PERRY JOHNSON LABORATORY ACCREDITATION, INC.

Certificate of Accreditation

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

ELETTRA S.r.l.

Via F. Matteucci, 10, 50041 Calenzano (FI), Italy
Via Meucci, 93, 50041 Calenzano (FI), Italy

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

ISO/IEC 17025:2017
& Meets the Requirements of the FDA Accreditation Scheme for Conformity Assessment (ASCA) Program

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):

Acoustic, Electrical, Mechanical, and Thermal 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:*
April 14, 2020	March 23, 2022	June 30, 2024

Accreditation No.:	*Certificate No.:*
106573	L22-294

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

Certificate of Accreditation: Supplement

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Dott. Ing. Lorenzo Spinelli Phone: +39 055-8827323

Accreditation is granted to the facility to perform the following testing:

FIELD OF TEST	ITEMS, MATERIALS OR PRODUCTS TESTED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED	RANGE (WHERE APPROPRIATE) AND DETECTION LIMIT
Electrical Thermal Mechanical Acoustic[F]	Medical electrical equipment – General requirements for basic safety and essential performance Particular requirements for basic safety and essential performance of medical beds	General requirements (par. 4); General requirements for testing ME equipment (par. 5); Classification of ME equipment and ME systems (par. 6); ME equipment identification, marking and documents (par.7); Protection against electrical hazards from ME equipment (par.8) ; Protection against mechanical hazards of me equipment and me systems (par. 9); Radiation (par. 10) Excessive temperatures (par. 11); Accuracy of controls and instruments and protection against hazardous outputs (par. 12) Hazardous situations and fault conditions (par. 13); Programmable electrical medical system (par. 14) Construction of me equipment (par. 15); ME systems (par. 16) Electromagnetic compatibility (par. 17)	IEC 60601–1:2005 / A1:2012/ IEC 60601-1/ A2: 2020 EN 60601–1:2006 / A11:2011 / A1:2013 / AC:2014/A12:2014 IEC 80601–2–60:2012; EN 80601–2–60:2015 IEC 60601–2–52:2009; EN 60601–2–52:2010 A1:2015	Visual examination Power/current absorption up to 63A 35kW Grounding and bonding Up to 12 V, current up to 60 A; 0.01 Ω to 0.5 Ω Leakage current 2µA to 5 000 mA Up to 95% of relative humidity Dielectric strength test: 500 V to 30 kV/50 Hz–50 Hz Clearance, creepage 0.01 mm to 1 m Speed 0.1m/s to 1 m/s Angle: 5° to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: –70 °C to 150 °C Data Recorder: –50 °C to 400 °C Fault condition up to 63A Pull force up to 100 N; Torque 0.35 Nm Up to 1 J Drop up to 1 m

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Electrical[F]	Medical electrical equipment – Particular requirements for the basic safety and essential performance of nerve and muscle stimulators	General requirements (par. 201.4); General requirements for testing ME equipment (par. 201.5); Classification of ME equipment and ME systems (par. 201.6); ME equipment identification, marking and documents (par. 201.7);. 201.12.4); Accuracy of controls and instruments and protection against hazardous outputs (par. 201.12) Accuracy of controls and instruments and protection against hazardous outputs (par. 201.13) HAZARDOUS SITUATIONS and fault conditions ; (par 201.14) PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS); (par. 201.15) Construction of ME EQUIPMENT; (par.) 201.16 ME SYSTEMS; (par)201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS; (par. 202) Electromagnetic compatibility – Requirements and tests	IEC 60601–2–10: 2012/A1:2016 EN 60601–2–10:2015/A1:2016	Voltage up to 1000 V Currents up to 20 mA Frequency up to 10 MHz

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Electrical[F]	Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	201.4 General requirements 201.5 General requirements for testing of ME EQUIPMENT 201.6 Classification 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 for ME EQUIPMENT 201.15 Construction of ME EQUIPMENT 201.16 ME SYSTEMS	IEC 60601–2–2:2019/ EN 60601–2–2:218 EN 60825-1:2014/ IEC 60825-1:2014 /AC:2017/A11:2020	Measurements with 500V from Insulation resistance 1 MΩ up to 199 MΩ Defibrillator discharge test up to 2 kV High frequency leakage current up to 300mA with frequency up to 10 MHz High frequency dielectric test with frequency 400 kHz and voltage up to 7000 V peak Flexing test with angle ± 45° High frequency output power up to 5000 W frequency up to 10 MHz Continuity test with current up to 5A

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Electrical Acoustic[F]	Medical electrical equipment – General requirements for safety – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	4 General requirements 5 ME EQUIPMENT identification marking and documents 6 ALARM SYSTEMS 6.1 ALARM CONDITION 6.2 Disclosures for INTELLIGENT ALARM SYSTEM 6.3 Generation of ALARM SIGNALS 6.4 Disclosure of delays 6.5 ALARM PRESETS 6.6 ALARM LIMIT 6.7 ALARM SYSTEM security 6.8 ALARM SIGNAL inactivation states 6.9 ALARM RESET 6.10 NON–LATCHING and LATCHING ALARM SIGNALS 6.11 DISTRIBUTED ALARM SYSTEM 6.12 ALARM CONDITION logging	IEC 60601–1–8:2003 / A1:2006/A1:2012 A2:2020 EN 60601–1–8:2004 / A1:2006/A1:2013/A1 1:2017 A2:2021	Acoustic noise up to 140 dBA Time interval from 10 ms to 10 s

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Electrical[F]	Medical electrical equipment – Medical electrical equipment Part 2: Particular requirements for basic safety and essential performance of electrocar–diographs Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems	201.4 General requirements 201.5 General requirements for testing of 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	IEC 60601–2–25:2015 EN 60601–2–25:2015 IEC 60601–2–27:2011, EN 60601–2–27:2014 IEC 60601–2–47:2012/A1:2015; EN 60601–2–47:2015	Defibrillator discharge test up to 5 kV Performance verification by means of accuracy tests with voltage range AC from 0 mV to 5 mV and DC from 0 V to 5 V

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Electrical[F]	Medical electrical equipment – Medical electrical equipment Part 2: Particular requirements for basic safety and essential performance of electrocar–diographs Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems	201.4 General requirements 201.5 General requirements for testing of 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	IEC 60601–2–25:2015 EN 60601–2–25:2015 IEC 60601–2–27:2011, EN 60601–2–27:2014 IEC 60601–2–47:2012/A1:2015; EN 60601–2–47:2015	Defibrillator discharge test up to 5 kV Performance verification by means of accuracy tests with voltage range AC from 0 mV to 5 mV and DC from 0 V to 5V

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Electrical Climatic and Mechanical[F]	Medical electrical equipment – General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	4 general requirements 4.1 additional requirements for supply mains 4.2 environmental conditions 5 general requirements for testing 6 classification 7 me equipment identification, marking and documents 8 protection against excessive temperatures and other hazards 8.5 additional requirements for an internal electrical power source 9 accuracy of controls and instruments and protection against hazardous outputs 10 construction of me equipment 10.1 additional requirements for mechanical strength 10.1.1 general requirements for mechanical strength 10.1.2 requirements for mechanical strength for non–transit–operable me equipment 10.1.3 requirements for mechanical strength for transit–operable me equipment 10.2 additional requirements for actuating parts of controls of me equipment 11 protection against strangulation or asphyxiation 12 additional requirements for electromagnetic emissions of me equipment and me systems 13 additional requirements for alarm systems of me equipment and me systems	IEC 60601–1–11:2010 IEC 60601–1–11:2015 IEC 60601-1-11/ A1: 2020 EN 60601–1–11:2010, EN 60601–1–11:2015 A1:2021	Max acceleration 30 g Max sinusoidal force 6670 N peak Max random force 5340 N rms Max Shock 50,8 mm.peak to peak Max Speed 1.78 m/s peak Static load 160 kg Climatic chamber: –50 °C to 70 °C Relative humidity from 10% to 95% IP grade IPX1 and IPX2 Power/current absorption up to 63A 35kW

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Electrical Thermal, Mechanical Acoustic[F]	Safety requirements for electrical equipment for measurement, control and laboratory use Part 1: General requirements Part 2–032: Particular requirements for hand–held and hand–manipulated current sensor for electrical test and measurement Part2–040: Prticular requirements for sterilizers and washer–disinfectors used to treat medical materials Part2–051: Particular requirements for laboratory equipment for mixing and stirring Part2–101: Particular requirements for in vitro diagnostic (IVD) medica equipment Part2–033: Particular requirements for hand–held multimeters and other hand–held meters, for domestic and professional use, capable of measuring mains voltage Part 2–030: Particular requirements for testing and measuring circuits Part 2–081: Particular requirements for automatic and semi–automatic laboratory equipment for analysis and other purposes Part 2–020: Particular requirements for laboratory centrifuges	4.4 Testing in SINGLE FAULT CONDITION 5 Marking and documentation 6 Protection against electric shock 7 Protection against mechanical HAZARDS . 8. Resistance to mechanical stresses 9 Protection against the spread of fire 10 Equipment temperature limits and resistance to heat 11 Protection against HAZARDS from fluids 12 Protection against radiation, including laser sources, and against sonic and 13 Protection against liberated gases and substances, explosion and implosion 14 Components and subassemblies 15 Protection by interlocks 16 HAZARDS resulting from	IEC 61010–1:2010/A1:2016 EN 61010–1:2010/A1:2019 IEC61010-2-032 :2019 EN 61010-2-032:2021/A11:2021 IEC 61010–2–040:2020; EN 61010–2–040:2020 IEC 61010–2–051:2015; IEC 61010–2–051:2018 EN 61010–2–051:2015 IEC 61010–2–101:2002; IEC 61010–2–101:2015 EN 61010–2–101:2002; EN 61010–2–101:2017; IEC 61010–2–101:2018 IEC 61010–2–033:2019; EN 61010–2–033:2021/A11:2021	Visual examination Power/current absorption up to 63A 35kW Grounding and bonding Up to 12 V, current up to 60A; 0.01 Ω to 0.5 Ω Leakage current 2µA to 5000 mA Up to 95% of relative humidity Dielectric strength test with voltage range from 500V to 30 kV and frequency 50 Hz and 60 Hz Clearance, creepage 0.01 mm to 1 m Speed 0,1 to 1m/s Angle: 5° to 10° Force up to 250N Acoustic noise up to 140 dBA Climatic chamber: –70 °C to 150 °C Data Recorder: –50 °C to 400 °C Fault condition up to 63A Pull force up to 100 N; Torque 0.35 Nm Up to 1 J Drop up to 1m Pressure test up to 100 bar

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Electrical Thermal, Mechanical Acoustic[F]	Part2–010: Particular requirements for laboratory equipment for the heating of materials	4.4 Testing in SINGLE FAULT CONDITION 5 Marking and documentation 6 Protection against electric shock 7 Protection against mechanical HAZARDS . 8. Resistance to mechanical stresses 9 Protection against the spread of fire 10 Equipment temperature limits and resistance to heat 11 Protection against HAZARDS from fluids 12 Protection against radiation, including laser sources, and against sonic and 13 Protection against liberated gases and substances, explosion and implosion 14 Components and subassemblies 15 Protection by interlocks 16 HAZARDS resulting from	IEC 61010–2–030:2010; IEC 61010–2–030/Ec1:2011 EN 61010–2–030:2010 IEC 61010–2–030:2017 EN 61010-2-030:2021/A11:2021 IEC 61010–2–81:2015 EN 61010–2–81:2015; IEC 61010–2–081:2019 EN IEC 61010-2-081:2020 IEC 61010–2–020:2006; EN 61010–2–020:2006 IEC 61010–2–020:2016; EN 61010–2–020:2017 IEC 61010–2–010:2014; IEC 61010-2-010:2019 EN IEC 61010-2-010:2020 EN 61010–2–010:2014	Visual examination Power/current absobtion up to 63 A 35 kW Grounding and bonding Up to 12 V, current up to 60A; 0.01 Ω to 0.5 Ω Leakage current 2 µA to 5000 mA Up to 95% of relative humidity Dielectric strength test with voltage range from and frequency 50 Hz and 60 Hz Clearance, creepage 0.01 mm to 1 m Speed 0.1 m/s to 1 m/s Angle: 5° to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: –70 °C to 150 °C Data Recorder: –50 °C to 400 °C Fault condition up to 63 A Pull force up to 100 N; Torque 0.35 Nm Up to 1 J Drop up to 1m Pressure test up to 100 bar

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Electrical Thermal, Mechanical Acoustic[F]	Part2–010: Particular requirements for laboratory equipment for the heating of materials	4.4 Testing in SINGLE FAULT CONDITION 5 Marking and documentation 6 Protection against electric shock 7 Protection against mechanical HAZARDS . 8. Resistance to mechanical stresses 9 Protection against the spread of fire 10 Equipment temperature limits and resistance to heat 11 Protection against HAZARDS from fluids 12 Protection against radiation, including laser sources, and against sonic and 13 Protection against liberated gases and substances, explosion and implosion 14 Components and subassemblies 15 Protection by interlocks 16 HAZARDS resulting from	IEC 61010–2–030:2010; IEC 61010–2–030/Ec1:2011 EN 61010–2–030:2010 IEC 61010–2–030:2017 IEC 61010–2–81:2015 EN 61010–2–81:2015; IEC 61010–2–081:2019 IEC 61010–2–020:2006; EN 61010–2–020:2006 IEC 61010–2–020:2016; EN 61010–2–020:2016 IEC 61010–2–010:2019; EN 61010–2–010:2014	Visual examination Power/current absorption up to 63 A/35 kW Grounding and bonding Up to 12 V, current up to 60 A; 0.01 Ω to 0.5 Ω Leakage current from 2 µA to 5000 mA Up to 95% of relative humidity Dielectric strength test: with voltage range from 500V to 30 kV and frequency 50 Hz and 60 Hz Clearance, creepage 0.01 mm to 1 m Speed 0.1 m/s to 1m/s Angle: 5° to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: –70 °C to 150 °C Data Recorder: –50 °C to 400 °C Fault condition up to 63 A Pull force up to 100 N; Torque 0.35 Nm Up to 1 J Drop up to 1 m Pressure test up to 100 bar

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Electrical, Thermal, Mechanical Acoustic[F]	Audio/Video, information and communication technology equipment Part 1: safety requirements	4. General requirements 5 Electrically-caused injury 6 Electrically-caused fire 7 Injury caused by hazardous substances 8 Mechanically-caused injury 9 Thermal burn injury 10 Radiation	IEC 62368-1:2014/COR1:2015 EN 62368-1:2014/EC:2015 EN 62368-1/A11:2017-01; EN 62368-1/AC:2017-03. IEC 62368-1: 2018-10/COR1:2020-04 EN 62368-1: 2020-03/A11: 2020-03/ AC: 2020-05	Visual examination Power/current absorption up to 63A 35kW Grounding and bonding Up to 12 V, current up to 60A; 0.01 Ω to 0.5 Ω Leakage current 2µA to 5000mA Up to 95% of relative humidity Dielectric strength test with voltage range from 500V to 30 kV and frequency 50 Hz and 60 Hz Clearance, creepage 0.01 mm to 1 m Speed 0.1 m/s to 1m/s Angle: 5 °to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: –70 °C to 150 °C Data Recorder: –50 °C to 400 °C Fault condition up to 63 A Pull force up to 100 N; Torque 0.35 Nm Up to 1 J Drop up to 1 m

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Verification tests of the degree of protection of enclosures[F]	Equipment enclosures and electrical components	Grado IP/IP Grade 1X, 2X, 3X, 4X, 5X, 6X, X1, X2, X3, X4;X5; X6; X7	IEC 60529:1989/ A1:1999/A2:2013 EN 60529:1991/A1:2000/ A2:2013	Water flow from 1mm/min to 100l/min Probes diameter: 50 mm to 1 mm Depression of enclosures 20mbar
Mechanical testing of vibrations and shocks[F]	Electrical and electronic equipment and components	Prove di vibrazione sinusoidali Sinusoidal vibration tests Prove di vibrazioni random Random vibration tests Prove di urto Impact tests	IEC 60068–1:2013 EN 60068–1: 2014 IEC 60068–2–27:2008/ EN 60068–2–27:2009 IEC 60068–2–64:2007/ A1:2019 EN 60068–2–64: 2008 IEC 60068–2–6: 2007/ EN 60068–2–6:2008 IEC 60068–2–47:2004 EN 60068–2–47:2005 EN 50155:2007 AC:2012 IEC 61373 2010 EN 61373:1999 EN 61373:2010 EN 50125–3 IS 402:2000 ASTM 4169	Max acceleration 30g Max sinusoidal force 6670 N peak Max random force 5340 N rms Max Shock 50,8 mm.peak-peak Max Speed 1.78 m/s peak Static load 160 Kg

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Electromagnetic Compatibility[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, EN 61547:1995 / A1:2000, EN 61547:2009	Electromagnetic fields 3 V/m in the frequency range from 80 MHz to 2700 MHz Magnetic field at 50/60 Hz with level 3 A/m RF currents from 150 kHz to 80 MHz with level 3V
	Household appliances, electric tools and similar apparatus	Immunity tests to Radiated em fields, conducted rf currents, burst, surge, ESD and dips Conducted emission tests	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 55014-2:2021	Electromagnetic fields 3 V/m in the frequency range from 80 MHz to 1000 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 30 KV Conducted emissions in the frequency range 150 kHz to 30 MHz Immunity to dips and voltage variations from 10 ms to 5 s

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Electromagnetic Compatibility[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	IEC 61326–1:2012, IEC 61326–1:2020, EN 61326–1:2013, EN 61326–1:2021	Electromagnetic fields 10 V/m in the frequency range from 80 MHz to 2700 MHz RF currents from 150 kHz to 80 MHz with level up to 10 V Magnetic field at 50/60 Hz with level up to 30A/m Burst and fast transient up to 4 KV Surge up to 4 KV ESD up to 30 KV Conducted emissions in the frequency range 150 kHz to 30 MHz Immunity to dips and voltage variations from 10ms to 5s Radiated emission tests from 30 MHz to 6 GHz

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Electromagnetic Compatibility[F]	Medical electrical equipment	Identification, marking and documents (par. 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 and radiated emission tests (par. 6, 7, 8, 9)	IEC 60601–1–2:2001 / A1:2004 IEC 60601–1–2:2007, IEC 60601–1–2:2014 IEC 60601-1-2/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 28V/m in the frequency range from 80 MHz to 6000 MHz RF currents from 150 kHz to 80 MHz with level up to 10 V Magnetic field at frequency 50 Hz and 60 Hz with level up to 30 A/m Burst and fast transient up to 4 KV Surge up to 4 KV ESD up to 30 KV Conducted emissions in the frequency range 150 kHz to 30 MHz Immunity to dips and voltage variations from 10ms to 5s Radiated emission tests from 30 MHz to 6 GHz
Electromagnetic Compatibility Tests[FO]	Electrosensitive protective equipment	immunity tests to electromagnetic Radiated fields, injected rf currents, magnetic fields at mains frequency, burst, surge, ESD and dips	IEC 61496–1:2004 / A1:2007, IEC 61496–1:2012, IEC 61495-1:2020 EN 61496–1:2004 / A1:2008, EN 61496–1:2013/AC:2015 EN 61496-1:2020	RF currents from 150 kHz to 80 MHz with level up to 20V Magnetic field at frequency 50 Hz and 60 Hz with level up to 100A/m Burst and fast transient up to 4 KV Surge up to 4 KV Esd up to 30 KV Conducted emissions in the frequency range 150 kHz to 30 MHz Immunity to dips and voltage variations from 10 ms to 5 s

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Electromagnetic Compatibility Tests[FO]	Railway applications – Electromagnetic compatibility Part 4: Emission and immunity of the signalling and telecommunications apparatus	Immunity to electromagnetic fields (2.1, 2.2) Immunity to magnetic fields at line frequency (2.3); Immunity to radiofrequency common mode currents (3.1; 4.1; 5.1; 6.1) Immunity to burst, surge, ESD and dips Conducted emission test	EN 50121–4:2006, EN 50121–4:2015; EN 50121–4:2016 A1:2019	Electromagnetic fields up to 20 V/m in the frequency range from 80 MHz to 6000MHz RF currents from 150 kHz to 80 MHz with level up to 10 V Magnetic field at frequencies 0 Hz, 15.7 Hz and 50 Hz with level up to 300 A/m Burst and fast transient up to 4 KV Surge up to 4 KV Esd up to 30 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 tests from 30 MHz to 6 GHz

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Electromagnetic Compatibility Tests[F]	Appliances for railway applications – Fixed power supply installations and apparatus	Immunity tests to electromagneti fields Immunity to magnetic fields at line frequency; Immunity to radiofrequency common mode currents Immunity to burst, surge, ESD and dips Conducted emission test	EN 50121–5:2006, EN 50121–5:2015, EN 50121–5:2017/ A1:2019	Electromagnetic fields up to 20 V/m in the frequency range from 80 MHz to 6000MHz RF currents from 150 kHz to 80 MHz with level up to 10 V Magnetic field at frequencies 0, 15,7Hz and 50 Hz with level up to 300A/m Burst and fast transient up to 4 KV Surge up to 4 KV ESD up to 30 KV Conducted emissions in the frequency range 150 kHz to30 MHz Immunity to dips and voltage variations from 10 ms to 5 s Radiated emission tests from 30 MHz to 6 GHz

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Electromagnetic Compatibility Tests[F]	Railway applications – Electromagnetic compatibility Part 3–2: Rolling stock – Apparatus	Immunity tests to electromagnetic fields Immunity to magnetic fields at line frequency; Immunity to radiofrequency common mode currents Immunity to burst, surge, ESD and dips Conducted emission test	EN 50121–3–2:2006; EN 50121–3–2:2015; EN 50121–3–2:2016/ A1:2019	Electromagnetic fields up to 20 V/m in the frequency range from 80 MHz to 6 000MHz RF currents from 150 kHz to 80 MHz with level up to 10 V Burst and fast transient up to 4 KV Surge up to 4 KV ESD up to 30 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 tests from 30 MHz to 6 GH
Electromagnetic Compatibility Tests[FO]	Electric and electronic equipment for industrial environments	Immunity to electromagneti fields Immunity to magnetic fields at line frequency; Immunity to radiofrequency common mode currents Immunity to burst, surge, ESD and dips Conducted emission test	IEC 61000–6–2:2005 IEC 61000-6-2:2016 EN 61000–6–2:2007 /EC:2005 EN61000-6-2:2019	Electromagnetic fields up to 10 V/m in the frequency range from 80 MHz to 6 000 MHz RF currents from 150 kHz to 80 MHz with level up to 10 V Magnetic field at frequencies 50 Hz and 60 Hz with level up to 10 A/m Burst and fast transient up to 4 KV Surge up to 4 KV ESD up to 8 KV Conducted emissions in the frequency range 150 kHz to 30 MHz Immunity to dips and voltage variations from 10 ms to 5s

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Electromagnetic Compatibility Tests[F]	Electric and electronic equipment for residential, commercial and light–industrial environments	Immunity to electromagneti fields Immunity to magnetic fields at line frequency; Immunity to radiofrequency common mode currents Immunity to burst, surge, ESD and dips Conducted emission test	IEC 61000–6–1:2005, IEC 61000-6-1:2019 EN 61000–6–1:2007	Electromagnetic fields up to 3 V/m in the frequency range from 80 MHz to 6000 MHz RF currents in the frequency range from 150 kHz to 80 MHz with level up to 3 V Magnetic field at 50/60 Hz with level up to 3 A/m Burst and fast transient up to 4 KV Surge up to 4 KV ESD up to 8 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 tests from 30 MHz to 6GHz
	Apparecchiature multimediali/Multimedia equipment	Immunity tests to continuous rf disturbances; Power frequency magnetic fields; broadband impulsive conducted disturbances; Immunity to burst, surge, ESD and dips	CISPR35:2016; EN 55035:2017/A11:2020 ETSI 301 489-1 v.2.2.3	Electromagnetic fields up to 3 V/m in the frequency range from 80 MHz to 6 000 MHz RF currents in the frequency range from 150 kHz to 80 MHz with level up to 3 V Magnetic field with level up to 3 A/m at frequencies 50 Hz and 60 Hz 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 5 s Radiated emission tests from 30 MHz to 6 GHz

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Electromagnetic Compatibility Tests[FO]	Adjustable speed electrical power drive system	Immunity tests to continuous rf disturbances; Power frequency magnetic fields ; broadband impulsive conducted disturbances Immunity to burst, surge, ESD and dips Conducted emission test	IEC 61800–3:2004+A1:2011; IEC 61800–3:2017 EN 61800–3:2004+A1:2012 EN61800-3:2018	Electromagnetic fields up to 10 V/m in the frequency range from 80 MHz to 1000 MHz RF currents from 150 kHz to 80 MHz with level up to 10 V Magnetic field with level up to 30A/m at frequencies 50 Hz and 60 Hz 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 10ms to 5s Conducted emissions in the frequency range 150 kHz to 30 MHz Radiated emission tests from 30 MHz to 6 GHz

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Electromagnetic Compatibility Tests[F]	Programmable controllers	Immunity tests to electromagnetic fields, rf injected currents, magnetic fields Immunity to burst, surge, ESD and dips Conducted emission test	IEC 61131–2:2007, EN 61131–2:2007 IEC 61131–2:2017	Electromagnetic fields up to 10 V/m in the frequency range from 80 MHz to 2700 MHz RF currents from 150 kHz to 80 MHz with level up to 10 V 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 5 s Conducted emissions in the frequency range 150 kHz to 30 MHz Radiated emission tests from 30 MHz to 6 GHz
	Road traffic signal systems	Immunity tests to electromagnetic fields, rf injected currents, magnetic fields Immunity to burst, surge, ESD and dips	EN 50293:2000, EN 50293:2012	Electromagnetic fields up to 10 V/m in the frequency range from 80 MHz to 2700 MHz RF currents from 150 kHz to 80 MHz with level up to 10 V Magnetic field with level up to 30A/m at frequencies 50 Hz and 60 Hz Burst and fast transient up to 4 KV Surge up to 4 KV ESD up to 8KV Immunity to dips and voltage variations from 10ms to 5s Radiated emission tests from 30 MHz to 6 GHz

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Electromagnetic Compatibility Tests[F]	Alarm systems, components of fire, intruder and social alarm systems	Immunity tests to electromagnetic fields, rf injected currents Immunity to burst, surge, ESD and dips	EN 50130–4:1995 / A1:1998 / A2:2003, EN 50130–4:2011 / A1:2014	Electromagnetic fields up to 10 V/m in the frequency range from 80 MHz to 2700 MHz RF currents from 150 kHz to 80 MHz with level up to 10 V Burst and fast transient up to 4 KV Surge up to 4 KV ESD up to 8KV Immunity to dips and voltage variations from 10ms to 5s Radiated emission tests from 30 MHz to 6 GHz
	Uninterruptible power systems (UPS) Part 2: Electromagnetic compatibility (EMC) requirements	Immunity tests to electromagnetic fields, rf injected currents, magnetic fields	IEC 62040–2:2005; EN 62040–2:2006 IEC 62040-2:2016 EN IEC 62040-2:2018	Electromagnetic fields up to 10 V/m in the frequency range from 80 MHz to 2700 MHz RF currents from 150 kHz to 80 MHz with level up to 10 V Magnetic field with level up to 30A/m at frequencies 50 Hz and 60 Hz Burst and fast transient up to 4 KV Surge up to 4 KV ESD up to 8KV Immunity to dips and voltage variations from 10ms to 5s Conducted emission tests in the frequency range 150-30MHz Radiated emission tests from 30 MHz to 6 GHz

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Electromagnetic Compatibility Tests[F]	Electromedical equipment, industrial equipment, information technology, lighting equipment, household appliances	Immunity to the electromagnetic field Radiated with radiofrence	EN 61000–4–3:2006/A1:2009/A2:2010 IEC 61000–4–3:2006/A1:2007/A2:2010	Electromagnetic fields 80MHz to 6GHz 20Vm max
		Immunity to rf current	EN 61000–4–6:2014/AC:2015 IEC 61000–4–6:2013/A1:2017	Rf currents from 150 kHz–80 MHz Voltage level up to 30 V
		Immunity to ESD	EN 61000–4–2: 2009/ IEC 61000–4–2:2008	Electrostatic discharge test in air and contact from ±1 kV to ±15 kV
		Immunity to Burts/fast transient	IEC 61000-4-4:1995 / A1:2000 / A2:2001, IEC 61000-4-4:2004 / A1:2010, IEC 61000-4-4:2012, EN 61000-4-4:1995 / A1:2001 / A2:2001, EN 61000-4-4:2004 / A1:2010, EN 61000-4-4:2012	Immunity to burst/fast transients up to 4 KV, 100 KHz
		Immunity to Surge	IEC 61000-4-5:2014/A1:2017, EN 61000-4 5:2014/A1:2017	Immunity to surge up to 4 KV
		Immunity to dips and voltage variations	IEC 61000-4-11:2004 / A1:2017 IEC 61000-4-11:2020 EN 61000-4-11:2004 / A1:2007 EN IEC 61000-4-11:2020/AC:2020	Immunity to dips and voltage variation
		Harmonic current emissions	EN 61000–3–2:2019/A1:2021 IEC 61000–3–2:2018	Max current 16 A

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Electromagnetic Compatibility Tests[FO]	Electromedical equipment, industrial equipment, information technology, lighting equipment, household appliances	Flicker measurment (parameters pst, plt, dt, dc, dmax)	EN 61000–3–3:2013/A1:2019 IEC 61000–3–3:2013/A1:2017/A2:2021	Max current 16 A
	Electromedical equipment, industrial equipment, information technology, lighting equipment, household appliances	Immunity to magnetic fields	EN 61000–4–8:2010 IEC 61000–4–8:2009	100A/m
Measurement of conducted electromagnetic disturbance[FO] and measurement of radiated electromagnetic distrubance[F]	Luminaries and associated products Household appliances, electric tools and similar apparatus Electronic appliances Industrial, scientific and medical appliances	Conducted emission tests Radiate emission tests	CISPR 15:2013/A1:2015; CISPR 15:2018 EN 55015:2013/A1:2015 EN IEC 55015:2019/A11:2020 CISPR 14-1:2016; CISPR 14-1:2020 EN 55014:2016 EN55014-1:2017 EN55014-1:2021 CISPR 32:2015; EN 55032:2015/AC:2016/A1:2020 ETSI 301 489-1 v.2.2.3 CISPR 11:2015/A1:2016 EN 55011:2016	Voltage disturbances in the frequency range 9 kHz to 30 MHz Radiated emission tests from 30 MHz to 6 GHz
	Electric and electronic equipment for residential, commercial and light–industrial environments	Conducted emission tests Harmonics Flicker Emission tests	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 Radiated emission tests from 30 MHz to 6 GHz

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Measurement of conducted electromagnetic disturbance[FO] and measurement of radiated electromagnetic distrubance[F]	Electric and electronic equipment for industrial environments	Conducted emission tests Harmonics Flicker Radiated emission tests	IEC 61000–6–4:2006/A1:2010, IEC 61000-6-4:2018 EN 61000–6–4:2007/A1:2011; EN 61000-6-4 2019	Conducted emissions in the frequency range 150 kHz to 30 MHz Harmonics on power line Flicker on power line Radiated emission tests from 30 MHz to 6 GHz
Electrical, Mechanical and Laser Radiation Measurement[F]	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 tests 201.6 Classification 201.7 Identification, nameplate data and documentation 201.8 Protection against electrical HAZARDS 201.9 Protection against MECHANICAL HAZARDS 201.10 Protection against undesirable and excessive radiation HAZARDS 201.11 Protection against excessive temperatures and other DANGERS 201.12 Accuracy of controls and instruments and protection against hazardous emissions dangerous emissions 201.13 DANGER SITUATIONS and failure conditions 201.14 PROGRAMMABLE ELECTROMEDICAL SYSTEMS (PEMS) 201.15 Construction 201.16 EM SYSTEMS 201.17 Electromagnetic compatibility	IEC/60601-2-22:2007/A1:2012 IEC 60601-2-22:2019/ A1:2012 EN 60601-2-22:2013 EN60601-2-22:2020	Force up to 200 N Laser power measurements up to 30 W

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Effective use of Radio Spectrum[F]	Radio equipment : Short Range Devices Wideband transmission Systems	Radio tests : Conducted power: Spectrum analyzer method Power meter method Radiated power: Anechoic chamber + Spectrum analyzer method	ETSI 300 328 V.2.1.1 V.2.2.1 ETSI 300 220 V.3.1.1	Frequency range: 9 kHz to 30 GHz
Electrical Safety Tests[FO]	Control panels and machine electrical equipments	Dielectric strength test Insulation Residual voltage Temperature Grounding and bonding	IEC 61439-1:2011/EN 61439-1:2011/AC:2013 IEC 61439-1:2020 IEC 61439-2/2011; EN 61439-2:2011 IEC 60204-1:2016/EN 60204-1:2019	Dielectric strength up to 30 KV Grounding and bonding up to 60A Insulation resistance up to 1000 V Residual voltage on supply and internal capacitive circuits Temperature test up to 300 °C
	UPS; Power electronic converter	Dielectric strength test Insulation Residual voltage Temperature Grounding and bonding Leakage test	IEC 62040-1 :2017 EN 62040-1 :2019/AC :2019 EN 62477-1 : 2012/ A11 : 2014/ A1 :2017/A12:2021	Dielectric strength up to 6 kV Grounding and bonding up to 60 A Insulation resistance up to 1000 V Residual voltage on supply and internal capacitive circuits Temperature test up to 300 °C Leakage current from 0.1 mA to 1000 mA

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Electrical; Optical [F]	Medical electrical equipment of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use Luminaries	201.4 General requirements 201.5 General requirements for testing 201.6 Classification of me equipment and ME SYSTEMS 201.7 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	EN 60601-2-57: 2014 IEC 60601-2-57: 2011 EN 62471:2008 IEC 62471:2006	Radiance and irradiance tests form 200 to 1000 nm resolution 1 nm Luminance 0.2 cd/m² to 100 000 cd/m² Illuminance 1 lx to 1 500 000 lx Pedal activation force: 2 Nm to 200 Nm Uniformity radiation with resolution 2 mm Pulse length measurement form 1ms to 1s Irradiance measurements under fault conditions up to 300 W

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Electrical[F]	Medical electrical equipment - microwave therapy equipment	201.4 General requirements 201.5 General requirements for testing 201.6 Classification of me equipment and ME SYSTEMS 201.7 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	EN 60601-2-6: 2015/A1:2016 IEC 60601-2-6: 2012/A1:2016	RF power up to 300 W Radiated field from 0.8 V/m to 800 V/m and Radiated power density from 0.3 mW/m^2 up to 300 000 W/m^2 Acoustic noise up to 140 dBA Time interval from 10 ms to 30 min

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Electrical Thermal[F]	Screening thermographs for human febrile temperature screening	201.4 General requirements 201.5 General requirements for testing of 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	EN 80601-2-59: 2009 IEC 80601-2-59:2008/Ec:2009	Temperature accuracy, drift, uniformity and stability from 20 °C to 45 °C with accuracy 0.2 °C

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FIELD OF TEST	ITEMS, MATERIALS OR PRODUCTS TESTED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED	RANGE (WHERE APPROPRIATE) AND DETECTION LIMIT
Electrical; Thermal[F]	Screening thermographs for human febrile temperature screening	compatibility of ME EQUIPMENT and ME SYSTEMS 201.101 Laboratory accuracy of a screening thermograph 201.102 Screening thermograph alarm conditions	EN 80601-2-59: 2009 IEC 80601-2-59:2008/Ec:2009	Temperature accuracy, drift, uniformity and stability from 20 °C to 45 °C with accuracy 0.2 °C
Documental Analysis[F]	Medical electrical equipment Usability	General requirements (par. 4); Replacement of requirements given in IEC 62366 (par. 5)	IEC 60601-1-6:2010/A1:2013/A2:2020, EN 60601-1-6:2010/A1:2015 A2:2021*	Usability validation document analysis

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Electrical Mechainical[F]	Particular requirements for basic safety and essential performance of :critical care ventilators ventilatory support equipment for ventilatory impairment ventilatory support equipment for ventilatory insufficiency Home healthcare environment ventilators for ventilator-dependent patients Particular requirements for basic safety and essential performance of an anaesthetic workstation	201. 4 General requirements 201. 5 General requirements for testing of 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 for ME equipment 201. 14 Programmable electrical medical systems (PEMS) 201. 15 Construction of ME equipment 201. 16 ME systems 201. 17 Electromagnetic	EN 80601-2-12:2020 ISO 80601-2-12:2020 EN 80601-2-79:2019 ISO 80601-2-79:2018 EN 80601-2-80:2019 ISO 80601-2-80:2018 EN 80601-2-72:2015 ISO 80601-2-72:2015 EN 80601-2-13:2012 ISO 80601-2-13:2011	Max acceleration 30 g Max sinusoidal force 6 670 N peak Max random force 5 340 N rms Mx Shock 50,8 mm.peak to peak Max Speed 1.8 m/s peak Static load 160 Kg IP grade IPX1 and IPX2 ventilation pressure 0 kPa to 10 kPa ± 1 % or 0.02 kPa FlowSense high flow sensor ± 300 L/min ± 2 % or 0.1 L/min FlowSense low flow sensor ± 12 L/min ± 2 % or 0.01 L/min differential pressure ± 2 kPa ± 0.5 % or ± 0.002 kPa differential pressure ± 20 kPa ± 0.5 % or ± 0.02 kPa differential pressure ± 100 kPa ± 0.5 % or ± 0.1 kPa Breath Rate (frequency) 1 BrPM to 100 BrPM ± 0.1 BrPM 101 BrPM to 200 BrPM ± 0.2 BrPM high pressure 0 MPa to 1 MPa (0 - 10 bar) ± 1.5 % or ± 1 kPa O2-concentration: 0 % to 100 % ± 1 Vol % Multi-Gas Sensor: CO2 0 – Vol % to 10 Vol % ± 0.2 Vol% + 2% of reading

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Electrical Mechainical[F]	Particular requirements for basic safety and essential performance of :critical care ventilators ventilatory support equipment for ventilatory impairment ventilatory support equipment for ventilatory insufficiency Home healthcare environment ventilators for ventilator-dependent patients Particular requirements for basic safety and essential performance of an anaesthetic workstation	compatibility of ME equipment and ME systems 201. 101 Gas connections 201. 102 Requirements for the VBS and accessories 201. 103 Spontaneous breathing during loss of power supply 201. 104 Indication of duration of operation 201. 105 Functional connection 201. 106 Display loops 201. 107 Timed ventilatory pause 202 Electromagnetic disturbances — Requirements and tests 206 Usability 208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	EN 80601-2-12:2020 ISO 80601-2-12:2020 EN 80601-2-79:2019 ISO 80601-2-79:2018 EN 80601-2-80:2019 ISO 80601-2-80:20188 EN 80601-2-72:2015 ISO 80601-2-72:2015 EN 80601-2-13:2012 ISO 80601-2-13:2011	Max acceleration 30 g Max sinusoidal force 6 670 N peak Max random force 5 340 N rms Max Shock 50,8 mm.peak to peak Max Speed 1.8 m/s peak Static load 160 Kg IP grade IPX1 and IPX2 Ventilation pressure 0 kPa to 10 kPa ± 1 % or 0.02 kPa FlowSense high flow sensor ± 300 L/min ± 2 % or 0.1 L/min FlowSense Low flow sensor ± 12 L/min ± 2 % or 0.01 L/min Differential ± 20 mbar ± 2 kPa ± 0.5 % or ± 0.002 kPa Differential pressure ± 200 mbar ± 20 kPa ± 0.5 % or ± 0.02 kPa Differential pressure ± 1 bar ± 100 kPa ± 0.5 % or ± 0.1 kPa Breath Rate (frequency) 1 BrPM to 100 BrPM ± 0.1 BrPM 101 BrPM to 200 BrPM ± 0.2 BrPM High pressure 0 Mpa to 1 Mpa (0 bar to 10 bar) ± 1.5 % or ± 1 kPa O2-concentration: 0 % to 100 % ± 1 Vol % Multi-Gas Sensor: CO2 0 Vol % to 10 Vol % ± 0.2 Vol% + 2% of reading

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Electrical Mechanical[F]	Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment	201.4 General requirements 201.5 General requirements for tests on EM equipment 201.6 Classification of EM EQUIPMENT and EM SYSTEM 201.7 Identification, nameplate data and documentation of EM equipment 201.8 Protection against electrical hazards due to EM EQUIPMENT 201.9 Protection against MECHANICAL HAZARDS of EM EQUIPMENT and EM SYSTEMS 201.10 Protection against DANGERS from unintended and excessive radiation 201.11 Protection against excessive temperatures and other HAZARDS 201.12 Protection against DANGEROUS emissions 201.13 DANGER SITUATIONS and fault conditions 201.14 PROGRAMMABLE ELECTROMEDICAL SYSTEMS (SEMP) 201.15 CONSTRUCTION OF EM EQUIPMENT 201.16 EM SYSTEM 201.17 Electromagnetic compatibility of EM EQUIPMENT and the	EN 60601-2-16:2019 IEC 60601-2-16:2018	Temperature measurements in the range 37 °C ± 5 °C Medium liquid flux measurements with gravity method (from 0.1 ml/min to 500 ml/min) Liquid pressure from 10 mmHg to 400 mmHg Treatment time from 1s to 30 min IP grade test for IPX1

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Electrical Mechanical[F]	Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment	EM SYSTEM 202 Electromagnetic compatibility - Requirements and tests 208 General requirements, tests and guidelines for alarm systems used in electromedical equipment and systems 210 Process requirements for the development of PHYSIOLOGICAL CLOSED RING CONTROLS CLOSED RING PHYSICAL CONTROLLERS 211 Prescriptions for ELECTROMEDICAL EQUIPMENT and ELECTROMEDICAL SYSTEMS ELECTROMEDICAL EQUIPMENT AND SYSTEMS FOR HOME USE	EN 60601-2-16:2019 IEC 60601-2-16:2018	Temperature measurements in the range 37 °C ±5 °C Medium liquid flux measurements with gravity method (from 0.1 ml/min to 500 ml/min) Liquid pressure from 10 mmHg to 400 mmHg Treatment time from 1 s to 30 min IP grade test for IPX1

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Electrical Mechanical[F]	Particular requirements for basic safety and essential performance of ultrasonic physiotherapy equipment	201.4 General requirements 201.5 General requirements for testing of 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 5 201.10 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 9 201.13 HAZARDOUS SITUATIONS and fault conditions 201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) 1 201.15 Construction of	EN 60601-2-5:2015 IEC 60601-2-5:2009	Ultrasound power 0 W to 30 W frequency 0.5 MHz up to 10 MHz Ultrasound intensity up to 5 W/cm^2 in the range 0.5 MHz up to 10 MHz Radiating surface from 0.7 cm^2 to 80 cm^2 Homogeneity of the radiation field from 1 to 10 Stability of ultrasound radiating emission in time and with voltage supply variation Pull force up to 100 N; Torque 0.35 Nm Up to 1 J Drop up to 1 m

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Electrical Mechanical[F]	Particular requirements for basic safety and essential performance of ultrasonic physiotherapy equipment	ME EQUIPMENT 201.16 ME SYSTEMS 201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS 202 Electromagnetic compatibility – Requirements and tests	EN 60601-2-5:2015 IEC 60601-2-5:2009	Ultrasound power 0-30W frequency 0.5 MHz to 10 MHz Ultrasound intensity up to 5W/cm^2 in the range 0.5 MHz to10 MHz Radiating surface from 0.7 cm^2 to 80 cm^2 Homogeneity of the radiation field from 1 to 10 Stability of ultrasound radiating emission in time and with voltage supply variation Pull force up to 100 N; Torque 0.35 Nm Up to 1 J Drop up to 1 m
Climatic[F]	Electrical, electronic, electromechanical appliances	Cold Test Dry Heat Test Damp heat Test Temperature variation test Low temperature storage test	IEC 60068-2-1:2007; EN 60068-2-1:2007 IEC 60068-2-2:2007; EN 60068-2-2:2007 IEC 60068-2-30:2005; EN 60068-2-30:2005 IEC 60068-2-14:2009; EN 60068-2-14:2009 FS IS 402:2000 EN 50155:2007 /AC:2012 EN 50155:2017	Temperature range: -70°C to 180°C Relative humidity range 5 % to 95 %

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Electrical[F]	Electrical, electronic, electromechanical appliances	AC dielectric strength test DC insulation test Impulse High voltage test	FS IS 402:2000 EN 50155:2007 /AC:2012 EN 50155:2017 IEC 61851-1:2010, EN 61851-1:2011; IEC 61851-1:2017; EN IEC 61851-1:2019 IEC 60060-1:2010; EN 60060-1:2010	AC dielectric strength test up to 30 kV DC dielectric strength test up to 6.5 kV HV impulse test up to 20kV
	Electrical, electronic, electromechanical appliances	Power supply test: Voltage variation test Frequency variation test; Overvoltage test Dips and short interruption test Third harmonic test	FS IS 402:2000 EN 50155:2007 /AC:2012 EN 50155:2017	AC voltage up to 300 V DC Voltage up to 425 V Frequency up to 5000 Hz Dips form 10 ms to 5 s
Mechanical[F]	Electrical, electronic, electromechanical appliances	Free fall test	EN 60068-2-31:2008 IEC 60068-2-31:2008	Drop height: 300 mm to 1500 mm Max load 85 kg

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Electrical [F]	Household and similar electrical appliances	Classification	IEC 60335-1:2010/COR1:2010/ COR2:2011 / A1:2013 / COR1:2014/A2:2016/COR1:2016/A12:2017/A13:2017; IEC60335-1:2020 EN 60335-1:2012/EC:2014/A11:2014/A1:2019/A2:2019/A15/2021 IEC 60335-2-32:2019; EN 60335-2-32:2003/A1:2008/A2:2015 IEC 60335-2-65:2002/A1:2008; EN 60335:2002/A1:2008 IEC 60335-2-102:2004 / A1:2008 / A2:2012, EN 60335-2-102:2006 / A1:2010, ABNT NBR NM 60335-2-102:2013; EN60335-2-102:2016	Visual Evaluation
		Marking and instructions		
		Construction Internal Cables		
		Components		
		Terminals for external Cables		Visual Evaluation and torque up to 2.5 Nm
		Protection against access to live parts		Force up to 20 N
		Starting of Motor Appliances		Power/current absorption up to 63A 35kW
		Protection against overload of transformers and associated circuits		Overload up to 35kW
		Power and current absorbed		Power/current absorption up to 63A 35kW
		Heating		Climatic chamber: -10 °C to 60 °C Data Recorder: -10 °C to 300 °C
		Abnormal operation		Data Recorder: –50 °C to 400 °C Power/current up to 63A 35kW
		Leakage current and dielectric strength at operating temperature		Up to 1 mA/kW; Up to 5 000 Vac
		Leakage current and Dielectric strength		Dielectric strength test with voltage range from 500V to 30 kV and frequency 50 Hz and 60 Hz Leakage current 2µ to 5 000mA
		Resistance to humidity		Up to 95 % RH
		Stability and Mechanical Hazards		Up to 20°
		Mechanical Resistance		Up to 1 J
		Connection to the mains and external flexible cables		Flexing test up to 10 N; 20 000 flexing; 360° Pull force up to 100 N; Torque 0.35 Nm
		Grounding Provisions		Up to 12 V; 0.01 Ω to 0.5 Ω
		Screws and Connections		Up to 2.5 Nm
		Surface distances, in the air and distances through a solid insulation		0.01 mm to 1 m
		Resistance to Heat and Fire		Glow wire Up to 960 °C Flammability test according to IEC 60695-11-10
		Toxicity Radiation and Similar Hazards		EMF: Up to 100 %
		Protection against rust		100 °C ± 5 °C; 10 min

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Electrical [F]	Household and similar electrical appliances	Classification	IEC 60335-2-54:2008/A1:2015 /A2:2019, EN 60335-2-54:2008 / A11:2012/A1:2015 IEC 60335-2-24:2020; IEC 60335-2-24:2010 / A1:2012/A2:2017/A2:2017, EN 60335-2-24:2010/A1:2019/A2:2019/A11:2020 IEC 60335-2-30:2009/EC:2014/A1:2016/A2:2021EN 60335-2-30:2009/EC:2014 / A11:2012/A1:2020/A2:2020/A12:2020 IEC 60335-2-89:2010 / A1:2012/A2:2015/IEC 60335-2-89:2019; EN 60335-2-89:2002 / A1:2005 / A11:2004 / A2:2007 + EC:2010, EN 60335-2-89:2010/A1:2016/A2:2017	Visual Evaluation
		Marking and instructions		
		Construction Internal Cables		
		Components		
		Terminals for external Cables		Visual Evaluation and torque up to 2.5 Nm
		Protection against access to live parts		Force up to 20 N
		Starting of Motor Appliances		Power/current absorption up to 63A 35kW
		Protection against overload of transformers and associated circuits		Overload up to 35kW
		Power and current absorbed		Power/current absorption up to 63A 35kW
		Heating		Climatic chamber: -10 °C to 60 °C Data Recorder: -10 °C to 300 °C
		Abnormal operation		Data Recorder: –50 °C to 400 °C Power/current up to 63A 35kW
		Leakage current and dielectric strength at operating temperature		Up to 1 mA/kW; Up to 5 000 Vac
		Leakage current and Dielectric strength		Dielectric strength test with voltage range from 500V to 30 kV and frequency 50 Hz and 60 Hz Leakage current 2µ÷5 000mA
		Resistance to humidity		Up to 95 % RH
		Stability and Mechanical Hazards		Up to 20°
		Mechanical Resistance		Up to 1 J
		Connection to the mains and external flexible cables		Flexing test up to 10 N; 20 000 flexing; 360° Pull force up to 100 N; Torque 0.35 Nm
		Grounding Provisions		Up to 12 V; 0.01 Ω to 0.5 Ω
		Screws and Connections		Up to 2.5 Nm
		Surface distances, in the air and distances through a solid insulation		0.01 mm to 1 m
		Resistance to Heat and Fire		Glow wire Up to 960 °C Flammability test according to IEC 60695-11-10
		Toxicity Radiation and Similar Hazards		EMF: Up to 100 %
		Protection against rust		100 °C ± 5 °C; 10 min

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Electrical [F]	Household and similar electrical appliances	Classification	IEC 60335-2-101:2002 / A1:2008 / A2:2014; EN 60335-2-101:2002 / A1:2008 / A2:2014 IEC 60335-2-6:2014/A1:2018; EN 60335-2-6:2015/A11:2020/A1:2020 IEC 60335-2-36:2002 / A1:2004 / A2:2008; IEC 60335-2-36:2017; EN 60335-2-36:2002 / A1:2004 / A2:2008 / A11:2012 IEC 60335-2-75:2002 / A1:2004 / A2:2008, IEC 60335-2-75:2012/A1:2015/A2:2018; EN 60335-2-75:2004/A1:2005/A11:2006/A2:2008/A12:2010 IEC 60335-2-43:2017; EN 60335-2-43:2020/A11:2020	Visual Evaluation
		Marking and instructions		
		Construction Internal Cables		
		Components		
		Terminals for external Cables		Visual Evaluation and torque up to 2.5 Nm
		Protection against access to live parts		Force up to 20 N
		Starting of Motor Appliances		Power/current absorption up to 63A 35kW
		Protection against overload of transformers and associated circuits		Overload up to 35kW
		Power and current absorbed		Power/current absorption up to 63A 35kW
		Heating		Climatic chamber: -10 °C to 60 °C Data Recorder: -10 °C to 300 °C
		Abnormal operation		Data Recorder: –50 °C to 400 °C Power/current up to 63A 35kW
		Leakage current and dielectric strength at operating temperature		Up to 1 mA/kW; Up to 5 000 Vac
		Leakage current and Dielectric strength		Dielectric strength test with voltage range from 500V to 30 kV and frequency 50 Hz and 60 Hz Leakage current 2µ÷5 000mA
		Resistance to humidity		Up to 95 % RH
		Stability and Mechanical Hazards		Up to 20°
		Mechanical Resistance		Up to 1 J
		Connection to the mains and external flexible cables		Flexing test up to 10 N; 20 000 flexing; 360° Pull force up to 100 N; Torque 0.35 Nm
		Grounding Provisions		Up to 12 V; 0.01 Ω to 0.5 Ω
		Screws and Connections		Up to 12 V; 0.01 Ω to 0.5 Ω
		Surface distances, in the air and distances through a solid insulation		Up to 2.5 Nm
		Resistance to Heat and Fire		0.01 mm to 1 m
		Toxicity Radiation and Similar Hazards		Glow wire Up to 960 °C Flammability test according to IEC 60695-11-10
		Protection against rust		EMF: Up to 100 %

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Electrical [F]	Household and similar electrical appliances	Classification	IEC 60335-2-21:2012/A1:2012; EN 60335-2-21:2021 IEC 60335-2-35:2012/A1:2016/A2:2020 EN 60335-2-35:2016/A1:2019 IEC 60335-2-98:2002/A1:2004/A2:2008/A11:2019, EN 60335-2-98:2003 / A1:2005 / A2:2008/A11:2019 IEC 60335-2-80:2002 / A1:2004 / A2:2008, IEC 60335-2-80:2015; EN 60335-2-80:2003 / A1:2004 / A2:2009 IEC 60335-2-50:2002 / A1:2007/A2:2017, EN 60335-2-50:2003 / A1:2008	Visual Evaluation
		Marking and instructions		
		Construction Internal Cables		
		Components		
		Terminals for external Cables		Visual Evaluation and torque up to 2.5 Nm
		Protection against access to live parts		Force up to 20 N
		Starting of Motor Appliances		Power/current absobtion up to 63A 35kW
		Protection against overload of transformers and associated circuits		Overload up to 35kW
		Power and current absorbed		Power/current absorption up to 63A 35kW
		Heating		Climatic chamber: -10 °C to 60 °C Data Recorder: -10 °C to 300 °C
		Abnormal operation		Data Recorder: –50 °C to 400 °C Power/current up to 63A 35kW
		Leakage current and dielectric strength at operating temperature		Up to 1 mA/kW; Up to 5 000 Vac
		Leakage current and Dielectric strength		Dielectric strength test with voltage range from 500V to 30 kV and frequency 50 Hz and 60 Hz Leakage current 2µ÷5 000mA
		Resistance to humidity		Up to 95 % RH
		Stability and Mechanical Hazards		Up to 20°
		Mechanical Resistance		Up to 1 J
		Connection to the mains and external flexible cables		Flexing test up to 10 N; 20 000 flexing; 360° Pull force up to 100 N; Torque 0.35 Nm
		Grounding Provisions		Up to 12 V; 0.01 Ω to 0.5 Ω
		Screws and Connections		Up to 12 V; 0.01 Ω to 0.5 Ω
		Surface distances, in the air and distances through a solid insulation		Up to 2.5 Nm
		Resistance to Heat and Fire		0.01 mm to 1 m
		Toxicity Radiation and Similar Hazards		Glow wire Up to 960 °C Flammability test according to IEC 60695-11-10
		Protection against rust		EMF: Up to 100 %

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Electrical [F]	Household and similar electrical appliances	Classification	IEC 60335-2-14:2006 / A1:2008 / A2:2012, IEC 60335-2-14:2016/A1:2019; EN 60335-2-14:2006 / A1:2008 / A11:2012 / A11:2012/EC:2013/EC:206/A12:2016 IEC 60335-2-15:2012/A1:2016/A2:2018 EN 60335-2-15:2016/A11:2018 IEC 60335-2-59:2002 / A1:2006 / A2:2009, EN 60335-2-59:2003 / A1:2006 / A2:2009/A11:2018 IEC 60335-2-2:2009 / A1:2012, IEC 60335-2-2/2019; EN 60335-2-2:2003 / A1:2004 / A2:2006 / A11:2010 / A11:2010/AC:2012, EN 60335-2-2:2010 / A11:2012 / A1:2013	Visual Evaluation
		Marking and instructions		
		Construction Internal Cables		
		Components		
		Terminals for external Cables		Visual Evaluation and torque up to 2.5 Nm
		Protection against access to live parts		Force up to 20 N
		Starting of Motor Appliances		Power/current absobtion up to 63A 35kW
		Protection against overload of transformers and associated circuits		Overload up to 35kW
		Power and current absorbed		Power/current absorption up to 63A 35kW
		Heating		Climatic chamber: -10 °C to 60 °C Data Recorder: -10 °C to 300 °C
		Abnormal operation		Data Recorder: –50 °C to 400 °C Power/current up to 63A 35kW
		Leakage current and dielectric strength at operating temperature		Up to 1 mA/kW; Up to 5 000 Vac
		Leakage current and Dielectric strength		Dielectric strength test with voltage range from 500V to 30 kV and frequency 50 Hz and 60 Hz Leakage current 2µ÷5 000mA
		Resistance to humidity		Up to 95 % RH
		Stability and Mechanical Hazards		Up to 20°
		Mechanical Resistance		Up to 1 J
		Connection to the mains and external flexible cables		Flexing test up to 10 N; 20 000 flexing; 360° Pull force up to 100 N; Torque 0.35 Nm
		Grounding Provisions		Up to 12 V; 0.01 Ω to 0.5 Ω
		Screws and Connections		Up to 12 V; 0.01 Ω to 0.5 Ω
		Surface distances, in the air and distances through a solid insulation		Up to 2.5 Nm
		Resistance to Heat and Fire		0.01 mm to 1 m
		Toxicity Radiation and Similar Hazards		Glow wire Up to 960 °C Flammability test according to IEC 60695-11-10
		Protection against rust		EMF: Up to 100 %

Certificate of Accreditation: Supplement

ELETTRA S.r.l.

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Via Meucci, 93, 50041 Calenzano (FI), Italy
Dott. Ing. Lorenzo Spinelli Phone: +39 055-8827323

Accreditation is granted to the facility to perform the following testing:

FIELD OF TEST	ITEMS, MATERIALS OR PRODUCTS TESTED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION STANDARD METHOD OR TECHNIQUE USED	RANGE (WHERE APPROPRIATE) AND DETECTION LIMIT
Electrical [F]	Household and similar electrical appliances	Classification	IEC 60335-2-39:2002 / A1:2004 / A2:2008; IEC 60335-2-39:2012/A1:2017, EN 60335-2-39:2003 / A1:2004 / A2:2008 IEC 60335-2-17:2012/A1:2015/A2:2019, EN 60335-2-17:2013/A1:2020/A2:2021 IEC 60335-2-3:2012/A1:2015, EN 60335-2-3:2002 / A1:2005 / A2:2008 / A11:2010 / A11:2010/AC:2012; EN 60335-2-3:2016 IEC 60335-2-23:2016/A1:2019; EN 60335-2-23:2003 / A1:2008 / A11:2010 / A11:2010/AC:2012 / A2:2015/A12:2016	Visual Evaluation
		Marking and instructions		
		Construction Internal Cables		
		Components		
		Terminals for external Cables		Visual Evaluation and torque up to 2.5 Nm
		Protection against access to live parts		Force up to 20 N
		Starting of Motor Appliances		Power/current absoption up to 63A 35kW
		Protection against overload of transformers and associated circuits		Overload up to 35kW
		Power and current absorbed		Power/current absorption up to 63A 35kW
		Heating		Climatic chamber: -10 °C to 60 °C Data Recorder: -10 °C to 300 °C
		Abnormal operation		Data Recorder: –50 °C to 400 °C Power/current up to 63A 35kW
		Leakage current and dielectric strength at operating temperature		Up to 1 mA/kW; Up to 5 000 Vac
		Leakage current and Dielectric strength		Dielectric strength test with voltage range from 500V to 30 kV and frequency 50 Hz and 60 Hz Leakage current 2µ÷5 000mA
		Resistance to humidity		Up to 95 % RH
		Stability and Mechanical Hazards		Up to 20°
		Mechanical Resistance		Up to 1 J
		Connection to the mains and external flexible cables		Flexing test up to 10 N; 20 000 flexing; 360° Pull force up to 100 N; Torque 0.35 Nm
		Grounding Provisions		Up to 12 V; 0.01 Ω to 0.5 Ω
		Screws and Connections		Up to 12 V; 0.01 Ω to 0.5 Ω
		Surface distances, in the air and distances through a solid insulation		Up to 2.5 Nm
		Resistance to Heat and Fire		0.01 mm to 1 m
		Toxicity Radiation and Similar Hazards		Glow wire Up to 960 °C Flammability test according to IEC 60695-11-10
		Protection against rust		EMF: Up to 100 %

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Electrical [F]	Household and similar electrical appliances	Classification	IEC 60335-2-9:2008 / A1:2012/A2:2016,IEC 60335-2-9:2019; EN 60335-2-9:2003 / A1:2004 / A2:2006 / A12:2007 / A13:2010 / A13:2010/AC:2011 / A13:2010/AC:2012 IEC 60335-2-48:2002 / A1:2008, IEC 60335-2-48:2021; EN 60335-2-48:2003 / A1:2008 / A11:2012/A2:2019 IEC 60335-2-5:2012/A1:2018; EN 60335-2-5:2015/A11:2019/A1:2019 IEC 60335-2-105:2004 / A1:2008 / A2:2013; IEC 60335-2-105:2016/A1:2019; EN 60335-2-105:2005 / A1:2008 / A11:2010/A2:2020;	Visual Evaluation
		Marking and instructions		
		Construction Internal Cables		
		Components		
		Terminals for external Cables		Visual Evaluation and torque up to 2.5 Nm
		Protection against access to live parts		Force up to 20 N
		Starting of Motor Appliances		Power/current absorption up to 63A 35kW
		Protection against overload of transformers and associated circuits		Overload up to 35kW
		Power and current absorbed		Power/current absorption up to 63A 35kW
		Heating		Climatic chamber: -10 °C to 60 °C Data Recorder: -10 °C to 300 °C
		Abnormal operation		Data Recorder: –50 °C to 400 °C Power/current up to 63A 35kW
		Leakage current and dielectric strength at operating temperature		Up to 1 mA/kW; Up to 5 000 Vac
		Leakage current and Dielectric strength		Dielectric strength test with voltage range from 500V to 30 kV and frequency 50 Hz and 60 Hz Leakage current 2µ÷5 000mA
		Resistance to humidity		Up to 95 % RH
		Stability and Mechanical Hazards		Up to 20°
		Mechanical Resistance		Up to 1 J
		Connection to the mains and external flexible cables		Flexing test up to 10 N; 20 000 flexing; 360° Pull force up to 100 N; Torque 0.35 Nm
		Grounding Provisions		Up to 12 V; 0.01 Ω to 0.5 Ω
		Screws and Connections		Up to 12 V; 0.01 Ω to 0.5 Ω
		Surface distances, in the air and distances through a solid insulation		Up to 2.5 Nm
		Resistance to Heat and Fire		0.01 mm to 1 m
		Toxicity Radiation and Similar Hazards		Glow wire Up to 960 °C Flammability test according to IEC 60695-11-10
		Protection against rust		EMF: Up to 100 %

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FIELD OF TEST	ITEMS, MATERIALS OR PRODUCTS TESTED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION STANDARD METHOD OR TECHNIQUE USED	RANGE (WHERE APPROPRIATE) AND DETECTION LIMIT
Electrical [F]	Household and similar electrical appliances	Classification	IEC 60335-2-41:2012, EN 60335-2-41:2003 / A1:2004 / A2:2010 IEC 60335-2-8:2012/A1:2015/ A2:2018; EN 60335-2-8:2015/A1:2016 IEC 60335-2-60:2002 / A1:2004 / A2:2008; IEC 60335-2-60:2017 EN 60335-2-60	Visual Evaluation
		Marking and instructions		
		Construction Internal Cables		
		Components		
		Terminals for external Cables		Visual Evaluation and torque up to 2.5 Nm
		Protection against access to live parts		Force up to 20 N
		Starting of Motor Appliances		Power/current absorption up to 63A 35kW
		Protection against overload of transformers and associated circuits		Overload up to 35kW
		Power and current absorbed		Power/current absorption up to 63A 35kW
		Heating		Climatic chamber: -10 °C to 60 °C Data Recorder: -10 °C to 300 °C
		Abnormal operation		Data Recorder: –50 °C to 400 °C Power/current up to 63A 35kW
		Leakage current and dielectric strength at operating temperature		Up to 1 mA/kW; Up to 5 000 Vac
		Leakage current and Dielectric strength		Dielectric strength test with voltage range from 500V to 30 kV and frequency 50 Hz and 60 Hz Leakage current 2µ÷5 000mA
		Resistance to humidity		Up to 95 % RH
		Stability and Mechanical Hazards		Up to 20°
		Mechanical Resistance		Up to 1 J
		Connection to the mains and external flexible cables		Flexing test up to 10 N; 20 000 flexing; 360° Pull force up to 100 N; Torque 0.35 Nm
		Grounding Provisions		Up to 12 V; 0.01 Ω to 0.5 Ω
		Screws and Connections		Up to 12 V; 0.01 Ω to 0.5 Ω
		Surface distances, in the air and distances through a solid insulation		Up to 2.5 Nm
		Resistance to Heat and Fire		0.01 mm to 1 m
		Toxicity Radiation and Similar Hazards		Glow wire Up to 960 °C Flammability test according to IEC 60695-11-10
		Protection against rust		EMF: Up to 100 %

Accreditation is granted to the facility to perform the following testing:

FIELD OF TEST	ITEMS, MATERIALS OR PRODUCTS TESTED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED	RANGE (WHERE APPROPRIATE) AND DETECTION LIMIT
Electrical F	Luminaires – General requirements and tests	Appliance components / Components of luminaires	IEC 60598-1:2020; EN 60598-1:2021	No tools
		Equipment classification / Classification of luminaires /Marking	IEC 60598-2-22:2014/A1:2017, EN 60598-2-22:2014/AC:2015/ A1:2020	Visual Evaluation
		Construction		0.2 Nm to 20 Nm 0.2 J to 1 J 1 N to 1 200 N
		External and internal wiring		30 N to 120 N 0.08 Nm to 0.35 Nm
		Provision for earthing	IEC 60598-2-4:1997, EN 60598-2-4:1997;	0.01 Ω to 0.5 Ω
		Protection against electric shock		Test gauges D.L. = 100 Nm
		Capacitors discharge	IEC 60598-2-18:1993/EC:2013/ A1:2012, EN 60598-2-18:1994/EC:1996/ A1:2012	Up to 250 Vac
		Protection against the penetration of dust, solid bodies and humidity / Resistance to dust, solid object and moisture		1 Nm to 3 Nm 0.07 l/m to 100 l/m
		Insulation resistance and dielectric strength, contact current and current in the protective conductor / Insulation resistance and electric resistance, current and protective conductor current	IEC 60598-2-1:2020; EN 60598-2-1:2021 IEC 60598-2-7:1982 / A1:1987 / A2:1994, IEC 60598-2-7:2017; EN 60598-2-7:1989 / A2:1996 / A13:1997	0.5 M Ω to 50 M Ω 1 V to 5 000 V 0 mA to 10 mA
		Surface and air insulation distances / Creepage distances and clearances		0.1 mm to 150 mm
		Endurance and heating tests	IEC 60598-2-3:2002 / A1:2011, EN 60598-2-3:2003 / A1:2011 + EC:2005	Climatic chamber: -10 °C to 60 °C Data Recorder: -10 °C to 300 °C
		Resistance to heat, fire and surface currents / Resistance to heat, fire and tracking		25 °C to 280 °C 550 °C to 960 °C
		Screw terminals Terminals and electrical connections without screws / Screwless terminals and electrical connections	IEC 60598-2-20:2014, EN 60598-2-20:2015/AC:2017 IEC 60598-2-2:2011, EN 60598-2-2:2012	1 Nm to 100 Nm

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Electrical Climatic and Mechanical[F]	Medical electrical equipment – General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment	4 general requirements 4.1 additional requirements for supply mains 4.2 environmental conditions 5 Classification of me equipment and me systems 6 ME equipment identification, marking and documents 7 Protection against electrical hazards from me equipment 8 protection against excessive temperatures and other hazards 9 accuracy of controls and instruments and protection against hazardous outputs 10 construction of me equipment 10.1 additional requirements for mechanical strength 10.1.1 general requirements for mechanical strength 10.1.2 requirements for mechanical strength for for fixed or permanently installed me equipment intended for use in a road ambulance 10.1.3 requirements for mechanical strength for transportable 10.1.4 requirements for mechanical strength for me equipment intended for airborne use me equipment 10.2 requirements for mounting of ME 11 additional requirements for electromagnetic emissions of me equipment and me systems	IEC 60601–1–12:2014/A1:2020 EN 60601–1–12:2015/A1:2020	Max acceleration 30 g Max sinusoidal force 6670 N peak Max random force 5340 N rms Max Shock 50,8 mm peak to peak Max Speed 1.78 m/s peak Static load 160 kg Climatic chamber: –50 °C to 70 °C Data Relative humidity from 10% to 95% IP grade IPX1 and IPX2 Power/current absorption up to 63A 35kW

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Electromagnetic Compatibility Tests[FO]	Electromedical equipment, industrial equipment, information technology, lighting equipment, household appliances, railway electronic equipment	Immunity to pulsed magnetic fields	EN 61000–4–9:2016 IEC 61000–4–9:2016	1 000A/m
		Condcuted immunity tests in the frequency range 0 Hz a 150 kHz	EN 61000–4–16:2016 IEC 61000–4–16:2015	Continuous disturbances up to 150V Transitory disturbances up to 700V
Flamability Tests[F]		Fire hazard testing Test flames. 50 W horizontal and vertical flame test methods	IEC 60695-11-10: 2013 EN 60695-11-10:2013	Horizontal and vertical combustion
		Glow wire test	IEC 60695-2-10: 2013 EN 60695-2-11:2013	Temperature from 550°C to 960°C
	information technology, lighting equipment, household appliances,	Needle flame test	IEC 60695-11-5: 2016 EN 60695-11-5:2017	8mm height flame for time from 5s to 120s

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Accreditation is granted to the facility to perform the following testing:

FDA ASCA Basic Safety and Essential Performance
Scope of Accreditation

METHOD USED
IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION
IEC 60601-1-6 Edition 3.1 2013-10
IEC 60601-2-5: Edition 3.0 2009-07
IEC 60601-2-6: Edition 2.1 2016-04
IEC 60601-2-16 Edition 5.0 2018-4
IEC 60601-2-57 Edition 1.0 2011-01
ISO 80601-2-12 Second edition 2020-02
ISO 80601-2-13 First edition 2011-08-11
ISO 80601-2-59 Edition 2.0 2017-09
ISO 80601-2-72 First edition 2015-04-11
ISO 80601-2-79 First Edition 2018-07
ISO 80601-2-80 First edition 2018-07

1. The presence of a superscript F means that the laboratory performs testing of the indicated parameter at its fixed location. Example: Outside Micrometer^{F} would mean that the laboratory performs this testing at its fixed location.

2. The presence of a superscript FO means that the laboratory performs testing of the indicated parameter both at its fixed location and onsite at customer locations. Example: Outside Micrometer^{FO} would mean that the laboratory performs this testing at its fixed location and onsite at customer locations.