

PERRY JOHNSON LABORATORY ACCREDITATION, INC.

Certificate of Accreditation

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

White Lab S.r.l.

Via del Consorzio 41 - Falconara Marittima, 60015 Italy

(Hereinafter called the Organization) and hereby declares that Organization is accredited in accordance with the recognized International Standard:

ISO/IEC 17025:2017

This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (as outlined by the joint ISO-ILAC-IAF Communiqué dated April 2017):

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

Accreditation claims for such testing and/or calibration services shall only be made from addresses referenced within this certificate. This Accreditation is granted subject to the system rules governing the Accreditation referred to above, and the Organization hereby covenants with the Accreditation body's duty to observe and comply with the said rules.

For PJLA:

Tracy Szerszen President

Perry Johnson Laboratory Accreditation, Inc. (PJLA) 755 W. Big Beaver, Suite 1325 Troy, Michigan 48084 Initial Accreditation Date: Issue Date: Expiration Date:

November 13, 2020 January 24, 2023 February 28, 2025

Revision Date:Accreditation No.:Certificate No.:February 6, 2024111347L23-59-R2

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

FLEX CODE	FIELD OF TEST	ITEMS, MATERIALS, OR PRODUCTS TESTED	COMPONENT, CHARACTERISTIC, PARAMETER TESTED	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED
F1, F2	Electromagnetic compatibility tests ^F	Electrical lighting and similar equipment	Immunity tests to radiofrequency electromagnetic field; magnetic fields at mains frequency; injected currents; bursts, surge, dips, ESD	IEC 61547:1995 / A1:2000, IEC 61547:2009, IEC 61547:2020 EN 61547:1995 / A1:2000, EN 61547:2009	Electromagnetic fields up to 3 V/m from 80 MHz to 2700 MHz Magnetic field with level 3 A/m Burst and fast transient up to 4 KV Surge up to 4 KV ESD up to 15 KV RF currents from 150 kHz to 80 MHz with level 3V Immunity to dips and voltage variations from 10 ms to 5 s
F1, F2		Household appliances, electric tools and similar apparatus	Immunity tests to radiated em fields, conducted RF currents, burst, surge, ESD and dips	CISPR 14-2:1997 / A1:2001 / A2:2008; CISPR 14-2:2015; CISPR 14-2:2020 EN 55014-2:1997 + EC:1997 / A1:2001 + IS1:2007 / A2:2008; EN 55014-2:2015 EN IEC 55014- 2:2021	Electromagnetic fields up to 3 V/m from 80 MHz to 1 000 MHz RF currents from 150 kHz to 230 MHz with level up to 3V Burst and fast transient up to 4 KV Surge up to 4 KV ESD up to 15 KV Immunity to dips and voltage variations from 10 ms to 5 s
F1, F2			Conducted emission tests Power disturbance test Radiated emission test	EN 55014-1:2017 EN IEC 5014- 1:2021 CISPR 1-14:2016/ COR1:2016 CISPR 14-1:2020	Conducted emissions in the frequency range 150kHz to 30 MHz Power disturbance test 30 MHz to 300 MHz Radiated emission test 30 MHz to 1 000 MHz





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F1, F2	Electromagnetic compatibility tests ^F	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
				3	Radiated emission test 30 MHz to 1 GHz Immunity to dips and voltage variations from 10ms to 5s
F1, F2		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- 2:2007, 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 1 GHz Proximity magnetic field up to 65 A/m





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		OR PRODUCTS TESTED	PARAMETER TESTED		
F1, F2	Electromagnetic	Multimedia	Conducted	EN 55032:2015/AC:2016	Conducted emissions in
	compatibility	equipment	emission tests	/A1:2020/A11:2020	the frequency range
	tests F		Radiated emission		150kHz to 30 MHz
			test	CISPR 32:2015/AMD1:2019	
					Radiated emission test
					30 MHz to 6000 MHz
F1, F2		Electromedical	Immunity to the	EN 61000-4-	Electromagnetic fields
		equipment,	electromagnetic	3:2006/A1:2009/A2:2010	10V/m from
		industrial	field radiated with	TTG (1000 4	80 MHz to 3 GHz
		equipment,	radiofrequence	IEC 61000-4-	
E1 E2		information	I	3:2006/A1:2007/A2:2010	RF currents from 150
F1, F2		technology, lighting	Immunity to RF current	EN 61000-4-6:2014/AC:2015	kHz to 80MHz
		equipment,	Current	IEC 61000-4-6:2013	Voltage level up to 30
		household		1LC 01000-4-0.2013	Voltage level up to 30
F1, F2		appliances	Immunity to ESD	EN 61000-4-2: 2009/ IEC 61000-	Electrostatic air
				4-2:2008	discharge test up to
					15kV and electrostatic
					contact discharge up to
		,			± 8 kV
F1, F2			Immunity to	IEC 61000-4-4:2012, EN	Immunity to burst/fast
			Burst/fast transient	61000-4-4:2012	transients up to 4 kV,
					with frequency
E1 E2			T : G	HEG (1000 4.5.2014/4.1.2017, EN	repetition 5 or 100 KHz
F1, F2			Immunity to Surge	IEC 61000-4-5:2014/A1:2017, EN	Immunity to surge up to
F1, F2			Immunity to dips	61000-4-5:2014/A1:2017 IEC61000-4-11:2004 / A1:2017	4kV Immunity to 0%; 40%;
Γ^1, Γ^2		_/	and voltage	IEC 61000-4-11:2004 / A1:201 / IEC 61000-4-11:2020	70%; 80% voltage dips
			variations	EN 61000-4-11:2004 / A1:2007	and variation
			variations	EN 61000-4-11:2020	and variation
F1, F2		4	Harmonic current	EN 61000-3-2:2019/A1:2021	Max current 16 A
			emissions	IEC 61000-3-2:2018/A1:2020	-
F1, F2	Electromagnetic	Electromedical	Flicker	EN 61000-3-	Max current 16A
	compatibility	equipment,	measurement	3:2013/A1:2019/A2:2021/AC:202	
	tests F	industrial	(parameters pst,	2	
		equipment,	plt, dt, dc, dmax)		
		information		IEC 61000-3-	
		technology,		3:2013/A1:2017/A2:2021/COR1:2	
E1 E2		lighting	T	022	II. 4. 100 A /
F1, F2		equipment, household	Immunity to	EN 61000-4-8:2010	Up to 100 A/m
		appliances	magnetic fields	IEC 61000 4 8:2000	
L		appliances		IEC 61000-4-8:2009	



Issue: 01/2023

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CODE	OF TEST	MATERIALS, OR PRODUCTS	PARAMETER TESTED	STANDARD METHOD	TECHNIQUE USED
F1, F2	Electromagnetic	TESTED Electric and	Conducted emission tests	IEC 61000-6-	Conducted emissions
	compatibility	electronic		3:2006/A1:2010	in the frequency
	tests ^F	equipment for	Harmonics	IEC 61000-6-	range 150 kHz to
		residential,	F1' 1.	3:2020	30 MHz
		commercial and light-	Flicker	EN 61000-6- 3:2007/A1:2011+A	Harmonics on power line
		industrial		1:2011/EC:2012	Flicker on power line
		environments		EN 61000-6-	Theker on power line
				3:2021	
F1, F2		Electric and	Conducted emission tests	IEC 61000-6-	Conducted emissions
		electronic		4:2009,	in the frequency
		equipment for	Harmonics	IEC 61000-6-	range 150kHz to
		industrial environments	Flicker	4:2018 EN 61000-6-	30 MHz Harmonics on power
		Chynomichts	THORE	4:2007/A1:2011;	line
				EN 61000-6-	Flicker on power line
				4:2019	1
F1, F2	Electrical and	Medical	§ 4 - General requirements; §5 -	EN 60601-	Visual examination
	Mechanical F	electrical	General requirements for testing	1:2006/AC:2010/A	Power/current
		equipment -	ME EQUIPMENT	1:2013/	absorption up to 16 A
		General	§6 - Classification of ME	A12:2014/A2:2021	Leakage current up to
		requirements for basic safety	EQUIPMENT and ME SYSTEMS; §7 - ME EQUIPMENT	IEC 60601-	5 mA Up to 93% of relative
		and essential	identification, marking and	1:2005/AMD1:201	humidity
		performance	documents; §8 Protection against	2/AMD2:2020	Dielectric strength
		1	electrical HAZARDS from ME		test up to 5500 V
			EQUIPMENT		Clearance, creepage
		7	§ 9 - Protection against		0.01 mm to 1 m
		/	MECHANICAL HAZARDS of ME		Angle up to 10°
			EQUIPMENT and ME SYSTEMS; §10 - Protection against unwanted		Force up to 250 N Acoustic noise up to
			and excessive radiation HAZARDS;		140 dBA
			§11 Protection against excessive		Climatic chamber: 20
			temperatures and other HAZARDS;		to 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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FLEX CODE	FIELD OF TEST	ITEMS, MATERIALS, OR PRODUCTS	COMPONENT, CHARACTERISTIC, PARAMETER TESTED	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED
CODE	OF TEST	TESTED	TAKAMETER TESTED	STANDARD METHOD	TECHNIQUE USED
F1, F2	Electrical and	Medical electrical	201.4 General requirements;	IEC 60601-2-	Visual examination
	Mechanical F	equipment	201.5 General requirements		Power/current
		Part 2: Particular	for testing ME EQUIPMENT;	22:2007/A1:2012	absorption up to 16 A
	ļ	requirements for	201.6 Classification of ME		Leakage current up to
	ļ	basic safety and	EQUIPMENT and ME	IEC 60601-2-22:2019	5 mA
	ļ	essential	SYSTEMS;	120 00001 2 22:2019	Up to 93% of relative
	ļ	performance	201.7 ME EQUIPMENT	EN 60601-2-22:2013	humidity
	ļ	of surgical,	identification, marking and	E1 (00001	Dielectric strength
	ļ	cosmetic,	documents;	EN IEC 60601-2-	test up to 5500 V
	ļ	therapeutic and	201.8 Protection against	22:2020	Clearance, creepage
	ļ	diagnostic laser	electrical HAZARDS from	22.2020	0.01 mm to 1 m
	ļ	equipment	ME EQUIPMENT;		Angle up to 10°
	ļ	equipment	201.9 Protection against		Force up to 250 N
	ļ		MECHANICAL HAZARDS		Acoustic noise up to
	ļ				140 dBA
	ļ		of ME EQUIPMENT and ME SYSTEMS;		Climatic chamber: 20
	ļ				to 32 °C
	ļ		201.10 Protection against unwanted and excessive		
	ļ			/ 1	Fault condition up to
	ļ		radiation HAZARDS;	/	63 A
	ļ		201.11 Protection against		Force up to 200 N
	ļ		excessive temperatures and		Laser power
	ļ	/	other HAZARDS:		measurements up to
	ļ		201.12 Accuracy of controls		30 W
	ļ		and instruments and protection		
	ļ	/	against hazardous outputs;		
	ļ		201.13 HAZARDOUS		
	ļ		SITUATIONS and fault		
	ļ	/	conditions;	1	
	ļ		201.14 PROGRAMMABLE		
	ļ		ELECTRICAL MEDICAL		
	ļ		SYSTEMS (PEMS);		
	ļ		201.15 Construction of ME		
	ļ		EQUIPMENT;		
			201.16 ME SYSTEMS;		
			201.17 Electromagnetic		
			compatibility of ME		
	ļ		EQUIPMENT and ME		
			SYSTEMS		





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FLEX	FIELD	ITEMS, MATERIALS,	COMPONENT,	SPECIFICATION OR	TECHNOLOGY OR
CODE	OF TEST	OR PRODUCTS	CHARACTERISTIC,	STANDARD METHOD	TECHNIQUE USED
		TESTED	PARAMETER TESTED		
F1, F2	Electrical and	Medical electrical	201.4 General requirements;	CEI EN 60601-2-	Visual examination
	Mechanical F	Medical electrical	201.5 General requirements	57:2012, EN 60601-2-	Power/current
		equipment - Part 2-	for testing ME	57:2011, IEC 60601-2-	absorption up to 16 A
		57: Particular	EQUIPMENT;	57:2011	Leakage current up to
		requirements for the	201.6 Classification of ME		5 mA
		basic safety and	EQUIPMENT and ME		Up to 93% of relative
		essential	SYSTEMS;		humidity
		performance of non-	201.7 ME EQUIPMENT		Dielectric strength test
		laser light source	identification, marking and		up to 5500 V
		equipment intended	documents;		Angle up to 10°
		for therapeutic,	201.8 Protection against		Force up to 250 N
		diagnostic,	electrical HAZARDS from		Acoustic noise up to
		monitoring and	ME EQUIPMENT;		140 dBA
		cosmetic/aesthetic	201.9 Protection against		Climatic chamber: 20
		use	MECHANICAL		−32 °C
			HAZARDS of ME		Fault condition up to
			EQUIPMENT and ME		63 A
			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	1	
			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		



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CODE	OF TEST	OR PRODUCTS TESTED	CHARACTERISTIC, PARAMETER TESTED	STANDARD METHOD	TECHNIQUE USED
F1, F2	Electrical and	Household	4 - General requirement;	EN 60335-	Visual examination
	Mechanical F	appliances, electric	5 - General conditions for	1:2012/AC:2014/A11:201	Power/current
		tools and similar	the tests;	4/A13:2017/A1:	absorption up to 16 A
		apparatus	6 - Classification;	2019/A2:2019/A14:2019	3 kW
			7 - Marking and	CEI EN 60335-	Leakage current up to
			instructions;	1:2013/A11:2015/EC	5 mA
			8 - Protection against	:2014/A13:2019/A1/A2/A	Up to 93% of relative
			access to live parts;	14:2019	humidity
			9 - Starting of motor-	IEC 60335-	Dielectric strength
			operated appliances;	1:2010/AMD1:2013/	test up to 5500 V
			10 - Power input and	AMD2:2016/ISH1:2020	Clearance, creepage 0.01 mm to 1 m
			current;	IEC 60335-1:2020	Angle up to 10°
			11 - Heating; 13 - Leakage current and		Force up to 250 N
			electric strength at		Acoustic noise up to
			operating temperature;		140 dBA
			14 - Transient		Climatic chamber: 20
			overvoltages;		to 32 °C
			15 - Moisture resistance;		Fault condition up to
			16 - Leakage current and		63 A
			electric strength;		Pull force up to 100
			17 - Overload protection of		N;
			transformers and	N/III	
			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		





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CODE	OI ILSI	TESTED	PARAMETER TESTED	STANDING METHOD	TECH NQUE USED
F1, F2	Electrical and	Safety requirements	4 - Tests;	CEI EN 61010-	Power/current
	Mechanical F	for electrical	5 - Marking and	1:2013/EC:2017/A1:2019	absorption up to
		equipment for	documentation;	EN 61010-1:2010/A1:2019	16 A 3 kW
		measurement,	6 - Protection against	IEC 61010-	Leakage current
		control and	electric shock;	1:2010/AMD1:2016	up to 5 mA
		laboratory use	7 -Protection against		Up to 93% of
			mechanical HAZARDS;		relative humidity
			8 - Resistance to		Dielectric
			mechanical stresses;		strength test up
			9 - Protection against the		to 5500 V
			spread of fire;		
			10 - Equipment		
			temperature limits and		
			resistance to heat;		
			11 - Protection against		
			HAZARDS from fluids;		
			14 - Components and		
			subassemblies;		
			15 - Protection by		
			interlocks;		
			16 - HAZARDS resulting		
			from application;		
F1, F2		Audio/video,	17 - RISK assessment	CEI EN 62368-	Power/current
F1, F2		information and	4 - General requirements; 5 - Electrically-caused	1:2016/EC:2018/A11:2017	absorption up to
		communication	injury;	EN 62368-	16 A 3 kW
		technology	6 - Electrically-caused fire;	1:2014/AC:2015/A11:2017/	Leakage current
		equipment	7 - Injury caused by	AC:2017	up to 5 mA
		equipment	hazardous substances;	EN IEC 62368-	Up to 93% of
			8 - Mechanically-caused	1:2020/A11:2020/AC:2020	relative humidity
			injury;	IEC 62368-1:2018	Dielectric
			9 - Thermal burn injury;	120 02300 1.2010	strength test:up
			10 - Radiation		to 5 500 V
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CODE	OF TEST	MATERIALS, OR PRODUCTS	PARAMETER TESTED	STANDARD METHOD	TECHNIQUE USED
		TESTED			
F1, F2	Electrical and	Luminaires	2 - Classification of luminaires;	CEI EN 60598-	Power/current
	Mechanical F		3 - Marking;	1:2015/A1:2019/EC:2015/	absorption up to
			4 - Construction;	EC:2016	16 A
			5 - External and internal wiring;	EN 60598-	Leakage current
			7 - Provision for earthing;	1:2015/A1:2018/AC:2015/	up to5 mA
			8 - Protection against electric	AC:2016/AC:2017	Up to 93 % of
			shock;	IEC 60598-1:2020	relative humidity
			9 - Resistance to dust, solid	IEC 60598-	Dielectric strength
			object and moisture;	1:2014/AMD1:2017	test up to 5 500 V
			10 - Insulation resistance and		
			electric strength, touch current		
			and protective conductor		
			current;		
			11 - Creepage distances and		
			clearances;		
			12 - Endurance test and thermal		
			test;		
			13 - Resistance to heat, fire and		
			tracking;		
			14 - Screw terminals;		
			15 - Screwless terminals and		
			electrical connections		
F1, F2		Medical devices	Medical devices - Application	EN ISO 14971:2019; EN	Documental
			of risk management to medical	ISO 14971:2012	Inspection
			devices		
F1, F2			Medical electrical equipment	IEC 60601-1-	Documental
			Part 1-6: General requirements	6:2010+AMD1:2013+AM	Inspection
		/	for basic safety and essential	D2:2020	
			performance - Collateral		
			standard: Usability		
F1, F2	Electrical and	Medical devices	Medical devices	EN 62366-	Documental
	Mechanical F		Application of usability	1:2015/AC:2015/A1:2020;	Inspection
			engineering to medical devices	IEC 62366	
F1 F2			26 1: 1 1 : 2	1:2015/A1:2020	
F1, F2			Medical device software	IEC 62304:2006+AMD	Documental
			Software life-cycle processes	1:2015; EN 62304-	Inspection
				1:2006/A1:2015	





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		OR PRODUCTS			
E1 E2	Electrical and	TESTED Hayaahald	4 Compand requirements	IEC 60335-2-	Visual
F1, F2	Mechanical F	Household	4 - General requirement;		
	Mechanical	appliances,	5 - General conditions for the	2:2009/AMD1:2012/AMD	examination
		electric tools and	tests;	2:2016	Power/current
		similar apparatus -	6 -Classification;	IEC 60335-2-2:2019	absorption up to
		vacuum cleaners	7 -Marking and instructions;	EN 60335-2-	16
		and water-suction	8 -Protection against access to	2:2010/A1:2013/A11:2012	A 3 kW
		cleaning	live parts;		Leakage current
		appliances	9 -Starting of motor operated		up
			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		test: up to 5500 V
			temperature;		Clearance,
			14- Transient overvoltages;		creepage
			15 - Moisture resistance;		0.01 mm to 1 m
			16 - Leakage current and		Angle up to 10°
			electric strength;	/ 1	Force up to 250 N
			17 -Overload protection of		Acoustic noise up
			transformers and associated		to
		<u> </u>	circuits;		140 dBA
			18 - Endurance;		Climatic chamber:
			19 - Abnormal operation;		–
			20 - Stability and mechanical	4	40 °C to 180 °C
			hazards;		Fault condition up
			21 - Mechanical strength;		to63 A
			22 -Construction;		Pull force up to
			23 -Internal wiring;		100 N
			24 -Components;	J	100 IV
			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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Via del Consorzio 41 - Falconara Marittima, 60015 Italy Contact Name: Massimo Ambrosi Phone: 071-915-6048

FLEX	FIELD	ITEMS,	COMPONENT, CHARACTERISTIC,	SPECIFICATION OR	TECHNOLOGY OR
CODE	OF TEST	MATERIALS, OR PRODUCTS	PARAMETER TESTED	STANDARD METHOD	TECHNIQUE USED
		TESTED			
F1, F2	Electrical and	Household	4 - General requirement;	IEC 60335-2-	Visual
	Mechanical F	appliances,	5 - General conditions for the	3:2012+A1:2015	examination
		electric tools and	tests;	EN 60335-2-	Power/current
		similar apparatus -	6 -Classification;	3:2016/A1:2020	absorption up to
		electric irons	7 -Marking and instructions;		16
			8 -Protection against access to		A 3 kW
			live parts;		Leakage current
			9 -Starting of motor operated		up
			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		test: up to 5500 V
			temperature;		Clearance,
			14- Transient overvoltages;		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
			transformers and associated		to
			circuits;		140 dBA
			18 - Endurance;		Climatic chamber:
			19 - Abnormal operation;		20 to 30 °C
			20 - Stability and mechanical		Fault condition up
			hazards;		to
			21 - Mechanical strength;	1	63 A
			22 -Construction;		Pull force up to
		/	23 -Internal wiring;	J	100 N
			24 -Components;		
			25 -Supply connection and		
		A	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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FLEX	FIELD OF TEST	ITEMS,	COMPONENT, CHARACTERISTIC,	SPECIFICATION OR	TECHNOLOGY OR
CODE	OF TEST	OR PRODUCTS	TAKAMETER TESTED	STANDARD METHOD	TECHNIQUE USED
FLEX CODE F1, F2	Electrical and Mechanical ^F	ITEMS, MATERIALS,	COMPONENT, CHARACTERISTIC, PARAMETER TESTED 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;		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
			30 - Resistance to heat and fire;		
			31 - Resistance to rusting; 32 - Radiation, toxicity and		
			similar hazards		





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FLEX	FIELD	ITEMS,	COMPONENT, CHARACTERISTIC,	SPECIFICATION OR	TECHNOLOGY OR
CODE	OF TEST	MATERIALS,	PARAMETER TESTED	STANDARD METHOD	TECHNIQUE USED
		OR PRODUCTS TESTED			
F1, F2	Electrical and	Household	4 - General requirement;	IEC 60335-2-9:2019,	Visual
11,12	Mechanical F	appliances,	5 - General conditions for the	1EC 00333 2 3.2013,	examination
	Wicchamear	electric tools and	tests:	EN 60335-2-	Power/current
		similar apparatus -	6 -Classification;	9:2003/A12:2007/A13:201	absorption up to
		grills, toasters and	7 -Marking and instructions;	0/AC:2011/AC:2012/A1:2	16
		similar portable	8 -Protection against access to	004/A2:2006	A 3 kW
		cooking	live parts;	004/A2.2000	Leakage current
		appliances	9 -Starting of motor operated		-
		apphances	appliances;		up 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		test: up to 5500 V
			temperature;		Clearance,
			14- Transient overvoltages;		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
		<u> </u>	transformers and associated		to
			circuits; 18 - Endurance;		140 dBA Climatic chamber:
			19 - Abnormal operation;		20 to 30 °C
			20 - Stability and mechanical		Fault condition up
			hazards;		to 63 A
			21 - Mechanical strength;	1	
			22 -Construction;		Pull force up to 100 N
			23 -Internal wiring;	J	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;		
			<u> </u>		
			32 - Radiation, toxicity and		
			similar hazards		





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FLEX	FIELD	ITEMS,	COMPONENT, CHARACTERISTIC,	SPECIFICATION OR	TECHNOLOGY OR
CODE	OF TEST	MATERIALS,	PARAMETER TESTED	STANDARD METHOD	TECHNIQUE USED
		OR PRODUCTS TESTED			
F1, F2	Electrical and	Household	4 - General requirement;	IEC 60335-2-	Visual
	Mechanical F	appliances,	5 - General conditions for the	12:2002+AMD1:2008+A	examination
		electric tools and	tests;	MD2:2017,	Power/current
		similar apparatus -	6 -Classification;	,	absorption up to
		warming plates	7 -Marking and instructions;	EN 60335-2-	16
		and similar	8 -Protection against access to	12:2003/A1:2008/A2:2019	A 3 kW
		appliances	live parts;	/A11:2019	Leakage current
			9 -Starting of motor operated		up
			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		test: up to 5500 V
			temperature;		Clearance,
			14- Transient overvoltages;		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 transformers and associated		Acoustic noise up
		<u> </u>			to
			circuits; 18 - Endurance;		140 dBA Climatic chamber:
			19 - Abnormal operation;		20 to 30 °C
			20 - Stability and mechanical		Fault condition up
		/	hazards;		to
			21 - Mechanical strength;		63 A
			22 -Construction;	1	Pull force up to
		/	23 -Internal wiring;	1	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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FLEX	FIELD	ITEMS,	COMPONENT, CHARACTERISTIC,	SPECIFICATION OR	TECHNOLOGY OR
CODE	OF TEST	MATERIALS,	PARAMETER TESTED	STANDARD METHOD	TECHNIQUE USED
		OR PRODUCTS			
		TESTED			
F1, F2	Electrical and	Household	4 - General requirement;	IEC 60335-2-13:2021;	Visual
	Mechanical F	appliances,	5 - General conditions for the		examination
		electric tools and	tests:	IEC 60335-2-	Power/current
		similar apparatus -	6 -Classification;	13:2009+AMD1:2016;	absorption up to
		deep fat fryers,	7 -Marking and instructions;	13.2009 1111121.2010,	16
				ENI (0225-2	
		frying pans and	8 -Protection against access to	EN 60335-2-	A 3 kW
		similar appliances	live parts;	13:2010/A11:2012/A1:201	Leakage current
			9 -Starting of motor operated	9	up
			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		test: up to 5500 V
			temperature;		Clearance,
			14- Transient overvoltages;		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
			transformers and associated		to
		- A	circuits;		140 dBA
			18 - Endurance;		Climatic chamber:
			19 - Abnormal operation;		20 to 30 °C
			20 - Stability and mechanical		Fault condition up
		/	hazards;		to
			21 - Mechanical strength;		63 A
			22 -Construction;	1	Pull force up to
		./	23 -Internal wiring;		100 N
			24 -Components;	9	10011
			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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FLEX	FIELD	ITEMS,	COMPONENT, CHARACTERISTIC,	SPECIFICATION OR	TECHNOLOGY OR
CODE	OF TEST	MATERIALS,	PARAMETER TESTED	STANDARD METHOD	TECHNIQUE USED
		OR PRODUCTS			
E1 E2	E1 . 1 1	TESTED	4.6.1	HEG (0225.2	X7' 1
F1, F2	Electrical and	Household	4 - General requirement;	IEC 60335-2-	Visual
	Mechanical F	appliances,	5 - General conditions for the	14:2016+AMD1:2019	examination
		electric tools and	tests;		Power/current
		similar apparatus -	6 -Classification;	EN 60335-2-	absorption up to
		kitchen machines	7 -Marking and instructions;	14:2006/A1:2008/A11:201	16
			8 -Protection against access to	2/AC:2016/A12:2016	A 3 kW
			live parts;		Leakage current
			9 -Starting of motor operated		up
			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		test: up to 5500 V
			temperature;		Clearance,
			14- Transient overvoltages;		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
			transformers and associated		to
			circuits;		140 dBA
			18 - Endurance;		Climatic chamber:
			19 - Abnormal operation;		20 to 30 °C
			20 - Stability and mechanical		Fault condition up
		/	hazards;		to
			21 - Mechanical strength;		63 A
			22 -Construction;	1	Pull force up to
		./	23 -Internal wiring;	1	100N
			24 -Components;		10011
			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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FLEX	FIELD	ITEMS,	COMPONENT, CHARACTERISTIC,	SPECIFICATION OR	TECHNOLOGY OR
CODE	OF TEST	MATERIALS,	PARAMETER TESTED	STANDARD METHOD	TECHNIQUE USED
		OR PRODUCTS			
		TESTED			
F1, F2	Electrical and	Household	4 - General requirement;	IEC 60335-2-	Visual
	Mechanical F	appliances,	5 - General conditions for the	15:2012+AMD1:2016+A	examination
		electric tools and	tests;	MD2:2018,	Power/current
		similar apparatus -	6 -Classification;		absorption up to
		heating liquids	7 -Marking and instructions;	EN 60335-2-	16
			8 -Protection against access to	15:2016/A11:2018/A12:20	A 3 kW
			live parts;	21/A1:2021/A2:2021	Leakage current
			9 -Starting of motor operated		up
			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		test: up to 5500 V
			temperature;		Clearance,
			14- Transient overvoltages;		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
			transformers and associated		to
			circuits;		140 dBA
			18 - Endurance;		Climatic chamber:
			19 - Abnormal operation;		20 to 30 °C
			20 - Stability and mechanical		Fault condition up
		/	hazards;		to
			21 - Mechanical strength;		63 A
			22 -Construction;	1	Pull force up to
		./	23 -Internal wiring;		100 N
			24 -Components;		10011
			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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FLEX	FIELD	ITEMS,	COMPONENT, CHARACTERISTIC,	SPECIFICATION OR	TECHNOLOGY OR
CODE	OF TEST	MATERIALS,	PARAMETER TESTED	STANDARD METHOD	TECHNIQUE USED
		OR PRODUCTS			
F1, F2	Electrical and	Household	4 Conoral requirements	IEC 60335-2-	Visual
F1, F2	Mechanical F		4 - General requirement;		examination
	Mechanical	appliances,	5 - General conditions for the	23:2016+AMD1:2019,	
		electric tools and	tests;	ENT 60225 2	Power/current
		similar apparatus -	6 -Classification;	EN 60335-2-	absorption up to
		appliances for	7 -Marking and instructions;	23:2003/A11:2010/AC:201	16
		skin or hair care	8 -Protection against access to	2/A1:2008/A2:2015	A 3 kW
			live parts;		Leakage current
			9 -Starting of motor operated		up
			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		test: up to 5500 V
			temperature;		Clearance,
			14- Transient overvoltages;		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
			transformers and associated		to
			circuits;		140 dBA
			18 - Endurance;		Climatic chamber:
			19 - Abnormal operation;		20 to 30 °C
			20 - Stability and mechanical		Fault condition up
		· //	hazards;		to
			21 - Mechanical strength;		63 A
			22 -Construction;	1	
				J.	Pull force up to 100 N
			23 -Internal wiring;)	100 IN
			24 -Components;		
			25 -Supply connection and		
		A.	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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FLEX	FIELD	ITEMS,	COMPONENT, CHARACTERISTIC,	SPECIFICATION OR	TECHNOLOGY OR
CODE	OF TEST	MATERIALS, OR PRODUCTS	PARAMETER TESTED	STANDARD METHOD	TECHNIQUE USED
		TESTED			
F1, F2	Electrical and	Household	4 - General requirement;	IEC 60335-2-24:2020	Visual
	Mechanical F	appliances,	5 - General conditions for the		examination
		electric tools and	tests;	EN 60335-2-24:2010	Power/current
		similar apparatus -	6 -Classification;	/A1:2019/A2:2019/A11:20	absorption up to
		refrigerating	7 -Marking and instructions;	20	16
		appliances, ice-	8 -Protection against access to		A 3 kW
		cream appliances	live parts;		Leakage current
		and ice makers	9 -Starting of motor operated		up
			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		test: up to 5500 V
			temperature;		Clearance,
			14- Transient overvoltages;		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
			transformers and associated		to
			circuits;		140 dBA
			18 - Endurance;		Climatic chamber:
			19 - Abnormal operation;		20 to 30 °C
			20 - Stability and mechanical	47-0	Fault condition up
			hazards;		to
			21 - Mechanical strength;	1	63 A
			22 -Construction;		Pull force up to
		//	23 -Internal wiring;	. /	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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		Accreation is gr	raniea io ine jaciilly lo perjorm	the jouowing testing.	
FLEX CODE	FIELD OF TEST	ITEMS, MATERIALS, OR PRODUCTS TESTED	COMPONENT, CHARACTERISTIC, PARAMETER TESTED	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED
F1, F2	Electrical and Mechanical F	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;	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
			32 - Radiation, toxicity and similar hazards		





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FLEX	FIELD	ITEMS,	COMPONENT, CHARACTERISTIC,	SPECIFICATION OR	TECHNOLOGY OR
CODE	OF TEST	MATERIALS,	PARAMETER TESTED	STANDARD METHOD	TECHNIQUE USED
		OR PRODUCTS			
E1 E2	T1	TESTED	4.6	TEG (0225.2	77' 1
F1, F2	Electrical and	Household	4 - General requirement;	IEC 60335-2-	Visual
	Mechanical- F	appliances,	5 - General conditions for the	29:2016+AMD1:2019,	examination
		electric tools and	tests;		Power/current
		similar apparatus -	6 -Classification;	EN 60335-2-	absorption up to
		battery chargers	7 -Marking and instructions;	29:2021/A1:2021	16
			8 -Protection against access to		A 3 kW
			live parts;		Leakage current
			9 -Starting of motor operated		up
			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		test: up to 5500 V
			temperature;		Clearance,
			14- Transient overvoltages;		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
			transformers and associated		to
			circuits;	X /	140 dBA
			18 - Endurance;		Climatic chamber:
			19 - Abnormal operation;		20 to 30 °C
			20 - Stability and mechanical		Fault condition up
		/	hazards;		to
			21 - Mechanical strength;		63 A
			22 -Construction;	1	Pull force up to
			23 -Internal wiring;	1	100 N
			24 -Components;		10011
			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		
L			similar nazards		





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

FLEX CODE	FIELD OF TEST	ITEMS, MATERIALS,	COMPONENT, CHARACTERISTIC, PARAMETER TESTED	SPECIFICATION OR	TECHNOLOGY OR
CODE	OF IESI	OR PRODUCTS TESTED	FARAMETER TESTED	STANDARD METHOD	TECHNIQUE USED
F1, F2	Electrical and	Household	4 - General requirement;	IEC 60335-2-	Visual
11,12	Mechanical F	appliances,	5 - General conditions for the	31:2012+AMD1:2016+A	examination
		electric tools and	tests:	MD2:2018,	Power/current
		similar apparatus -	6 -Classification;	,	absorption up to
		range hoods and	7 -Marking and instructions;	EN 60335-2-31:2014	16
		other cooking	8 -Protection against access to		A 3 kW
		fume extractors	live parts;		Leakage current
			9 -Starting of motor operated		up
			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		test: up to 5500 V
			temperature;		Clearance,
			14- Transient overvoltages;		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
		· · · · · · · · · · · · · · · · · · ·	transformers and associated		to
		/	circuits; 18 - Endurance;		140 dBA Climatic chamber:
			19 - Abnormal operation;		20 to 30 °C
			20 - Stability and mechanical		Fault condition up
		/	hazards;		to
			21 - Mechanical strength;		63 A
			22 -Construction;	1	Pull force up to
		-/-	23 -Internal wiring;	1	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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FLEX	FIELD	ITEMS,	COMPONENT, CHARACTERISTIC,	SPECIFICATION OR	TECHNOLOGY OR
CODE	OF TEST	MATERIALS, OR PRODUCTS	PARAMETER TESTED	STANDARD METHOD	TECHNIQUE USED
		TESTED			
F1, F2	Electrical and	Household	4 - General requirement;	IEC 60335-2:32:2019,	Visual
	Mechanical F	appliances,	5 - General conditions for the		examination
		electric tools and	tests;	EN 60335-2-32:2021;	Power/current
		similar apparatus -	6 -Classification;		absorption up to
		massage	7 -Marking and instructions;		16
		appliances	8 -Protection against access to		A 3 kW
			live parts;		Leakage current
			9 -Starting of motor operated		up
			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		test: up to 5500 V
			temperature;		Clearance,
			14- Transient overvoltages;		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
			transformers and associated		to
			circuits;		140 dBA
			18 - Endurance;	V	Climatic chamber:
			19 - Abnormal operation;		20 to 30 °C
			20 - Stability and mechanical		Fault condition up
		/	hazards;		to
			21 - Mechanical strength;	1	63 A
			22 -Construction;		Pull force up to
		//	23 -Internal wiring;	. /	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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FLEX	FIELD	ITEMS,	COMPONENT, CHARACTERISTIC,	SPECIFICATION OR	TECHNOLOGY OR
CODE	OF TEST	MATERIALS, OR PRODUCTS	PARAMETER TESTED	STANDARD METHOD	TECHNIQUE USED
E1 E2	E1 . 1 1	TESTED	4 0 1	HDG 60225 2	X7' 1
F1, F2	Electrical and	Household	4 - General requirement;	IEC 60335-2-	Visual
	Mechanical F	appliances,	5 - General conditions for the	35:2012+AMD1:2016+A	examination
		electric tools and	tests;	MD2:2020,	Power/current
		similar apparatus -	6 -Classification;		absorption up to
		instantaneous	7 -Marking and instructions;	EN 60335-2-	16
		water heaters	8 -Protection against access to	35:2016/A1:2019/A2:2021	A 3 kW
			live parts;		Leakage current
			9 -Starting of motor operated		up
			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		test: up to 5500 V
			temperature;		Clearance,
					•
			14- Transient overvoltages;15 - Moisture resistance;		creepage 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
			transformers and associated		to
			circuits;		140 dBA
			18 - Endurance;		Climatic chamber:
			19 - Abnormal operation;		20 to 30 °C
			20 - Stability and mechanical		Fault condition up
			hazards;		to
			21 - Mechanical strength;	1	63 A
			22 -Construction;		Pull force up to
		1/2	23 -Internal wiring;		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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FLEX	FIELD	ITEMS,	COMPONENT, CHARACTERISTIC,	SPECIFICATION OR	TECHNOLOGY OR
CODE	OF TEST	MATERIALS,	PARAMETER TESTED	STANDARD METHOD	TECHNIQUE USED
		OR PRODUCTS			
F1 F2	E1 . 1 1	TESTED		TEG (0225.2	TT' 1
F1, F2	Electrical and	Household	4 - General requirement;	IEC 60335-2-	Visual
	Mechanical F	appliances,	5 - General conditions for the	59:2002/A1:2006/A2:2009	examination
		electric tools and	tests;	,	Power/current
		similar apparatus -	6 -Classification;		absorption up to
		insect killers	7 -Marking and instructions;	IEC 60335-2-59:2021	16
			8 -Protection against access to		A 3 kW
			live parts;	EN 60335-2-	Leakage current
			9 -Starting of motor operated	59:2003/A1:2006/A2:2009	up
			appliances;	/A11:2018	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		test: up to 5500 V
			temperature;		Clearance,
			14- Transient overvoltages;		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
			transformers and associated		to
		<u> </u>	circuits;		140 dBA
		/	18 - Endurance;		Climatic chamber:
			19 - Abnormal operation;		20 to 30 °C
			20 - Stability and mechanical		Fault condition up
			hazards;		to
		/	21 - Mechanical strength;	1	63 A
			22 -Construction;		Pull force up to
		/	23 -Internal wiring;	J	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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FLEX	FIELD	ITEMS,	COMPONENT, CHARACTERISTIC,	SPECIFICATION OR	TECHNOLOGY OR
CODE	OF TEST	MATERIALS,	PARAMETER TESTED	STANDARD METHOD	TECHNIQUE USED
		OR PRODUCTS TESTED			
F1, F2	Electrical and	Household	4 - General requirement;	IEC 60335-2-	Visual
1 1,12	Mechanical F	appliances,	5 - General conditions for the	65:2002/Ec1:2004/A1:200	examination
	Wiconamour	electric tools and	tests:	8,,	Power/current
		similar apparatus -	6 -Classification;	0,,	absorption up to
		air-cleaning	7 -Marking and instructions;	EN 60335-2-	16
		appliances	8 -Protection against access to	65:2003/A1:2008/A11:201	A 3 kW
		appliances	live parts;	2/A12:2022/A2:2022	Leakage current
			9 -Starting of motor operated	2/112.2022/112.2022	up
			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		test: up to 5500 V Clearance,
			temperature; 14- Transient overvoltages;		· ·
			15 - Moisture resistance;		creepage 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 transformers and associated		Acoustic noise up
		<u> </u>			to
			circuits; 18 - Endurance;		140 dBA Climatic chamber:
					20 to 30 °C
			19 - Abnormal operation; 20 - Stability and mechanical		
		/	hazards;		Fault condition up to
			21 - Mechanical strength;		63 A
			22 -Construction;	1	Pull force up to
			23 -Internal wiring;	1	100 N
			24 -Components;	J	100 IN
			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		
		1	Similal Hazarus	1	





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FLEX	FIELD	ITEMS,	COMPONENT, CHARACTERISTIC,	SPECIFICATION OR	TECHNOLOGY OR
CODE	OF TEST	MATERIALS, OR PRODUCTS	PARAMETER TESTED	STANDARD METHOD	TECHNIQUE USED
		TESTED			
F1, F2	Electrical and	Household	4 - General requirement;	IEC 60335-2-	Visual
	Mechanical F	appliances,	5 - General conditions for the	75:2012+AMD1:2015+A	examination
		electric tools and	tests;	MD2:2018,	Power/current
		similar apparatus -	6 -Classification;		absorption up to
		commercial	7 -Marking and instructions;	EN 60335-2-	16
		dispensing	8 -Protection against access to	75:2004/A1:2005/A11:200	A 3 kW
		appliances and	live parts;	6/A2:2008/A12:2010	Leakage current
		vending machines	9 -Starting of motor operated		up
			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		test: up to 5500 V
			temperature;		Clearance,
			14- Transient overvoltages;15 - Moisture resistance;		creepage 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
			transformers and associated		to
		/	circuits;		140 dBA
			18 - Endurance;		Climatic chamber:
			19 - Abnormal operation;		20 to 30 °C
			20 - Stability and mechanical		Fault condition up
		/	hazards;		to
			21 - Mechanical strength;		63 A
			22 -Construction;	1	Pull force up to
		/	23 -Internal wiring;)	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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FLEX CODE	FIELD OF TEST	ITEMS, MATERIALS,	COMPONENT, CHARACTERISTIC, PARAMETER TESTED	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED
CODE	OF TEST	OR PRODUCTS	TARAMETER TESTED	STANDARD METHOD	TECHNIQUE USED
F1, F2	Electrical and Mechanical F	Household appliances, electric tools and similar apparatus - fans	4 - General requirement; 5 - General conditions for the tests; 6 - Classification; 7 - Marking and instructions; 8 - Protection against access to live parts; 9 - Starting of motor operated appliances; 10 - Power input and current; 11 - Heating; 13 - Leakage current and electric strength at operating temperature; 14 - Transient overvoltages; 15 - Moisture resistance; 16 - Leakage current and electric strength; 17 - Overload protection of transformers and associated circuits; 18 - Endurance; 19 - Abnormal operation; 20 - Stability and mechanical hazards; 21 - Mechanical strength; 22 - Construction; 23 - Internal wiring; 24 - Components; 25 - Supply connection and external flexible cords; 26 - Terminals for external conductors; 27 - Provision for earthing; 28 - Screws and connections; 29 - Clearances, creepage distances and solid insulation; 30 - Resistance to heat and fire; 31 - Resistance to rusting;	EN 60335-2- 80:2003/A1:2004/A2:2009 , IEC 60335-2-80:2015	Visual examination Power/current absorption up to 16 A 3 kW Leakage current up to 5 mA Up to 93% of relative humidity Dielectric strength test: up to 5500 V Clearance, creepage 0.01 mm to 1 m Angle up to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: 20 to 30 °C Fault condition up to 63 A Pull force up to 100 N
			32 - Radiation, toxicity and similar hazards		





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CODE	OF TEST	MATERIALS,	PARAMETER TESTED	STANDARD METHOD	TECHNIQUE USED
		OR PRODUCTS TESTED			
F1, F2	Electrical and	Medical	§ 4 - General requirements; §5 -	IEC 60601-2-2:2017;	Visual
	Mechanical F	electrical	General requirements for		examination
		equipment - high	testing ME EQUIPMENT	EN 60601-2-2:2018	Power/current
		frequency surgical	§6 - Classification of ME		absorption up to
		equipment and	EQUIPMENT and ME		16 A
		high frequency	SYSTEMS;		Leakage current
		surgical	§7 - ME EQUIPMENT		up to 5
		accessories	identification, marking and		mA
			documents;		Up to 93% of
			§8 Protection against electrical		relative
			HAZARDS from ME		humidity
			EQUIPMENT		Dielectric strength
			§ 9 - Protection against		test:
			MECHANICAL HAZARDS of		up to 5500 V
			ME EQUIPMENT and ME		Clearance,
			SYSTEMS;		creepage
			§10 - Protection against		0.01 mm to 1 m
			unwanted and excessive radiation HAZARDS;		Angle up to 10°
			§11 Protection against		Force up to 250 N Acoustic noise up
		<u> </u>	excessive temperatures and		to 140
			other HAZARDS;		dBA
			§12 - Accuracy of controls and		Climatic chamber:
			instruments and protection		20 °C to 30 °C
		/	against hazardous outputs;		20 0 10 20 0
			§13 HAZARDOUS		
			SITUATIONS and fault	1	
		//	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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FLEX	FIELD	ITEMS,	COMPONENT, CHARACTERISTIC,	SPECIFICATION OR	TECHNOLOGY OR
CODE	OF TEST	MATERIALS,	PARAMETER TESTED	STANDARD METHOD	TECHNIQUE USED
		OR PRODUCTS TESTED			
F1, F2	Electrical and	Medical	§ 4 - General requirements; §5 -	EN 60601-2-18:2015;	Visual
11,12	Mechanical F	electrical	General requirements for	210.2013,	examination
	1,100110111001	equipment -	testing ME EQUIPMENT	IEC 60601-2-18:2009	Power/current
		endoscopic	§6 - Classification of ME	120 00001 2 10.2009	absorption up to
		equipment	EQUIPMENT and ME		16 A
		-11	SYSTEMS;		Leakage current
			§7 - ME EQUIPMENT		up to 5
			identification, marking and		mA
			documents;		Up to 93% of
			§8 Protection against electrical		relative
			HAZARDS from ME		humidity
			EQUIPMENT		Dielectric strength
			§ 9 - Protection against		test:
			MECHANICAL HAZARDS of		up to 5500 V
			ME EQUIPMENT and ME		Clearance,
			SYSTEMS;		creepage
			§10 - Protection against		0.01 mm to 1 m
			unwanted and excessive		Angle up to 10°
			radiation HAZARDS;		Force up to 250 N
			§11 Protection against		Acoustic noise up
			excessive temperatures and		to 140
			other HAZARDS;		dBA
			§12 - Accuracy of controls and		Climatic chamber: 20 °C to 32 °C
		/	instruments and protection against hazardous outputs;		20 10 10 32 10
			§13 HAZARDOUS		
			SITUATIONS and fault	1	
		./	conditions;	1	
			§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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FLEX CODE	FIELD OF TEST	ITEMS, MATERIALS, OR PRODUCTS	COMPONENT, CHARACTERISTIC,	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED
		TESTED	PARAMETER TESTED		
F1, F2	Electrical and	Medical	§ 4 - General requirements;	EN 60601-2-50:2021;	Visual
	Mechanical F	electrical	§5 - General requirements for		examination
		equipment - infant	testing ME EQUIPMENT	IEC 60601-2-50:2020	Power/current
		phototherapy	§6 - Classification of ME		absorption up to
		equipment	EQUIPMENT and ME		16 A
			SYSTEMS;		Leakage current
			§7 - ME EQUIPMENT		up to 5
			identification, marking and		mA
			documents;		Up to 93% of
			§8 Protection against		relative
			electrical HAZARDS from		humidity
			ME EQUIPMENT		Dielectric strength
			§ 9 - Protection against		test:
			MECHANICAL HAZARDS		up to 5500 V
			of ME EQUIPMENT and		Clearance,
			ME SYSTEMS;		creepage
			§10 - Protection against		0.01 mm to 1 m
			unwanted and excessive	/)	Angle up to 10°
			radiation HAZARDS;		Force up to 250 N
			§11 Protection against		Acoustic noise up
			excessive temperatures and other HAZARDS;		to 140 dBA
			§12 - Accuracy of controls		Climatic chamber:
			and instruments and		20 °C to 32 °C
			protection against hazardous	40	20 C to 32 C
		/	outputs;		
			§13 HAZARDOUS		
			SITUATIONS and fault	1	
		/	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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F1, F2 Electrical and Mechanical F electrical electrical equipment - infant transport incubators F1, F2 Electrical and Mechanical F electrical equipment - infant transport incubators F1, F2 Electrical and Mechanical F electrical equipment - infant transport incubators F1, F2 Electrical and Mechanical F electrical electrical equipment - infant transport incubators F2 General requirements; \$5 - General requirements for testing ME EQUIPMENT F3 - Classification of ME EQUIPMENT and ME SYSTEMS; \$7 - ME EQUIPMENT identification, marking and documents; \$8 - Order Power/current absorption up to 16 A Up to 93% of relative humidity F3 - ME EQUIPMENT identification, marking and documents; \$8 - Order Power/current absorption up to 16 A Up to 93% of relative humidity F3 - ME EQUIPMENT identification, marking and documents; \$8 - Protection against electrical HAZARDS from ME EQUIPMENT F3 - ME EQUIPMENT F3 - ME EQUIPMENT F4 - General requirements; \$5 - General requirements; \$20:2020, Power/current absorption up to 16 A Up to 93% of relative to 10 in MA Dielectric strength test and the provided in MA Dielectric strength test	FLEX CODE	FIELD OF TEST	ITEMS, MATERIALS, OR PRODUCTS TESTED	COMPONENT, CHARACTERISTIC, PARAMETER TESTED	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED
	F1, F2		Medical electrical equipment - infant	§ 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	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





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FLEX	FIELD	ITEMS, MATERIALS,	COMPONENT,	SPECIFICATION OR	TECHNOLOGY OR
CODE	OF TEST	OR PRODUCTS	CHARACTERISTIC,	STANDARD METHOD	TECHNOLOGI OK TECHNIQUE USED
		TESTED	PARAMETER TESTED		
F1, F2	Electrical and	Medical	§ 4 - General requirements;	EN 60601-2-	Visual examination
	Mechanical F	electrical	§5 - General requirements for	52:2010/A1:2015/A	Power/current
		equipment - medical	testing ME EQUIPMENT	C:2011,	absorption up to 16 A
		beds	§6 - Classification of ME		Leakage current up to 5
			EQUIPMENT and ME	IEC 60601-2-	mA
			SYSTEMS;	52:2009/A1:2015	Up to 93% of relative
			§7 - ME EQUIPMENT		humidity
			identification, marking and		Dielectric strength test:
			documents;		up to 5500 V
			§8 Protection against		Clearance, creepage
			electrical HAZARDS from		0.01 mm to 1 m
			ME EQUIPMENT		Angle up to 10°
			§ 9 - Protection against		Force up to 250 N
			MECHANICAL HAZARDS		Acoustic noise up to 140
			of ME EQUIPMENT and		dBA
			ME SYSTEMS;		Climatic chamber: 20 °C
			§10 - Protection against		to 32 °C
			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	1	
			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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FLEX	FIELD	ITEMS, MATERIALS,	COMPONENT,	SPECIFICATION OR	TECHNOLOGY OR
CODE	OF TEST	OR PRODUCTS	CHARACTERISTIC,	STANDARD METHOD	TECHNIQUE USED
		TESTED	PARAMETER TESTED		_
F1, F2	Electrical and	Medical	§ 4 - General requirements;	EN 60601-21:2021,	Visual
	Mechanical F	electrical	§5 - General requirements for		examination
		equipment - infant	testing ME EQUIPMENT	IEC 60601-2-21:2020	Power/current
		radiant warmers	§6 - Classification of ME		absorption up to
			EQUIPMENT and ME		16 A
			SYSTEMS;		Leakage current
			§7 - ME EQUIPMENT		up to 5
			identification, marking and		mA
			documents;		Up to 93% of
			§8 Protection against		relative
			electrical HAZARDS from		humidity
			ME EQUIPMENT		Dielectric strength
			§ 9 - Protection against		test:
			MECHANICAL HAZARDS		up to 5500 V
			of ME EQUIPMENT and		Clearance,
			ME SYSTEMS;		creepage
			§10 - Protection against		0.01 mm to 1 m
			unwanted and excessive		Angle up to 10°
			radiation HAZARDS;		Force up to 250 N
			§11 Protection against		Acoustic noise up
			excessive temperatures and		to 140
		-/-	other HAZARDS;		dBA
			§12 - Accuracy of controls		Climatic chamber:
			and instruments and		20 °C to 32 °C
			protection against hazardous		
		/	outputs;		
			§13 HAZARDOUS	1	
			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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FLEX CODE	FIELD OF TEST	ITEMS, MATERIALS, OR PRODUCTS	COMPONENT, CHARACTERISTIC,	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED
		TESTED	PARAMETER TESTED		-
F1, F2	Electrical and	Medical	§ 4 - General requirements;	EN 60601-2-16:2019	Visual
	Mechanical F	electrical	§5 - General requirements for		examination
		equipment -	testing ME EQUIPMENT	IEC 60601-2-16:2018	Power/current
		haemodialysis,	§6 - Classification of ME		absorption up to
		haemodiafiltration	EQUIPMENT and ME		16 A
		and haemofiltration	SYSTEMS;		Leakage current
		equipment	§7 - ME EQUIPMENT		up to 5
			identification, marking and		mA
			documents;		Up to 93% of
			§8 Protection against		relative
			electrical HAZARDS from		humidity
			ME EQUIPMENT		Dielectric strength
			§ 9 - Protection against		test:
			MECHANICAL HAZARDS		up to 5500 V
			of ME EQUIPMENT and		Clearance,
			ME SYSTEMS;		creepage
			§10 - Protection against unwanted and excessive		0.01 mm to 1 m Angle up to 10°
			radiation HAZARDS;	/)	Force up to 250 N
			§11 Protection against	_ /	Acoustic noise up
			excessive temperatures and		to 140
			other HAZARDS;		dBA
			§12 - Accuracy of controls		Climatic chamber:
			and instruments and		20 °C to 32 °C
			protection against hazardous		20 0 10 02 0
		/	outputs;		
			§13 HAZARDOUS	1	
			SITUATIONS and fault		
		1	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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FLEX CODE	FIELD OF TEST	ITEMS, MATERIALS, OR PRODUCTS	COMPONENT, CHARACTERISTIC,	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED
		TESTED	PARAMETER TESTED		
F1, F2	Electrical and	Medical	§ 4 - General requirements;	EN 60601-2-	Visual
	Mechanical F	electrical	§5 - General requirements for	10:2015/A1:2016,	examination
		equipment - nerve	testing ME EQUIPMENT	IEC 60601-2-	Power/current
		and	§6 - Classification of ME	10:2012/A1:2016	absorption up to
		musclestimulators	EQUIPMENT and ME		16 A
			SYSTEMS;		Leakage current
			§7 - ME EQUIPMENT		up to 5
			identification, marking and		mA
			documents;		Up to 93% of
			§8 Protection against		relative
			electrical HAZARDS from		humidity
			ME EQUIPMENT		Dielectric strength
			§ 9 - Protection against		test:
			MECHANICAL HAZARDS		up to 5500 V
			of ME EQUIPMENT and		Clearance,
			ME SYSTEMS;		creepage
			§10 - Protection against		0.01 mm to 1 m
			unwanted and excessive	/)	Angle up to 10°
			radiation HAZARDS;		Force up to 250 N
			§11 Protection against		Acoustic noise up to 140
			excessive temperatures and other HAZARDS;		dBA
			§12 - Accuracy of controls		Climatic chamber:
			and instruments and		20 °C to 32 °C
			protection against hazardous		20 0 10 32 0
		/	outputs;		
			§13 HAZARDOUS	1	
			SITUATIONS and fault	1	
		/	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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FLEX CODE	FIELD OF TEST	ITEMS, MATERIALS, OR PRODUCTS	COMPONENT, CHARACTERISTIC,	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED
		TESTED	PARAMETER TESTED		
F1, F2	Electrical and	Medical	§ 4 - General requirements;	EN 60601-2-5:2015, IEC	Visual
	Mechanical F	electrical	§5 - General requirements for	60601-2-5:2009	examination
		equipment -	testing ME EQUIPMENT		Power/current
		ultrasonic	§6 - Classification of ME		absorption up to
		physiotherapy	EQUIPMENT and ME		16 A
		equipment	SYSTEMS;		Leakage current
			§7 - ME EQUIPMENT		up to 5
			identification, marking and		mA
			documents;		Up to 93% of
			§8 Protection against		relative
			electrical HAZARDS from		humidity
			ME EQUIPMENT		Dielectric strength
			§ 9 - Protection against		test:
			MECHANICAL HAZARDS		up to 5500 V
			of ME EQUIPMENT and		Clearance,
			ME SYSTEMS;		creepage
			§10 - Protection against		0.01 mm to 1 m
			unwanted and excessive		Angle up to 10°
			radiation HAZARDS;		Force up to 250 N
			§11 Protection against		Acoustic noise up
			excessive temperatures and		to 140
			other HAZARDS;		dBA
			§12 - Accuracy of controls		Climatic chamber:
			and instruments and		20 °C to 32 °C
			protection against hazardous		
			outputs;		
			§13 HAZARDOUS	1	
			SITUATIONS and fault	1	
			conditions;	9	
			§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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FLEX CODE	FIELD OF TEST	ITEMS, MATERIALS, OR PRODUCTS	COMPONENT, CHARACTERISTIC,	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED
		TESTED	PARAMETER TESTED		
F1, F2	Environmental ^F	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+AM D2:2020, EN 60601-1- 9:2008/A1:2013/A2:2020	Requirements for environmentally conscious design
F1, F2	Electromagnetic compatibility tests ^F	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





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FLEX CODE	FIELD OF TEST	ITEMS, MATERIALS, OR PRODUCTS	COMPONENT, CHARACTERISTIC,	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED
		TESTED	PARAMETER TESTED		
F1, F2	IP degrees F	Electrical equipment	4 designation	EN	All IP degrees
	_		5 degrees of protection	60529:1991/corr:1993/A1:	
			against access to	2000/A2:2013/EC:2016/A	
			Hazardous parts and against	2AC:2019	
			solid foreign		
			Objects indicated by the first	IEC 529:1989/IEC	
			characteristic	60529/A1:1999/A2:2013/C	
			Numeral	OR2:2015/A2/COR1:2019	
			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	1	
			solid foreign objects		
		/	indicated by the first	J	
			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		





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FLEX CODE	FIELD OF TEST	ITEMS, MATERIALS, OR PRODUCTS	COMPONENT, CHARACTERISTIC,	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED
F1, F2	Environmental	TESTED Components or	PARAMETER TESTED 4 general test procedure	IEC 60068-2-78:2012	UP TO 40°C
Γ_1, Γ_2	test ^F	equipment	5 measurements	EN 60068-2-78:2013	Up to 93% RH
			6 Information to be given in		1
			the relevant specification		
			7 Information to be given in		
			the test report		
F1, F2	Electrical and	Medical electrical	§ 4 - General requirements;	IEC 60601-2-	Visual
	mechanical F	equipment- short-	§5 - General requirements for	3:2012/AMD1:2016	examination
		wave therapy	testing ME EQUIPMENT	FD1 (0(01 0	Power/current
		equipment	§6 - Classification of ME	EN 60601-2-	absorption up to
			EQUIPMENT and ME	3:2015/A1:2016	16 A
			SYSTEMS; §7 - ME EQUIPMENT		Leakage current up to 5
			identification, marking and		mA
			documents;		Up to 93% of
			§8 Protection against		relative
			electrical HAZARDS from		humidity
			ME EQUIPMENT		Dielectric strength
			§ 9 - Protection against		test:
			MECHANICAL HAZARDS		up to 5500 V
			of ME EQUIPMENT and		Clearance,
			ME SYSTEMS;		creepage
			§10 - Protection against		0.01 mm to 1 m
			unwanted and excessive		Angle up to 10°
		/	radiation HAZARDS;		Force up to 250 N
			§11 Protection against		Acoustic noise up to 140
			excessive temperatures and other HAZARDS;	1	dBA
		/	§12 - Accuracy of controls		Climatic chamber:
			and instruments and		20 °C to 32 °C
			protection against hazardous		20 0 10 02 0
			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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FLEX CODE	FIELD OF TEST	ITEMS, MATERIALS, OR PRODUCTS	COMPONENT, CHARACTERISTIC,	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED
		TESTED	PARAMETER TESTED		
F1, F2	Electrical and	Machinery	4- general requirements	IEC 60204-	Visual
	mechanical F		5 Incoming supplly	1:2016/AMD1:2021	examination
			conductor terminations and		Documental
			devices for disconnecting and	EN 60204-1:2018	examination
			switching off		Clearance,
			6 Protection against electric		creepage
			shock		0.01 mm to 1 m
			7 Protection of equipment		IP grade
			8 equipotential bonding		Mechanical
			9 Control circuits and control		inspection
			functions		Marking
			10 Operator interface and		inspection
			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		





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FLEX	FIELD	ITEMS, MATERIALS,	COMPONENT,	SPECIFICATION OR	TECHNOLOGY OR
CODE	OF TEST	OR PRODUCTS	CHARACTERISTIC,	STANDARD METHOD	TECHNIQUE USED
E1 E2	E1 4 1 1	TESTED	PARAMETER TESTED	EN (0(01 2 25 2015	37' - 1
F1, F2	Electrical and	Medical electrical	§ 4 - General requirements;	EN 60601-2-25:2015	Visual
	Mechanical F	equipment - Part 2-	§5 - General requirements for	HEG (0(01 2 25 2011	examination
		25: Particular	testing ME EQUIPMENT	IEC 60601-2-25:2011	Power/current
		requirements for the	§6 - Classification of ME		absorption up to
		basic safety and	EQUIPMENT and ME		16 A
		essential	SYSTEMS;		Leakage current
		performance of	§7 - ME EQUIPMENT		up to 5 mA
		electrocardiographs	identification, marking and		Up to 93% of
			documents;		relative humidity
			§8 Protection against		Dielectric strength
			electrical HAZARDS from		test up to 5500 V
			ME EQUIPMENT		Clearance,
			§ 9 - Protection against		creepage 0.01 mm
			MECHANICAL HAZARDS		to 1 m
			of ME EQUIPMENT and		Angle up to 10°
			ME SYSTEMS;		Force up to 250 N
			§10 - Protection against		Acoustic noise up
			unwanted and excessive		to 140 dBA
			radiation HAZARDS;		Climatic chamber:
			§11 Protection against		20 °C to 32 °C
			excessive temperatures and		
		/	other HAZARDS;		
			§12 - Accuracy of controls		
			and instruments and		
			protection against hazardous		
			outputs;		
		/	§13 HAZARDOUS	1	
		/	SITUATIONS and fault		
		/	conditions;	J	
			§14 PROGRAMMABLE		
			ELECTRICAL MEDICAL		
		A	SYSTEMS (PEMS);		
			§15 - Construction of ME		
			EQUIPMENT;		
			§16 ME SYSTEMS;		
			§17 - Electromagnetic		
			compatibility of ME		
			EQUIPMENT and ME		
			SYSTEMS		





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FLEX	FIELD	ITEMS, MATERIALS,	COMPONENT,	SPECIFICATION OR	TECHNOLOGY OR
CODE	OF TEST	OR PRODUCTS TESTED	CHARACTERISTIC, PARAMETER TESTED	STANDARD METHOD	TECHNIQUE USED
F1, F2	Electrical and Mechanical F	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; \$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





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FLEX CODE	FIELD OF TEST	ITEMS, MATERIALS,	COMPONENT, CHARACTERISTIC,	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED
		OR PRODUCTS TESTED	PARAMETER TESTED		
	FIELD	ITEMS, MATERIALS, OR PRODUCTS	CHARACTERISTIC,	SPECIFICATION OR	
	2		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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Accreditation is granted to the facility to perform the following testing:

FLEX CODE	FIELD OF TEST	ITEMS, MATERIALS, OR PRODUCTS TESTED	COMPONENT, CHARACTERISTIC, PARAMETER TESTED	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED
F1, F2	Electromagnetic compatibility tests	Multimedia equipment	Immunity tests to continuous RF disturbances; Power frequency magnetic fields; broadband impulsive conducted disturbances; Immunity to burst, surge, ESD and dips	EN 55035:2017/A11:2020 CISPR 35:2016	Electromagnetic fields from 80 up to 3 000 MHz field up to 3 V/m RF currents from 150 kHz to 80 MHz with level up to 3 V
					Magnetic field with level up to 3A/m
			3	1	Burst and fast transient up to 4 KV
					Surge up to 4 KV ESD up to 8 KV
					Immunity to dips and voltage variations from 10 ms to 5s

1. The presence of a superscript F means that the laboratory performs testing of the indicated parameter at its fixed location.

2. Flex Code:

- F1-Introduction of the testing of a new item, material, matrix, or product for an accredited test method
- F2-Introduction of a new version of an accredited standard method (with no modifications)
- F3-Introduction of a new parameter/component/analyte to an accredited test method
- F4- Introduction of a new version or modifications of an accredited non-standard method
- F5-Introduction of a new method that is equivalent to an accredited method (using same technology or technique)