



**SCOPE OF TESTS  
SAFETY USE AND EMC**  
**CELAMED Centralne Laboratorium Aparatury Medycznej  
Aspel S.A.**

Order nr:

This form allows you to select the tests that are the subject of your order, prepare a test plan. For ease of choice the brief technical characteristics of the research capabilities and required documents are presented.

**SAFETY USE TESTING**

(Scope of tests requires arrangements)

Required documents:

- list of used elements for safety-oriented with CE certificates
- operating instructions complying with EN 60601-1 (refers to medical devices),
- technical description for the supply network part,
- biocompatibility certificates - if applicable.

subject of tests	standart	select	accreditation	comments
medical electrical equipment, general requirements for basic safety and essential performance	EN 60601-1:2006 EN 60601-1:2006/A1:2013 EN 60601-1:2011/A12:2014	<input type="checkbox"/>	accredited tests	
medical electrical equipment, particular requirements for the basic safety and essential performance of electrocardiographs	EN 60601-2-25:1995/A1:1999	<input type="checkbox"/>	accredited tests	
	EN 60601-2-25:2015	<input type="checkbox"/>	accredited tests	
medical electrical equipment, particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs	EN 60601-2-51:2003	<input type="checkbox"/>	accredited tests	
medical electrical equipment, particular requirements for the basic safety and essential performance of electroencephalographs	EN 60601-2-26:2015	<input type="checkbox"/>	accredited tests	
non-invasive sphygmomanometers, supplementary requirements for electro-mechanical blood pressure measuring systems	EN 1060-3:1997/A1:2005	<input type="checkbox"/>	tests outside the scope of accreditation	
medical electrical equipment, particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems	EN 60601-2-47:2001	<input type="checkbox"/>	accredited tests	
stationary training equipment, general safety requirements and test methods	EN ISO 20957-1:2013	<input type="checkbox"/>	accredited tests	



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stationary training equipment, stationary exercise bicycles and upper body crank training equipment, additional specific safety requirements and test methods	EN ISO 20957-5:2016	<input type="checkbox"/>	accredited tests	
stationary training equipment, treadmills, additional specific safety requirements and test methods	EN 957-6:2010	<input type="checkbox"/>	accredited tests	
medical electrical equipment, particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers	EN 60601-2-30:2010+A1:2015	<input type="checkbox"/>	tests outside the scope of accreditation	
medical electrical equipment, general requirements for basic safety and essential performance - usability	EN 60601-1-6:2010/A1:2015	<input type="checkbox"/>	tests outside the scope of accreditation	
medical devices, application of usability engineering to medical devices	EN 62366:2008/A1:2015	<input type="checkbox"/>	tests outside the scope of accreditation	
anaesthetic and respiratory equipment, peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans	EN ISO 23747:2009	<input type="checkbox"/>	tests outside the scope of accreditation	
anaesthetic and respiratory equipment, spirometers intended for the measurement of time forced expired volumes in humans	EN ISO 26782:2009	<input type="checkbox"/>	tests outside the scope of accreditation	



# SCOPE OF TESTS SAFETY USE AND EMC

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## ELECTROMAGNETIC COMPATIBILITY EMC

### Characteristics of the semi-anechoic chamber (SAC)

Internal dimensions of the chamber 8,80 x 5,50 x 5,40 [m]  
 Measuring distance 3m  
 Dimensions of the door 0,9 x 2,1 [m]  
 Antenna mast scanning height from 1 to 4 [m]  
 Turntable table diameter 2 [m]; lifting capacity 500 [kg]  
 Maximum dimensions of objects tested in the chamber: (width x depth x height) 1,2 x 0,8 x 2,0 [m],  
 lifting capacity ≤ 500 kg  
 NSA ≤2,5dB (od 30 MHz do 1000 MHz)  
 TL ≤2,5dB (od 1 GHz do 18 GHz)  
 VSWR ≤2,5dB (od 1 GHz do 18 GHz)

The ability to connection control, signal and power lines into the chamber:

- analog control lines: 6 control lines; band 0-5kHz
- signal lines : RS, LAN, USB (by fiber optic converters)
- power socket AC 230V/16A
- power socket AC 3x230V/32A

Laboratory terminals for AC / DC regulated power supply 0 do 300V AC 50/60Hz; 0 do 400VDC  
 Observation of test equipment - TV camera, event recording

### EMC TESTING according to the standards

*(enter the standard identifiers that set exposure levels for immunity tests and limit values)*

EN 61000-6-1:2007	<input type="checkbox"/>	accredited tests	EN 60601-1-2:2007	<input type="checkbox"/>	accredited tests
EN 61000-6-2:2005	<input type="checkbox"/>	accredited tests	EN 60601-2-25:2015	<input type="checkbox"/>	accredited tests
EN 61000-6-3:2007/A1:2011	<input type="checkbox"/>	accredited tests	EN 60601-2-26:2015	<input type="checkbox"/>	accredited tests
EN 61000-6-4:2007+A1:2017	<input type="checkbox"/>	accredited tests	EN 60601-2-27:2014	<input type="checkbox"/>	tests outside the scope of accreditation
EN 55011:2016	<input type="checkbox"/>	accredited tests	EN 60601-2-52:2010/A1:2015	<input type="checkbox"/>	accredited tests
EN 55022:2006/A1:2008	<input type="checkbox"/>	accredited tests	EN 60601-2-47:2001	<input type="checkbox"/>	accredited tests
EN 55024:2010/A1:2015	<input type="checkbox"/>	tests outside the scope of accreditation	EN 60601-2-49:2001	<input type="checkbox"/>	tests outside the scope of accreditation
other: .....	<input type="checkbox"/>		other: .....	<input type="checkbox"/>	



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	type of tests	standard test method	select	customer requirements
1	<b>Electrostatic discharge test (ESD)</b> Voltage pulse test for contact discharge      0,2 kV do 9,0 kV Voltage pulse test for discharge in the air      0,2 kV do 16,05 kV Accuracy of test voltages      ±5%	EN 61000-4-2:2009 accredited tests	<input type="checkbox"/>	voltage pulse test for contact discharge..... voltage pulse test for discharge in the air..... number of discharges..... time between discharges.....
2	<b>Electrical fast transient/burst immunity test (BURST)</b> Voltage test pulse      0,2kV do 4,4kV Accuracy of test voltages      ±10% Burst pulse frequency      1kHz do 100kHz Number of pulses in Burst      1 to 75 Period Burst      100ms to 99s Internal coupling      L, N, PE, L-N, L-PE, N-PE, L-N-PE Exposure mode      Single, continuous, number of exposure (1-9999) Exposure time      od 1s do 100h	EN 61000-4-4:2012 accredited tests	<input type="checkbox"/>	Voltage test pulse (power line)..... Voltage test pulse (signal lines)..... Burst pulse frequency ..... Duration of the series Burst..... Number of pulses in Burst..... Exposure time .....
3	<b>Surge immunity test (SURGE)</b> Voltage test pulse      0,2kV do 4,4kV Accuracy of test voltages      ±10% Short-circuit current      0,1kA to 2,2kA Output resistance      2Ω/12Ω ±20% Polarization      positive / negative Internal coupling      L, N, L-N, L-PE, N-PE, L-N-PE (symmetrical / asymmetrical) Phase shift with respect to the network      0 to 359° step 1°	EN 61000-4-5:2006 accredited tests	<input type="checkbox"/>	Voltage test pulse terminal input/output DC line - line..... line - PE..... Voltage test pulse terminal input/output AC line - line..... line - PE..... Amount of exposure for each polarization..... Frequency of repetition.....
4	<b>Voltage dips, short interruptions and voltage variations immunity tests (PQT)</b> Voltage testing AC (% power supply voltage)      0%, 40%, 70%, 100% Accuracy of test voltages      ±5% Adjustable phase shift      0 to 359° step 1° Duration time      0,5 to 250 periods, step 0,5 Break time      10s to 600s	EN 61000-4-11:2004 accredited tests	<input type="checkbox"/>	Test level for brake / phase / duration..... ..... Test level for voltage drop / phase / duration..... ..... Number of repetitions..... Time interval between exposures.....



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<b>5</b>	<b>Power frequency magnetic field immunity test (POWERM)</b> Intensity of the magnetic field 0,1 do 4 A/m, accuracy of setting 0,1A/m Frequency 50/60 Hz Deviation of field strength ±3dB Inductive coil square 1m x 1m The size of the object being tested 0,6m x 0,6m x 0,5m	EN 61000-4-8:2010 accredited tests	<input type="checkbox"/>	Intensity of the magnetic field .....
<b>6</b>	<b>Pulse magnetic field immunity test (PULSEM)</b> Intensity of the magnetic field 0,1 do 40 A/m, accuracy of setting 0,1A/m Frequency 50/60 Hz Deviation of field strength ±3dB Inductive coil square 1m x 1m The size of the object being tested 0,6m x 0,6m x 0,5m	EN 61000-4-9:1993/A1:2001 accredited tests	<input type="checkbox"/>	Intensity of the magnetic field .....
<b>7</b>	<b>Immunity to conducted disturbances, induced by radio-frequency fields</b> (CDN for single-phase power lines and signal lines with shielded connectors SUB9, shielded USB 2.0, unshielded RJ45, Injection Probe, Monitoring Current Probe) Frequency range 150kHz to 80 MHz (10kHz to 230MHz) Level of exposure 1 to 10 V Depth of modulation 80% (0% to 100%) Modulation frequency 1Hz to 1 kHz (0Hz to 5MHz) Network 16N single-phase load 16A, class I, and class II	EN 61000-4-6:2014 accredited tests	<input type="checkbox"/>	Frequency range..... Level of exposure..... Depth of modulation..... Modulation frequency..... Observation time.....
<b>8</b>	<b>Radiated, radio-frequency, electromagnetic field immunity test (test in a semi-anechoic chamber at 3m measuring distance)</b> Frequency range 80 MHz 2,5GHz Level of exposure 1 do 10 V Depth of modulation 80% (0% do 100%) Modulation frequency 0,01Hz do 1 MHz	EN 61000-4-3:2006 +A1:2008+A2:2010 accredited tests	<input type="checkbox"/>	Frequency range..... Level of exposure..... Depth of modulation..... Modulation frequency..... Observation time.....



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EMISSION TESTS				
9	<b>Electromagnetic disturbance characteristics, measurement of voltage level of RF electromagnetic disturbances on power supply lines</b> Frequency range 150 kHz to 30 MHz (9 kHz to 30 MHz) Measurement by artificial network V type, single phase / 16A devices	EN 55011:2016 accredited tests	<input type="checkbox"/>	class..A <input type="checkbox"/> class B <input type="checkbox"/> group 1 <input type="checkbox"/> group 2 <input type="checkbox"/>
		EN 55022:2010 accredited tests	<input type="checkbox"/>	Frequency range.....
10	<b>Electromagnetic disturbance characteristics, measurement of field strength of radiofrequency electromagnetic field radiation (test in a semi-anechoic chamber at 3m measuring distance)</b> Frequency range 30MHz to 1GHz (30MHz to 6GHz) Measuring distance 3 m Load capacity of the turntable 500kg Range of antenna height changes 1m to 4m	EN 55011:2016 accredited tests	<input type="checkbox"/>	class..A <input type="checkbox"/> class B <input type="checkbox"/> group 1 <input type="checkbox"/> group 2 <input type="checkbox"/>
		EN 55022:2010 accredited tests	<input type="checkbox"/>	Frequency range.....
11	<b>Measurement of harmonic currents of electrical and electronic equipment</b> Devices with single-phase power supply of up to 16 A, intended for connection to a public low-voltage distribution network.	EN 61000-3-2:2014 tests outside the scope of accreditation	<input type="checkbox"/>	class A <input type="checkbox"/> class B <input type="checkbox"/> class C <input type="checkbox"/> class D <input type="checkbox"/> Power of the device ..... Continuous work <input type="checkbox"/> Cyclic work <input type="checkbox"/> Cycle times .....
12	<b>Measurement of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems</b> Devices with single-phase power supply of up to 16 A and not subject to conditional connection	PN-EN 61000-3-3:2013 tests outside the scope of accreditation	<input type="checkbox"/>	Power of the device ..... Continuous work <input type="checkbox"/> Cyclic work <input type="checkbox"/> Cycle times .....
<b>PREPARED BY</b>		<b>COMMENTS</b>		
<i>stamp / signature / date</i>				