2017	Up to 93% of relative		
		9 - Thermal Burn Injury	EN IEC 62368-	humidity		
		10 - Radiation	1:2020/A11:2020/AC:2020	Dielectric strength		
			IEC 62368-1:2018	test:up to 5 500 V		
	Luminaires	2 - Classification of Luminaires	CEI EN 60598-	Power/current absorption	F1	F
		3 - Marking	1:2015/A1:2019/EC:2015/EC:	up to 16 A		
		4 - Construction	2016	Leakage current up to5		
		5 - External and Internal Wiring	EN 60598-	mA		
		7 - Provision for Earthing	1:2015/A1:2018/AC:2015/	Up to 93 % of relative		
		8 - Protection Against Electric Shock	AC:2016/AC:2017	humidity		
		9 - Resistance to Dust, Solid Object and	IEC 60598-1:2020	Dielectric strength test		
		Moisture	IEC 60598-	up to 5 500 V		
			1:2014/AMD1:2017			





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





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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 MechanicalHazards 21 - Mechanical Strength 22 - Construction 23 - Internal Wiring 24 - Components 25 - Supply Connection and	IEC 60335-2- 2:2009/AMD1:2012/AM D2:2016 IEC 60335-2-2:2019 EN 60335-2- 2:2010/A1:2013/A11:201	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 to63 A Pull force up to 100 N	F1	F
		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				





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





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Electrical and	Household	4 - General Requirement	IEC 60335-2-	Visual examination	F1	F
Mechanical	appliances,	5 - General Conditions for the Tests	8:2012+AMD1:2015+	Power/current		
	electric tools and	6 -Classification	AMD2:2018	absorption up to 16		
	similar apparatus - havers,	7 -Marking and Instructions		A 3 kW		
	hair clippers and similar	8 -Protection Against Access to Live Parts	EN 60335-2-	Leakage current up		
	appliances	9 -Starting of Motor Operated Appliances	8:2015/A1:2016/A2:2	to 5 mA		
		10 -Power Input and Current	022/A11:2022/A12:20	Up to 93% of		
		11 -Heating	22	relative humidity		
		13 -Leakage Current and		Dielectric strength		
		Electric Strength at Operating Temperature		test: up to 5500 V		
		14- Transient Overvoltages		Clearance, creepage		
		15 - Moisture Resistance		0.01 mm to 1 m		
		16 - Leakage Current and Electric Strength		Angle up to 10°		
		17 -Overload Protection of		Force up to 250 N		
		Transformers and Associated Circuits		Acoustic noise up to		
		18 - Endurance		140 dBA		
		19 - Abnormal Operation		Climatic chamber: 20 to		
		20 - Stability and Mechanical Hazards		30 °C		
		21 - Mechanical Strength		Fault condition up to		
		22 -Construction		63 A		
		23 -Internal Wiring		Pull force up to 100 N		
		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				





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FIELD ITEMS, MATERIALS, OF TEST OR PRODUCTS TESTED	COMPONENT, CHARACTERISTIC, PARAMETER TESTED	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED	FLEX CODE	LOCATION OF ACTIVITY
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:20 12/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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FIELD OF TEST	ITEMS, MATERIALS, OR PRODUCTS	COMPONENT, CHARACTERISTIC, PARAMETER TESTED	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED	FLEX CODE	LOCATION OF ACTIVITY
	TESTED					
Electrical and	Household	4 - General Requirement	IEC 60335-2-	Visual examination	F1	F
Mechanical	appliances,	5 - General Conditions for the Tests	12:2002+AMD1:2008	Power/current		
	electric tools and	6 -Classification	+AMD2:2017,	absorption up to 16		
	similar apparatus -	7 -Marking and Instructions		A 3 kW		
	warming plates and similar	8 -Protection Against Access to Live Parts	EN 60335-2-	Leakage current up		
	appliances	9 -Starting of Motor Operated Appliances	12:2003/A1:2008/A2:	to 5 mA		
		10 -Power Input and Current	2019/A11:2019	Up to 93% of		
		11 -Heating		relative humidity		
		13 -Leakage Current and		Dielectric strength		
		Electric Strength at Operating Temperature		test: up to 5500 V		
		14- Transient Overvoltages		Clearance, creepage		
		15 - Moisture Resistance		0.01 mm to 1 m		
		16 - Leakage Current and		Angle up to 10°		
		Electric Strength		Force up to 250 N		
		17 -Overload Protection of		Acoustic noise up to		
		Transformers and Associated Circuits		140 dBA		
		18 - Endurance		Climatic chamber: 20 to		
		19 - Abnormal Operation		30 °C		
		20 - Stability and Mechanical Hazards		Fault condition up to		
		21 - Mechanical Strength		63 A		
		22 - Construction		Pull force up to 100 N		
		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				





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





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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 and	Household	4 - General Requirement	IEC 60335-2-	Visual examination	F1	F
Mechanical	appliances,	5 - General Conditions for the Tests	14:2016+AMD1:2019	Power/current		1
TVICOILAITICAT	electric tools and	6 -Classification	11.2010 11.112019	absorption up to 16		
	similar apparatus - kitchen	7 -Marking and Instructions	EN 60335-2-	A 3 kW		
	machines	8 -Protection Against Access to Live Parts	14:2006/A1:2008/A11	Leakage current up		
	machines	9 -Starting of Motor Operated Appliances	:2012/AC:2016/A12:2	to 5 mA		
		10 -Power Input and Current	016	Up to 93% of		
		11 -Heating	010	relative humidity		
		13 -Leakage Current and		Dielectric strength		
		Electric Strength at Operating Temperature		test: up to 5500 V		
		14- Transient Overvoltages		Clearance, creepage		
		15 - Moisture Resistance		0.01 mm to 1 m		
		16 - Leakage Current and		Angle up to 10°		
		Electric Strength		Force up to 250 N		
		17 -Overload Protection of		Acoustic noise up to		
		Transformers and Associated Circuits		140 dBA		
		18 - Endurance		Climatic chamber: 20 to		
		19 - Abnormal Operation		30 °C		
		20 - Stability and Mechanical Hazards		Fault condition up to		
		21 - Mechanical Strength		63 A		
		22 -Construction		Pull force up to 100N		
		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				





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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 and	Household	4 - General Requirement	IEC 60335-2-	Visual examination	F1	F
Mechanical	appliances,	5 - General Conditions for the Tests	15:2012+AMD1:2016	Power/current		
	electric tools and	6 -Classification	+AMD2:2018,	absorption up to 16		
	similar apparatus - heating	7 -Marking and Instructions	,	A 3 kW		
	liquids	8 -Protection Against Access to Live Parts	EN 60335-2-	Leakage current up		
	1	9 -Starting of Motor Operated Appliances	15:2016/A11:2018/A1	to 5 mA		
		10 -Power Input and Current	2:2021/A1:2021/A2:2	Up to 93% of		
		11 -Heating	021	relative humidity		
		13 -Leakage Current and		Dielectric strength		
		Electric Strength at Operating Temperature		test: up to 5500 V		
		14- Transient Overvoltages		Clearance, creepage		
		15 - Moisture Resistance	7	0.01 mm to 1 m		
		16 - Leakage Current and		Angle up to 10°		
		Electric Strength		Force up to 250 N		
		17 -Overload Protection of		Acoustic noise up to		
		Transformers and Associated Circuits		140 dBA		
		18 - Endurance		Climatic chamber: 20 to		
		19 - Abnormal Operation		30 °C		
		20 - Stability and Mechanical Hazards		Fault condition up to		
		21 - Mechanical Strength		63 A		
		22 -Construction		Pull force up to 100 N		
		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				





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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 and	Household	4 - General Requirement	IEC 60335-2-	Visual examination	F1	F
Mechanical	appliances,	5 - General Conditions for the Tests	23:2016+AMD1:2019,	Power/current		1
TVICOILAITICAT	electric tools and	6 -Classification	23.2010 111112 1.2013,	absorption up to 16		
	similar apparatus -	7 -Marking and Instructions	EN 60335-2-	A 3 kW		
	appliances for skin or hair	8 -Protection Against Access to Live Parts	23:2003/A11:2010/AC	Leakage current up		
	care	9 -Starting of Motor Operated Appliances	:2012/A1:2008/A2:20	to 5 mA		
	Cure	10 -Power Input and Current	15	Up to 93% of		
		11 -Heating	13	relative humidity		
		13 -Leakage Current and		Dielectric strength		
		Electric Strength at Operating Temperature		test: up to 5500 V		
		14- Transient Overvoltages		Clearance, creepage		
		15 - Moisture Resistance		0.01 mm to 1 m		
		16 - Leakage Current and		Angle up to 10°		
		Electric Strength		Force up to 250 N		
		17 -Overload Protection of		Acoustic noise up to		
		Transformers and Associated Circuits		140 dBA		
		18 - Endurance		Climatic chamber: 20 to		
		19 - Abnormal Operation		30 °C		
		20 - Stability and Mechanical Hazards		Fault condition up to		
		21 - Mechanical Strength		63 A		
		22 -Construction		Pull force up to 100 N		
		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				





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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
	OR PRODUCTS				F1	
		31 - Resistance to Rusting 32 - Radiation, Toxicity and Similar Hazards				





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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 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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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 and Mechanical		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	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
	1	32 - Radiation, Toxicity and Similar Hazards			l .	





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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 and	Household	4 - General Requirement	IEC 60335-2-	Visual examination	F1	F
Mechanical	appliances,	5 - General Conditions for the Tests	31:2012+AMD1:2016	Power/current	11	1
Wicehamear	electric tools and	6 -Classification	+AMD2:2018,	absorption up to 16		
	similar apparatus -range	7 -Marking and Instructions	711111111111111111111111111111111111111	A 3 kW		
	hoods and other cooking	8 -Protection Against Access to Live Parts	EN 60335-2-31:2014	Leakage current up		
	fume extractors	9 -Starting of Motor Operated Appliances	E1(00333 E 31.201)	to 5 mA		
		10 -Power Input and Current		Up to 93% of		
		11 -Heating		relative humidity		
		13 -Leakage Current and		Dielectric strength		
		Electric Strength at Operating Temperature		test: up to 5500 V		
		14- Transient Overvoltages		Clearance, creepage		
		15 - Moisture Resistance	7	0.01 mm to 1 m		
		16 - Leakage Current and		Angle up to 10°		
		Electric Strength		Force up to 250 N		
		17 -Overload Protection of		Acoustic noise up to		
		Transformers and Associated Circuits		140 dBA		
		18 - Endurance		Climatic chamber: 20 to		
		19 - Abnormal Operation		30 °C		
		20 - Stability and Mechanical Hazards		Fault condition up to		
		21 - Mechanical Strength		63 A		
		22 -Construction		Pull force up to 100 N		
		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				





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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	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	F1	F
		9 -Starting of Motor OperatedAppliances 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		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		
		30 - Resistance to Heat and Fire 31 - Resistance to Rusting 32 - Radiation, Toxicity and Similar Hazards				





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





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Electrical and	Household	4 - General Requirement	IEC 60335-2-	Visual examination	F1	F
Mechanical	appliances,	5 - General Conditions for the Tests	59:2002/A1:2006/A2:	Power/current		1
	electric tools and	6 -Classification	2009,	absorption up to 16		
	similar apparatus - insect	7 -Marking and Instructions		A 3 kW		
	killers	8 -Protection Against Access to Live Parts	IEC 60335-2-59:2021	Leakage current up		
	1111010	9 -Starting of Motor Operated Appliances	120 00000 2 09.2021	to 5 mA		
		10 -Power Input and Current	EN 60335-2-	Up to 93% of		
		11 -Heating	59:2003/A1:2006/A2:	relative humidity		
		13 -Leakage Current and	2009/A11:2018	Dielectric strength		
		Electric Strength at Operating Temperature		test: up to 5500 V		
		14- Transient Overvoltages		Clearance, creepage		
		15 - Moisture Resistance	7	0.01 mm to 1 m		
		16 - Leakage Current and		Angle up to 10°		
		Electric Strength		Force up to 250 N		
		17 -Overload Protection of		Acoustic noise up to		
		Transformers and Associated Circuits		140 dBA		
		18 - Endurance		Climatic chamber: 20 to		
		19 - Abnormal Operation		30 °C		
		20 - Stability and Mechanical Hazards		Fault condition up to		
		21 - Mechanical Strength		63 A		
		22 -Construction		Pull force up to 100 N		
		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				
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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 and Mechanical	Household appliances, electric tools and similar apparatus - aircleaning 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/A2:2 022	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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FIELD OF TEST	ITEMS, MATERIALS, OR PRODUCTS	COMPONENT, CHARACTERISTIC, PARAMETER TESTED	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED	FLEX CODE	LOCATION OF ACTIVITY
Electrical and Mechanical	Household appliances, electric tools and	4 - General Requirement 5 - General Conditions for the Tests 6 -Classification 7 Marking and Instructions	IEC 60335-2- 75:2012+AMD1:2015 +AMD2:2018,	Visual examination Power/current absorption up to 16	F1	F
	similar apparatus - commercial dispensing appliances and vending machines	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	EN 60335-2- 75:2004/A1:2005/A11 :2006/A2:2008/A12:2 010	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		
		30 - Resistance to Heat and Fire 31 - Resistance to Rusting 32 - Radiation, Toxicity and Similar Hazards				





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FIELD OF TEST	ITEMS, MATERIALS, OR PRODUCTS	COMPONENT, CHARACTERISTIC, PARAMETER TESTED	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED	FLEX CODE	LOCATION OF ACTIVITY
	TESTED		ENT (0225 2	****	D1	-
Electrical and	Household	4 - General Requirement	EN 60335-2-	Visual examination	F1	F
Mechanical	appliances,	5 - General Conditions for the Tests	80:2003/A1:2004/A2:	Power/current		
	electric tools and	6 -Classification	2009,	absorption up to 16		
	similar apparatus - fans	7 -Marking and Instructions		A 3 kW		
		8 -Protection Against Access to Live Parts	IEC 60335-2-80:2015	Leakage current up		
		9 -Starting of Motor Operated Appliances		to 5 mA		
		10 -Power Input and Current		Up to 93% of		
		11 -Heating		relative humidity		
		13 -Leakage Current and		Dielectric strength		
		Electric Strength at Operating Temperature		test: up to 5500 V		
		14- Transient Overvoltages		Clearance, creepage		
		15 - Moisture Resistance	7	0.01 mm to 1 m		
		16 - Leakage Current and		Angle up to 10°		
		Electric Strength		Force up to 250 N		
		17 -Overload Protection of		Acoustic noise up to		
		Transformers and Associated Circuits		140 dBA		
		18 - Endurance		Climatic chamber: 20 to		
		19 - Abnormal Operation		30 °C		
		20 - Stability and Mechanical Hazards		Fault condition up to		
		21 - Mechanical Strength		63 A		
		22 -Construction		Pull force up to 100 N		
		23 -Internal Wiring		1		
		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				
	J	22 Tableton, Tomon, and Shimai Hazards	1	1	1	





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





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





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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 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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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 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 electrical edujment - ultrasonic physiotherapy equipment Mechanical Melical Mup to 9° your deletive 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 C to 32°C Mechanical Mecha	FIELD OF TEST	ITEMS, MATERIALS, OR PRODUCTS	COMPONENT, CHARACTERISTIC, PARAMETER TESTED	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED	FLEX CODE	LOCATION OF ACTIVITY
16 ME Systems	OF TEST Electrical and	ITEMS, MATERIALS, OR PRODUCTS TESTED Medical electrical equipment - ultrasonic	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	SPECIFICATION OR STANDARD METHOD EN 60601-2-5:2015,	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		





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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
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/A2:2	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/A2:20 13/COR2:2015/A2/C OR1:2019	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		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	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
		ME Equipment and ME Systems			<u> </u>	





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Electrical and Mechanical	Machinery	4- General Requirements 5 Incoming Supplly 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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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 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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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 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 20Stability 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	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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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 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 11heating 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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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 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 20Stability 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	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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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 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 11heating 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	F1	F
			27	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		
		6		Immunity to dips and voltage variations from 10 ms to 5s		





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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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FIELD OF TEST	ITEMS, MATERIALS, OR PRODUCTS	COMPONENT, CHARACTERISTIC, PARAMETER TESTED	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED	FLEX CODE	LOCATION OF ACTIVITY
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 20Stability 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	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
<u> </u>	L	32 Radiation, toxicity and similar hazards	<u> </u>	<u> </u>		





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FIELD ITEMS, MATERIALS, OF TEST OR PRODUCTS TESTED	COMPONENT, CHARACTERISTIC, PARAMETER TESTED	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED	FLEX CODE	LOCATION OF ACTIVITY
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 20Stability 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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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 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 11Heating 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 11Heating 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 11Heating 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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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 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 11Heating 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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FIELD ITEMS, MATERIA OF TEST OR PRODUCT TESTED		SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED	FLEX CODE	LOCATION OF ACTIVITY
Electrical and Mechanical Household appliance electric tools and sin apparatus- range ho other cooking fume extractors	nilar 5 General conditions for the tests	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 11Heating 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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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 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 clearences 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+AMD1:202 3	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	Medical	§ 4 General requirements	EN 60601-2-	Visual examination	F1	F
Mechanical-	electrical	§5 General requirements for testing ME	21:2021/A1:2023,	Power/current		
	equipment infant radiant	equipment		absorption up to 16 A		
	warmers	§6 Classification of ME	IEC 60601-2-	Leakage current up to 5		
		Equipment and ME Systems	21:2020+AMD1:2023	mA		
		§7 ME Equipment identification, marking		Up to 93% of relative		
		and documents		humidity		
		§8 Protection against electrical		Dielectric strength test:		
		hazards from ME		up to 5500 V		
		equipment		Clearance, creepage		
		§ 9 Protection against mechanical		0.01 mm to 1 m		
		hazards of ME equipment and ME systems		Angle: up to 10°		
		§10 Protection against		Force up to 250 N		
		unwanted and excessive		Acoustic noise up to		
		radiation hazards		140		
		§11 Protection against		dBA		
		excessive temperatures and		Climatic chamber: 20 to		
		other hazards		32 °C		
		§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				
		<u> </u>				
		Systems			ĺ	





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FIELD OF TEST	ITEMS, MATERIALS, OR PRODUCTS	COMPONENT, CHARACTERISTIC, PARAMETER TESTED	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR	FLEX CODE	LOCATION OF ACTIVITY
OF IESI	TESTED	PARAMETER TESTED	STANDARD METHOD	TECHNIQUE USED		OF ACTIVITY
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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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 and	Medical	§ 4 General requirements	EN 60601-2-	Visual examination	F1	F
Mechanical	electrical	§5 General requirements for testing ME	50:2021/A1:2023	Power/current		
	equipment infant	equipment		absorption up to 16 A		
	phototherapy equipment	§6 Classification of ME	IEC 60601-2-	Leakage current up to 5		
		Equipment and ME Systems	50:2020+AMD1:2023	mA		
		§7 ME Equipment identification, marking		Up to 93% of relative		
		and documents		humidity		
		§8 Protection against electrical		Dielectric strength test:		
		hazards from ME		up to 5500 V		
		equipment		Clearance, creepage		
		§ 9 Protection against mechanical		0.01 mm to 1 m		
		hazards of ME equipment and ME systems	7	Angle: up to 10°		
		§10 Protection against		Force up to 250 N		
		unwanted and excessive		Acoustic noise up to		
		radiation hazards		140		
		§11 Protection against		dBA		
		excessive temperatures and		Climatic chamber: 20 to		
		other hazards		32 °C		
		§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				





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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 and	Household appliances,	4 – General requirements,	EN IEC 60335-1:	Visual examination	F1	F
Mechanical	electric tools and similar	5 General conditions for the tests;	2023/A11:2023	Power/current		
Wicenamear	apparatus	6 – Classification;	2023/1111.2023	absorption up to 16 A 3		
	apparatus	7 – Marking and instructions;	CEI EN IEC 60335-1:	kW		
		8 – Protection against access to live parts;	2024/A11:2024	Leakage current up to 5		
		9 – Starting of omoto operated appliances	2024/A11.2024	mA		
		10 – Power input and current		Up to 93% of relative		
		10 – Power input and current 11 – Heating				
				humidity		
		13 – Leakage current and electric strength at		Dielectric strength test:		
		operating temperature		up to 5500 V		
		14 – Transient Voltage;;		Clearance, creepage		
		15 – Moisture resistance;		0.01 mm to 1 m		
		16 Leakage current and electric strength;		Angle: up to 10°		
		17 – Overload protection of transformers and		Force up to 250 N		
		associated circuits;		Acoustic noise up to		
		18 – Endurance;		140 dBA		
		19 – Abnormal operations;		Climatic chamber: 20 to		
		20Stability and mechanical hazards;		32 °C		
		21 – Mechanical Strength;		Fault condition up to 63		
		22 – Construction;		A		
		23 – Internal wiring;		Pull force up to 100 N;		
		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				
L		32 Tadadion, to Nietty and Shimal Hazards		<u>l</u>	1	





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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 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 11Heating 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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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 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 11Heating 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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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 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 11Heating 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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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 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 11Heating 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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FIELD ITEMS, MATERIAL OF TEST OR PRODUCTS TESTED	COMPONENT, CHARACTERISTIC, PARAMETER TESTED	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED	FLEX CODE	LOCATION OF ACTIVITY
Electrical and Mechanical Household appliances electric tools and similar apparatus range hood other cooking fume extractors		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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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 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 11Heating 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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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 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 – INSUALTION RESISTANCE AND ELECTRIC STRENGTH, TOCUH CURRENT AND PROTECTIVE CONDUCTOR CURRENT; 11 – CREEPAGE DISTANCES AND CLEARENCES; 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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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 and	Medical	§ 4 – General requirements;	EN IEC 60601-2-20:	Visual examination	F1	F
Mechanical	electrical	§5 – General requirements for testing	2020/A1:2023,	Power/current		
	equipment – infant	ME EQUIPMENT	,	absorption up to 16 A		
	transport incubators	§6 – Classification of ME EQUIPMENT	IEC 60601-2-20:	Leakage current up to 5		
	1	and ME SYSTEMS;		mA		
		§7 – ME EQUIPMENT identification,		Up to 93% of relative		
		marking and documents;		humidity		
		§8 Protection against electrical		Dielectric strength test:		
		HAZARDS from ME EQUIPMENT		up to 5500 V		
		§ 9 - Protection against MECHANICAL		Clearance, creepage		
		HAZARDS of ME EQUIPMENT and		0.01 mm to 1 m		
		ME	3	Angle: up to 10°		
		SYSTEMS;		Force up to 250 N		
		§10 -Protection against unwanted and		Acoustic noise up to		
		excessive radiation HAZARDS;		140		
		§11 Protection against excessive		dBA		
		temperatures and other HAZARDS;		Climatic chamber: 20 to		
		§12 - Accuracy of controls and		32 °C		
		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				





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FIELD ITEMS, MATERIALS, OF TEST OR PRODUCTS TESTED	COMPONENT, CHARACTERISTIC, PARAMETER TESTED	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED	FLEX CODE	LOCATION OF ACTIVITY
Electrical and Mechanical- Electrical and 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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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 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
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	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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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 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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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
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	F1	F
				RF currents from 150 kHz to 80 MHz with level up to 10 V		
			0	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		
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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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	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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Accreditation is granted to the facility to perform the following conformity assessment activities:

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 Location Code

F 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