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TESTING LABORATORY CAPABILITIES

ELECTROMEDICAL DEVICE

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Electromagnetic capability testing capacity

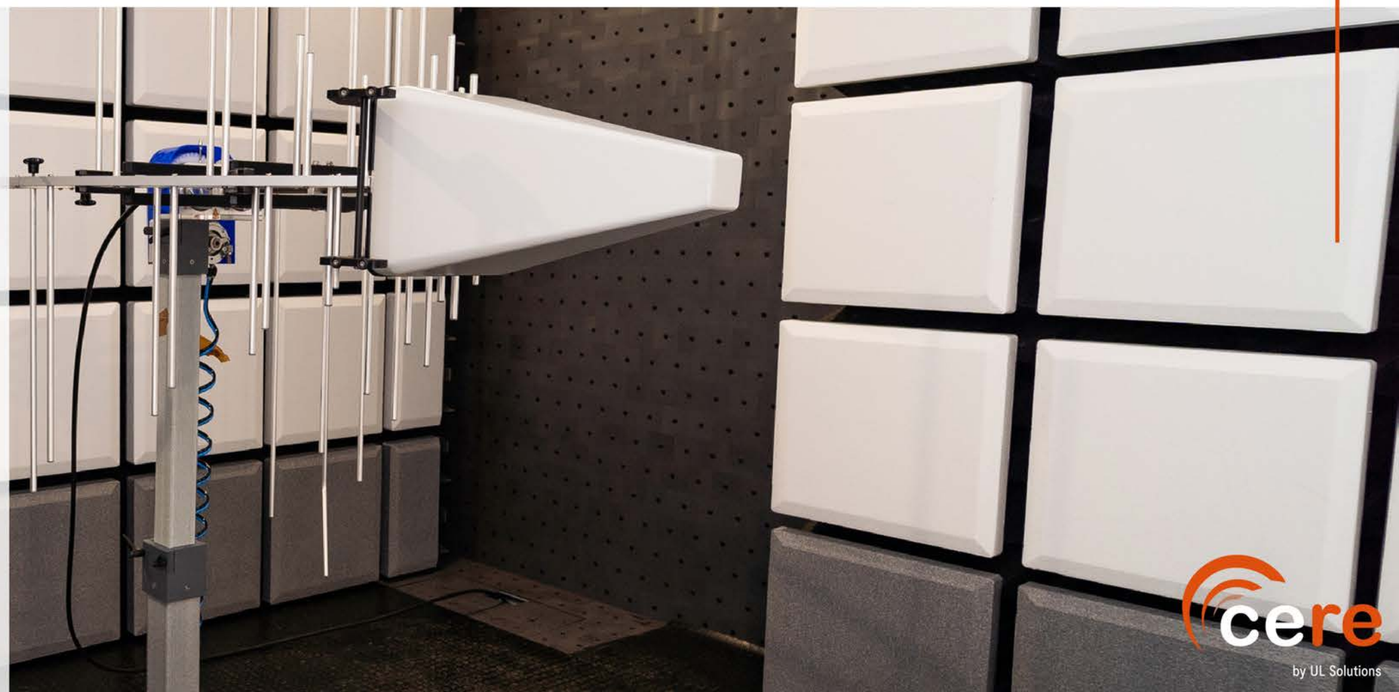
FULL ANECHOIC

CERE, by UL Solutions has a Chamber in its facilities Anechoic, with Quiera Zone (QZ) Ø1.5m (rotary platform), to perform Electromagnetic compatibility tests at 3m for Radiated Immunity and emission, and domestic and Industrial Environments: 80MHz range capability up to 6GHz

Exterior dimensions:
approx. 8.10m x 4.80m x 3.975m

Rotatory platform: 1,5m of diameter.
Door 1,5m x 2,4m H

Inner dimensions in between hybrid absorbers (HT45 model):
(L x W x H) approx. 7.08m x 3.78m x 2.81m.



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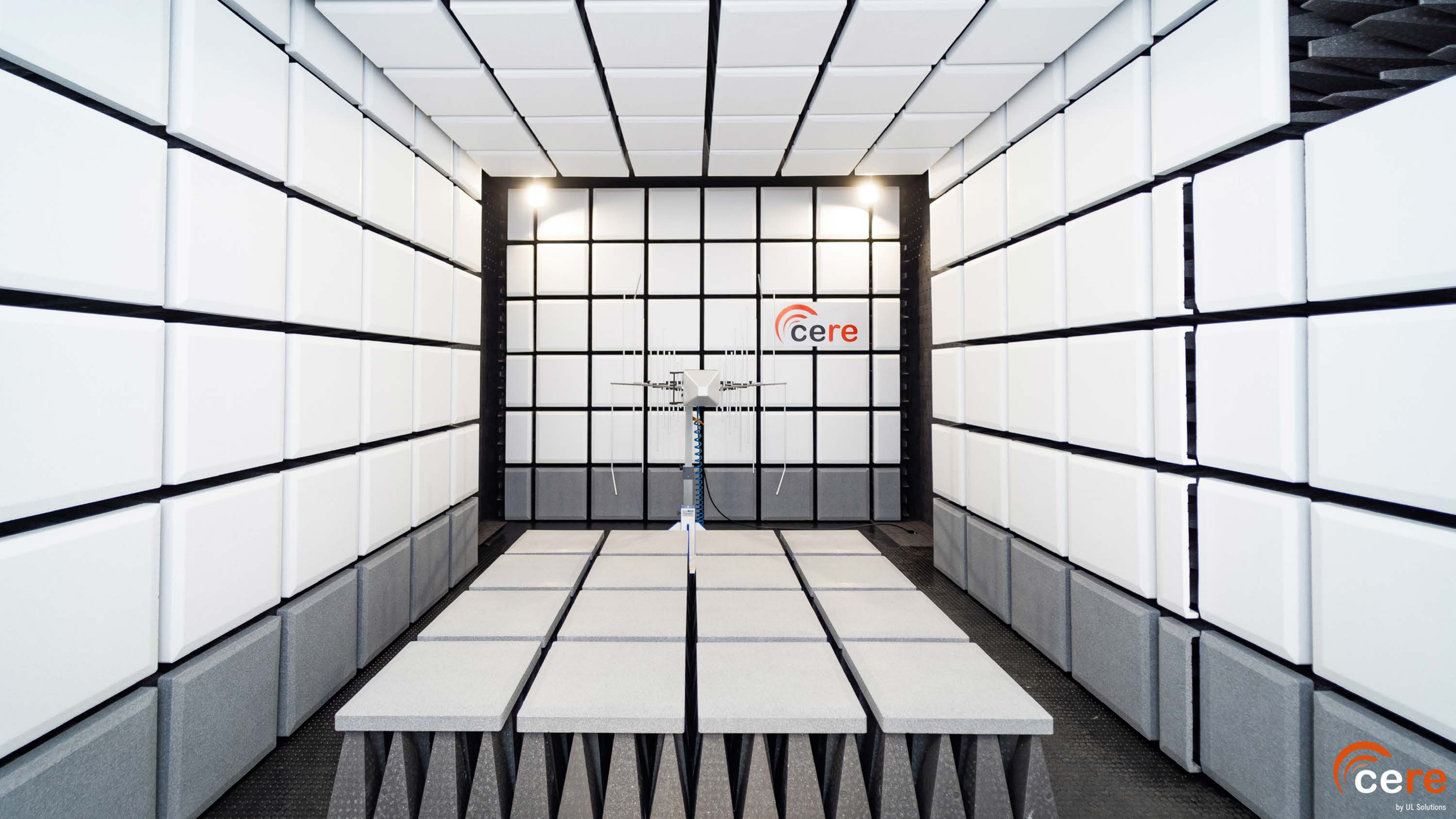

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Dimensions

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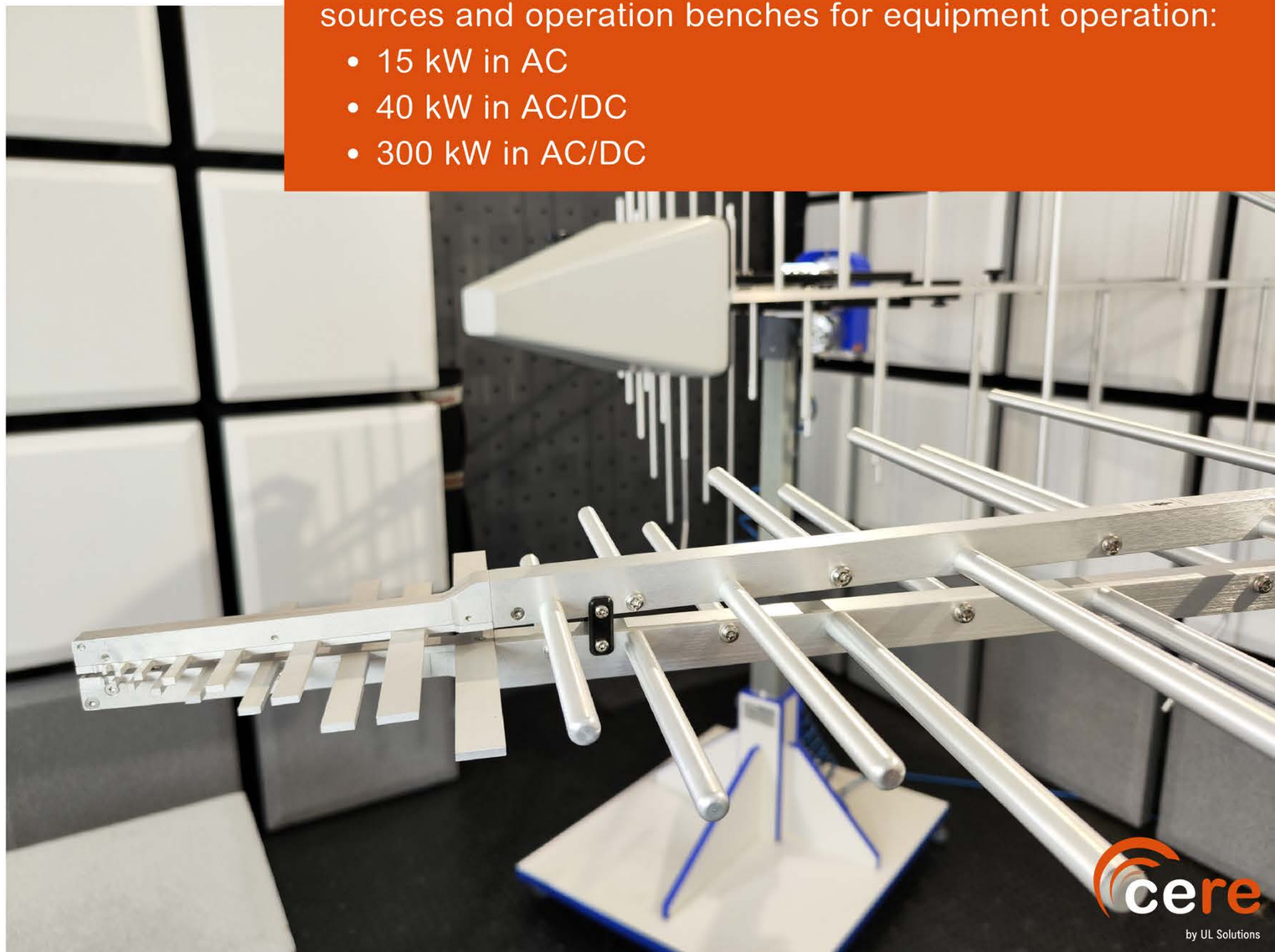
Inner dimensions in between hybrid absorbers (HT45 model):
(L x W x H) approx. 7.08m x 3.78m x 2.81m.

Maximum weight: 700kg.
Equipment up to 1 ton could be considered.

Operating power of the equipment under test

There are three possible configurations based on CERE sources and operation benches for equipment operation:

- 15 kW in AC
- 40 kW in AC/DC
- 300 kW in AC/DC



Technical features

Fully anechoic 3-meter chamber working in the time domain. The combination of these innovative technologies results in measurement time effort between 8 and 10 times shorter than timing required a classic chamber, providing more complete results, since it offers final results with all points in QP. 3D graphical representation of the equipment's emissions.
Measurements up to 6 GHz both in emission and radiated immunity.
Testing capacity for equipment with a power up to 300kW.

Emission

- Radiated emission
- Conducted emission measurements by LISN, voltage and current probe
- Clicks
- Harmonics and Flicker

Immunity

- IEC 61000-4-2: Electrostatic discharges (ESD)
- IEC 61000-4-3: Radiated immunity to electromagnetic fields
- IEC 61000-4-4: Bursts
- IEC 61000-4-5: Shock waves
- IEC 61000-4-6: Conducted immunity
- IEC 61000-4-8: Electromagentic fields immunity
- IEC 61000-4-11 & IEC 61000-4-34: Abnormal voltages
- IEC 61000-4-12: Ring wave

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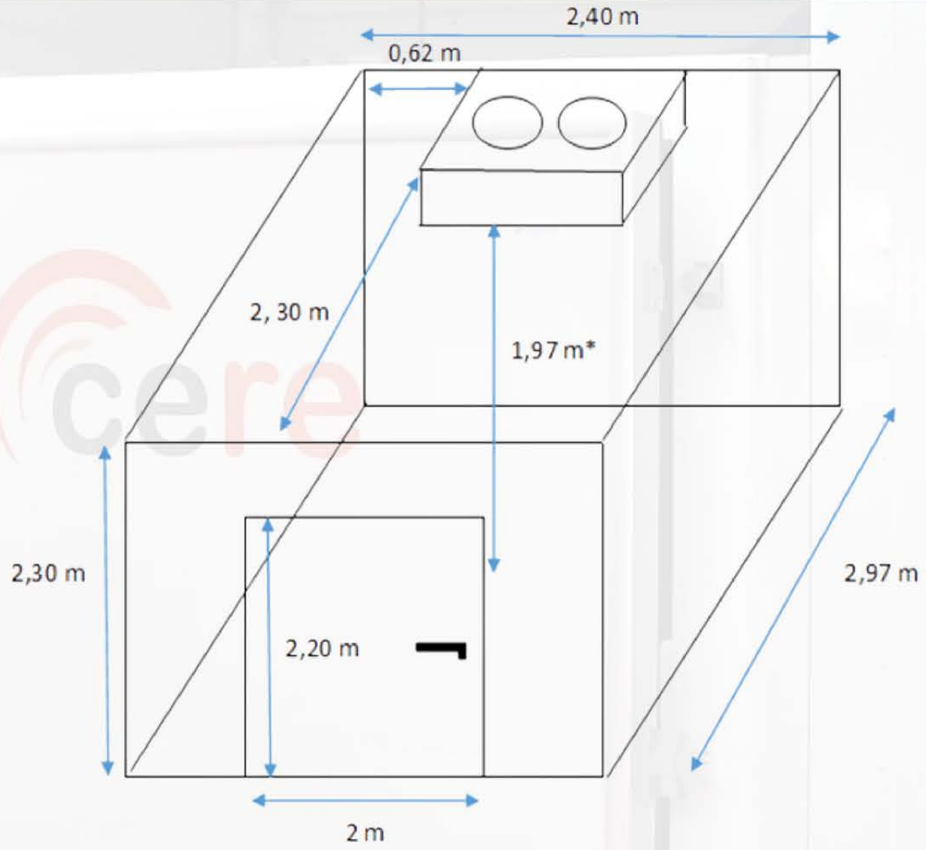
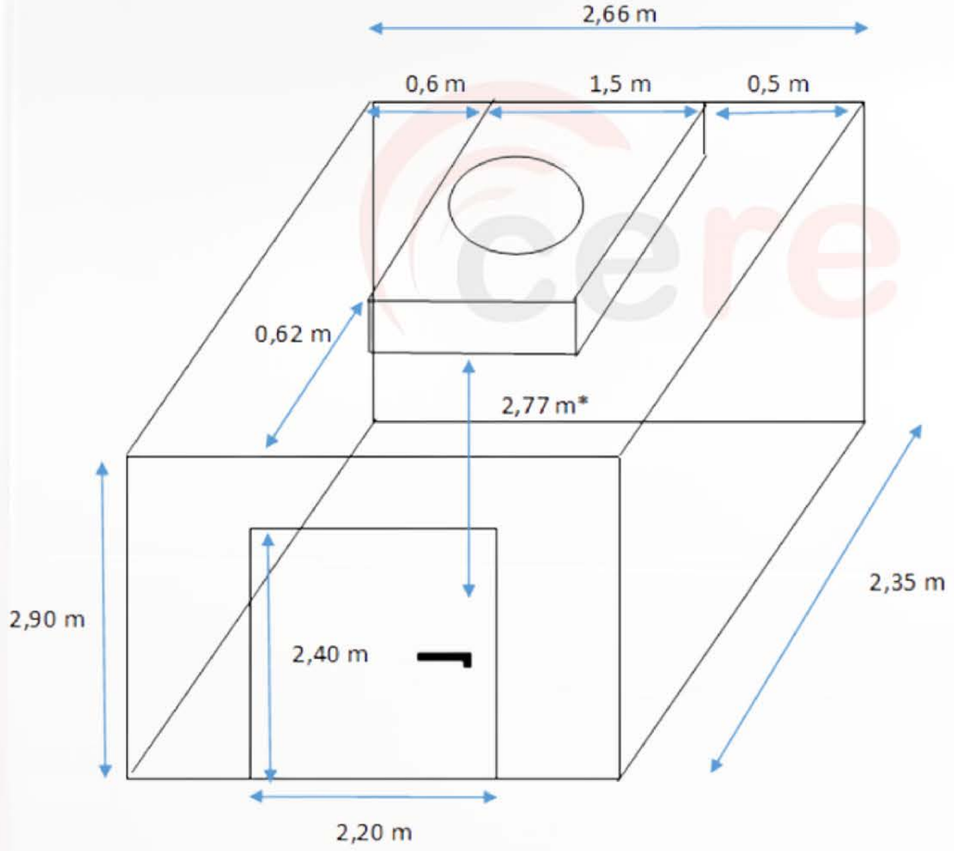
Environmental testing capability

CERE, by UL Solutions has several climatic chambers on the Laboratory facilities for temperature and humidity testing, for EUT within 3 tones and 2.4 meter high. Our capabilities include cycle programming, gradients, temperature steps, and all kind of variations. Temperature range is within -40°C and +125°C and RH up to 95%.



* Ground clearance

High temperature Chamber



* Ground clearance

Low temperature Chamber

High temperature chamber

- Upper and lower operating temperature limits with their respective relative humidity values: 85 °C with up to%RH: 85± 3 %, 70 °C with up to %RH: 95± 3 %
- Gradients range: Manual selection
- Max %RH: 95± 3 %
- EUT operating power: Power connected to power benches 1, 2 and 3 independently or in parallel up to 500kVA.

The dry heat test (without humidity), is performed at rated power and for the high humidity test, the equipment is not connected

Low temperature chamber

- Upper and lower operating temperature limits: +5°C to -40°C
- Gradients range: Manual selection
- EUT operating power: Power connected to power benches 1, 2 and 3 independently or in parallel up to 500kVA.

Heat drying oven

- Dimensions: 420x395x350 mm
- Volume: 50 liters Temperature
- Range: 25°C to 250°C
- Also used for pressure ball testing.

Dycometal temperature chamber

- Dimensions: 780 x 810 x 720 mm
- Upper and lower operating temperature limits: -40 to 125 ºC without humidity / 85º and 85 % H.R.
- Programable gradient range: 2ºC / minute of heating 1ºC / minute of cooling
- Max %RH: 95± 3 %
- EUT operating power: Depending on the source or operating bench.

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Binder temperature chamber

- Dimensions: 650 x 785 x 485 mm
- Upper and lower operating temperature limits: -40 to 125 ºC without humidity / 85º and 85 % H.R.
- Programable gradient range: 2ºC / minute of heating 1ºC / minute of cooling
- Max%RH: 95± 3 %
- EUT operating power: Depending on the source or operating bench

IPXX and Nema Laboratory Capabilities

- Tests can be performed up to IP 65
- Dust chamber dimensions for IP5X / IP6X: (960 x 960 x 980)
- NEMA tests: Rain Test
- Sprinkler test

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CTS Climatic chamber

- Chamber dimensions: 1000 x 1050 x 2000 mm
- Capacity: Aprox. 2000 l

CLIMATIC TESTS

- Upper and lower operating temperature limits: 10 to 95 ºC
- Temperature fluctuation: Temporary of ±0,1 to ±0,3 K
- Humidity range: 10 % to 98 %
- Dew point range: 5 to 89 ºC
- Humidity fluctuation: Temporary of ±1% to ±3 %

TEMPERATURE TESTS

- Upper and lower operating temperature limits: -70 to 180 ºC
- Temperature fluctuation: Temporary of ±0,3ºC
- Programable gradient ranger: 2ºC / minute of heating 2ºC / minute of cooling
- EUT: 200 Kg of photovoltaic panel

Incandescent wire chambrer

- Chamber dimensions: 1100 × 700 × 1300 mm, exhaust hole Ø100mm
- Power: 800 VA, 220 V, 48-60 Hz
- Capacity : >0.5 m3
- Upper and lower operating temperature limits: 500-1000°C ± 2 °C continuously adjustable
- Glow wire: Ø 4 mm ± 0.04 mm Ni/Cr (80/20)
- Penetration depth: 7 mm ± 0.5 mm

CTI test chamber

- Chamber dimensions: 1100 x 700 x 1300 mm.
- Power: 800 VA, 220 V, 48-60 Hz
- Capacity: >0.5 m3
- Electrode distance: 4 mm ± 0.1 mm, 60 ± 5° angle.
- Test voltage: 100 - 600 V adjustable.
- Test current: Limited to 1 A ± 0.1 A adjustable.

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Salt fog chamber

- Chamber dimensions: 600 x 450 x 400 mm
- Power: 220 V, 1.5 KW, 50 Hz
- Capacity : Aprox. 108 l
- Salt spray test: 35°C ± 1°C (Test room temperature), 47°C±1°C (Saturated air barrel temperature)
- Corrosion test: 50°C ± 1°C (Test room temperature), 63°C±1°C (Saturated air barrel temperature)

Needle flame chamber

- Chamber dimensions: 1100 × 700 × 1300 mm, exhaust orifice Ø100mm
- Power: 800 VA, 220 V, 48-60 Hz
- Capacity: >0.5 m3
- Test temperature range: 0 - 1000 °C
- Flame temperature: from 100 °C ± 2 °C liters to 700 °C ± 3 °C liters in 23.5 s ± 1 s

Standards for active electromedical products

MEDICAL DEVICE REGULATION 2017/745 (MDR) STANDARDS IEC 60601

The MD standards cover general and specific safety and EMC requirements for electromedical products.
They are divided into three parts:

- General standard: 60601-1
- Collateral standard: 60601-1-XX
- Specific standard: 60601-2-XX / 80601-2-XX / ISO

IN-VITRO DEVICE REGULATION 2017/746 (IVDR) STANDARDS IEC 61010

The IVD standards cover general and specific safety and EMC requirements for medical electrical products.
They are divided into two parts:

- General standard: 61010-1 y 61326-1
- Specific standard: 61010-2-XX / 61326-2-XX / ISO

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Product standards - EMC

Active MD and IVD equipment:

60601-1-2: Electromagnetic disturbances in electromedical equipment (MD).
61326-1: General EMC requirements (IVD).
61326-2-6: EMC requirements for In vitro diagnostic (IVD) medical equipment.

IMMUNITY

- IEC 61000-4-2: Electrostatic discharges (ESD)
- IEC 61000-4-3: Radiated immunity to electromagnetic fields
- IEC 61000-4-4: Bursts
- IEC 61000-4-5: Shock waves
- IEC 61000-4-6: Conducted immunity
- IEC 61000-4-8: Electromagentic fields immunity
- IEC 61000-4-11 & IEC 61000-4-34: Abnormal voltages
- IEC 61000-4-12: Ring wave

EMISSION

- CISPR 11: Radiated emission
- Conducted emission measurements by LISN, voltage and current probe
- Clicks
- IEC 61000-3-2: Harmonics
- IEC 61000-3-3: Flicker

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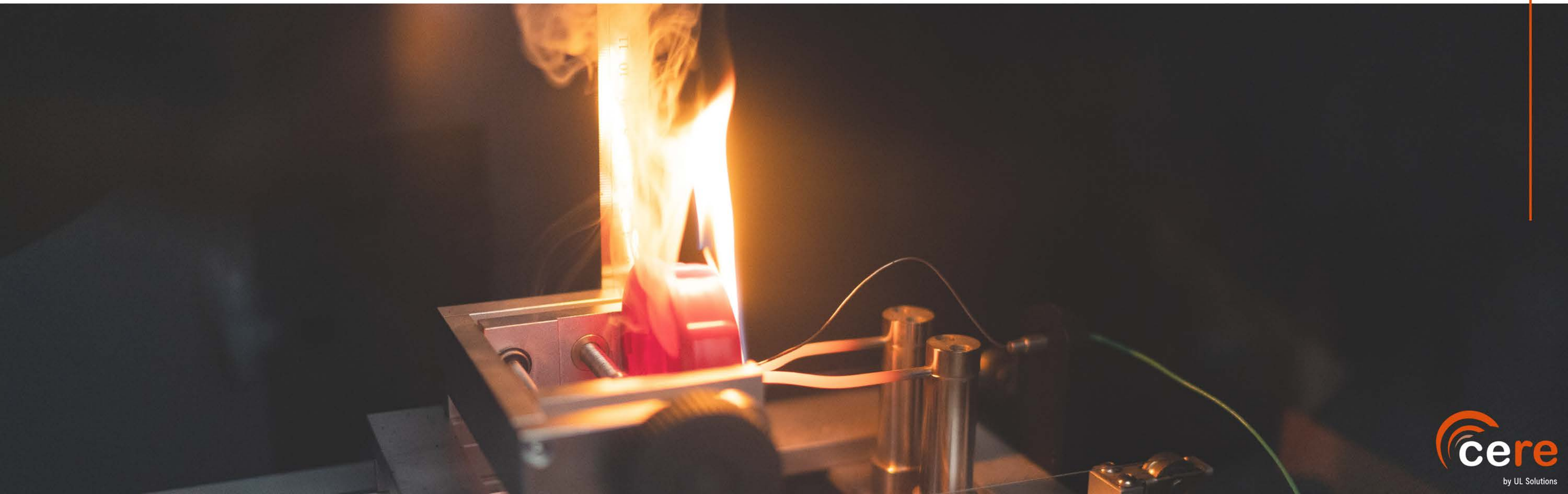
Medical Device regulation 2017/745 (MDR)
Standards IEC 60601



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Collateral standards for MD - Safety

60601-1	General requirements for basic safety and essential performance.
60601-1-2	Electromagnetic disturbances
60601-1-6	Usability
60601-1-8	Alarm systems
60601-1-9	Environmentally conscious design
60601-1-11	Home healthcare environment
60601-1-12	Emergency medical services environment

Specific standards for MD- Safety. 60601-2-XX

STANDARD	EQUIPMENT UNDER TEST
IEC 60601-2-1	Electron accelerators
IEC 60601-2-2	High frequency surgical equipment
IEC 60601-2-3	Short-wave therapy equipment
IEC 60601-2-4	Cardia defibrillator
IEC 60601-2-5	Ultrasonic physiotherapy equipment
IEC 60601-2-6	Microwave therapy equipment
IEC 60601-2-7	X-ray generator
IEC 60601-2-8	Radiotherapy X-ray equipment
IEC 60601-2-10	Nerve and musclestimulators
IEC 60601-2-11	Gamma beam therapy equipment
ISO 80601-2-12	Critical care ventilators
ISO 80601-2-13	Anaesthetic workstation
IEC 60601-2-16	Haemodialysis equipment
IEC 60601-2-17	Brachytherapy equipment
IEC 60601-2-18	Endoscopic equipment
IEC 60601-2-19	Infant incubators
IEC 60601-2-20	Infant transport incubators

STANDARD	EQUIPMENT UNDER TEST
IEC 60601-2-21	Infant radiant warmers
IEC 60601-2-22	Surgical, cosmetic, therapeutic and diagnostic laser equipment
IEC 60601-2-23	Transcutaneous partial pressure monitoring equipment
IEC 60601-2-24	Infussion pumps and controllers
IEC 60601-2-25	Electrocardiographs
IEC 80601-2-26	Electroencephalographs
IEC 60601-2-27	Electrocardipgraphic monitoring equipment
IEC 60601-2-28	X-ray tubes
IEC 60601-2-29	Radiotherapy simulators
IEC 80601-2-30	Automated non-invasive sphygmomanometers
IEC 80601-2-31	External cardaic pacemakers with internal power source
IEC 60601-2-33	Magnetic resonance equipment
IEC 60601-2-34	Invasive blood pressure monitoring equipment
IEC 60601-2-35	Heating devices
IEC 60601-2-36	Extracorporeally induced lithotripsy
IEC 60601-2-37	Ultrasonic medical diagnostic and monitoring
IEC 60601-2-39	Peritoneal dyalisis equipment
IEC 60601-2-40	Electromyographs and evoked response equipment

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Specific standards for MD- Safety. 60601-2-XX

STANDARD	EQUIPMENT UNDER TEST
IEC 60601-2-41	Surgical and diagnostic luminaires
IEC 60601-2-43	X-ray equipment for interventional procedures
IEC 60601-2-44	X-ray equipment for computed tomography
IEC 60601-2-45	X-ray equipment for mammographic stereotactic devices
IEC 60601-2-46	Operating tables
IEC 60601-2-47	Ambulatory electrocardiographic systems
IEC 80601-2-49	Multifunction patient monitors
IEC 60601-2-50	Infant phototherapy equipment
IEC 60601-2-52	Medical beds
IEC 60601-2-54	X-ray equipment for radiography and radioscopy
ISO 80601-2-55	Respiratory gas monitors
IEC 60601-2-56	Clinical thermometers for body temeprature measurement
IEC 60601-2-57	Non-laser light source equipment
IEC 60601-2-58	Lens removal and victrectomy devices
IEC 60601-2-59	Screening thermographs
IEC 80601-2-60	Dental equipment

STANDARD	EQUIPMENT UNDER TEST
IEC 80601-2-61	Pulse oximeter equipment
IEC 60601-2-62	High intensity therapeutic ultrasound (HITU)
IEC 60601-2-63	Dental extra-oral X-ray equipment
IEC 60601-2-64	Light ion beam medical electrical equipment
IEC 60601-2-65	Dental intra-oral X-ray equipment
IEC 60601-2-66	Hearing aids and hearing aid systems
ISO 80601-2-67	Oxygen-conserving equipment
IEC 60601-2-68	X-ray-based image-guided radiotherapy equipment
ISO 80601-2-69	Oxygen concentrator equipment
ISO 60601-2-70	sleep apnoea breathing therapy equipment
ISO 80601-2-71	Functional near-infrared spectroscopy (NIRS)
ISO 80601-2-72	Home healthcare environment ventilators
ISO 80601-2-74	Respiratory humidifying equipment
IEC 60601-2-75	Photodynamic therapy and photodynamic diagnosis equipment
IEC 60601-2-76	Low energy ionized gas haemostasis equipment
IEC 80601-2-77	Robotically assisted surgical equipment
IEC 80601-2-78	Medical robots for rehabilitation, assessment, compensation or alleviation
IEC 80601-2-79	Ventilatory support equipment for ventilatory impairment
ISO 80601-2-80	Ventilatory support equipment for ventilatory insufficiency

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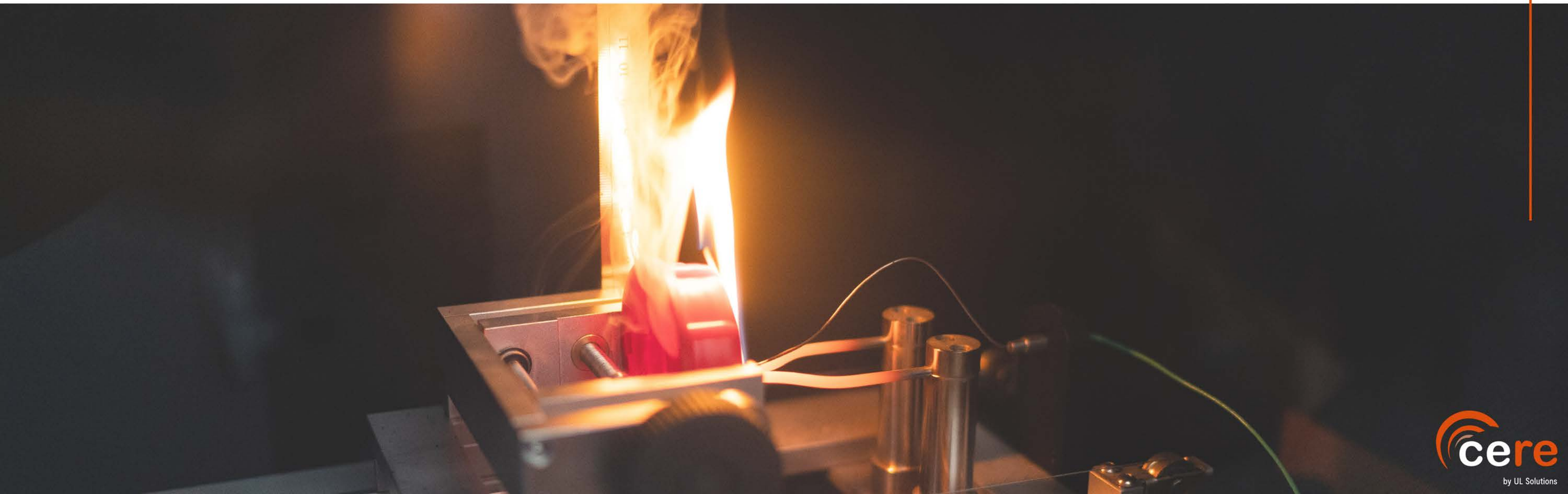
Specific standards for MD- Safety. 60601-2-XX

STANDARD	EQUIPMENT UNDER TEST
IEC 60601-2-83	Homelight therapy equipment
ISO 80601-2-84	Ventilators for the emergency medical services environment
ISO 80601-2-85	Cerebral tissue oximeter equipment
ISO 80601-2-87	High frequency ventilators
ISO 80601-2-90	Respiratory high-flow therapy equipment
IEC 60825-1	Laser products
IEC 62304	Medical device software
IEC 82304	Health software

In-Vitro Device regulation 2017/746 (IVDR)
Standards IEC 61010



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Specific standards for IVD - Safety 61010-2-XX

STANDARD	EQUIPMENT UNDER TEST
IEC 61010-2-010	Heating of materials
IEC 61010-2-011	Refrigerating equipment
IEC 61010-2-012	Climatic and environmental testing and other temperature conditioning equipment
IEC 61010-2-020	Laboratory centrifuges
IEC 61010-2-030	Equipment having testing or measuring circuits
IEC 61010-2-032	Hand-held and hand-manipulated current sensors for electrical test and measurement
IEC 61010-2-033	Hand-held multimeters and other meters for domestic and professional use
IEC 61010-2-034	Insulation resistance and test equipment for electric strength
IEC 61010-2-040	Sterilizers and washer-disinfectors used to treat medical materials
IEC 61010-2-051	Laboratory equipment for mixing and stirring
IEC 61010-2-061	Laboratory atomic spectrometers with thermal atomization and ionization
IEC 61010-2-081	Automatic and semi-automatic laboratory equipment
IEC-61010-2-091	Cabinet X-ray systems
IEC 61010-2-101	In vitro diagnostic (IVD) medical equipment
IEC 61010-2-130	Equipment intended to be used in educational establishments by children
IEC 61010-2-201	Control equipment
IEC 61010-2-202	Electrically operated valve actuators

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