

## Deutsche Akkreditierungsstelle GmbH

### Annex to the Accreditation Certificate D-PL-11250-01-02 according to DIN EN ISO/IEC 17025:2018

**Valid from: 11.11.2019**

Date of issue: 11.11.2019

Holder of certificate:

**Drägerwerk AG & Co. KGaA  
Moislinger Allee 53-55, 23558 Lübeck**

At the Location:

**Drägerwerk AG & Co. KGaA  
Product Qualification, Prüflabore  
Finkenstraße 5, 23558 Lübeck**

Test in the fields:

**Tests of security and information technology systems, Equipment, Facilities, Components and materials in the test areas Electromagnetic Compatibility, Safety of electrical equipment, Climate and temperature compatibility, mechanical safety, biological tests, chemical-biological tests, Acoustics and alarms, mechanical and physical material testing**

**Within the accredited testing field marked with \*(Category I) and \*\* (Category III) , the testing laboratory is permitted, without being required to inform and obtain prior approval from DAkkS, the following:**

**\*) the free choice of standard methods or equivalent/similar methods within a defined testing field**

**\*\* ) Application of standard test methods with different issue dates**

**Flexible area Page 2-10**

**Not flexible area Page 11**

**Category III \*\***

This document is a translation. The definitive version is the original German annex to the accreditation certificate.

Abbreviations used: see last page

Subject area	Standard / internal method / version	Title of the standard or internal procedure (specify deviations from /modifications of standard procedures)	Testing area / restrictions
EMC	IEC CISPR 11: 2015+A1:2016	Industrial, scientific and medical equipment - Radio frequency disturbance characteristics - Limits and methods of measurement	for test methods only clauses 8.2 & 8.5; for limits in clauses 6.2.2.3, and 6.3.2.3 only FAR 3 m
	DIN EN 55011:2018-05;VDE 0875-11:2018-05	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement (CISPR 11:2015, modified); German version EN 55011:2016 + A1:2017 + A1:2017	for test methods only clauses 8.2 & 8.5; for limits in clauses 6.2.2.3 and 6.3.2.3 only FAR 3 m
	IEC CISPR 16-2-1 2014+AMD1:2017	Specification for radio disturbance and immunity measuring apparatus and methods - Part 2-1: Methods of measurement of disturbances and immunity - Conducted disturbance measurements	
	DIN EN 55016-2-1: 2014-12	Specification for radio disturbance and immunity measuring apparatus and methods - Part 2-1: Methods of measurement of disturbances and immunity - Conducted disturbance measurements (CISPR 16-2-1:2014); German version EN 55016-2-1:2014	
	IEC CISPR 22 2008 mod.	Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement.	
	DIN EN 55022:2011-12	Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement (CISPR 22:2008, modified); German version EN 55022:2010	Without field strength in the frequency range 30 MHz to 1 GHz

**-Translation-**

Abbreviations used: see last page

**Valid from: 11.11.2019**

Date of issue: 11.11.2019

**Annex to the accreditation certificate D-PL-11250-01-02**

Subject area	Standard / internal method / version	Title of the standard or internal procedure (specify deviations from /modifications of standard procedures)	Testing area / restrictions
	IEC CISPR 16-2-3 2016	Specification for radio disturbance and immunity measuring apparatus and methods - Part 2-3: Methods of measurement of disturbances and immunity - Radiated disturbance measurements	only clause 7.4
	DIN EN 55016-2-3: 2014-11	Specification for radio disturbance and immunity measuring apparatus and methods - Part 2-3: Methods of measurement of disturbances and immunity - Radiated disturbance measurements (CISPR 16-2-3:2010 + A1:2010 + A2:2014); German version EN 55016-2-3:2010 + A1:2010 + AC:2013 + A2:2014	Only subchapter 7.4
	IEC 61000-3-2:2018	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current $\leq$ 16A per phase)	Single phase only
	DIN EN 61000-3-2: 2015-03	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current $\leq$ 16 A per phase) (IEC 61000-3-2:2014); German version EN IEC 61000-3-2:2014	Single phase only
	IEC 61000-3-3 2013 + A1:2017	Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current $\leq$ 16 A per phase and not subject to conditional connection	Single phase only
	DIN EN 61000-3-3: 2014-03	Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current $\leq$ 16 A per phase and not subject to conditional connection (IEC 61000-3-3:2013); German version EN 61000-3-3:2013	Single phase only
	IEC 61000-4-2 2008	Electromagnetic compatibility (EMC)- Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test	

**-Translation-**

Abbreviations used: see last page

**Valid from: 11.11.2019**

Date of issue: 11.11.2019

Annex to the accreditation certificate D-PL-11250-01-02

Subject area	Standard / internal method / version	Title of the standard or internal procedure (specify deviations from /modifications of standard procedures)	Testing area / restrictions
	IEC 61000-4-2 2008	Electromagnetic compatibility (EMC)- Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test	
	IEC 61000-4-3 2006+A1:2007 +A2:2010	Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	
	DIN EN 61000-4-3: 2011-04	Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test (IEC 61000-4-3:2006 + A1:2007 + A2:2010); German version EN 61000-4-3:2006 + A1:2008 + A2:2010	
	IEC 61000-4-4 2012	Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient / burst immunity test	
	DIN EN 61000-4-4: 2013-04	Electromagnetic compatibility (EMC) - Part 4- 4:Testing and measurement techniques - Electrical fast transient/burst immunity test (IEC 61000-4-4:2012); German version EN 61000-4-4:2012	
	IEC 61000-4-5 2014+AMD1:2017	Electromagnetic compatibility (EMC)- Part 4-5: Testing and measurement techniques - Surge immunity test	
	DIN EN 61000-4-5: 2015-03	Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test (IEC 61000-4-5:2014 + A1:2017); German version EN 61000-4-5:2014	
	IEC 61000-4-6 2013	Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields	
	DIN EN 61000-4-6: 2014-08	Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields (IEC 61000-4-6:2013); German version EN 61000-4-6:2014	

**-Translation-**

Abbreviations used: see last page

**Valid from: 11.11.2019**

Date of issue: 11.11.2019

**Annex to the accreditation certificate D-PL-11250-01-02**

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	IEC 61000-4-8 2009	Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test	
	DIN EN 61000-4-8: 2010-11	Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test (IEC 61000-4-8:2009); German version EN 61000-4-8:2010	
	IEC 61000-4-11 2004+A1:2017	Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests	Single phase only
	DIN EN 61000-4-11 : 2005-02	Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests (IEC 61000-4-11:2004); German version EN 61000-4-11:2004	Single phase only
	IEC 61000-6-1:2016	Electromagnetic compatibility (EMC) - Part 6-1: Generic standards - Immunity standard for residential, commercial and light-industrial environments	
	DIN EN 61000-6-1: 2007-10	Electromagnetic compatibility (EMC) - Part 6-1: Generic standards - Immunity for residential, commercial and light-industrial environments (IEC 61000-6-1:2005); German version EN 61000-6-1:2007	
	IEC 61000-6-2:2016	Electromagnetic compatibility (EMC) - Part 6-2: Generic standards - Immunity standard for industrial environments	
	DIN EN 61000-6-2: 2006-03	Electromagnetic compatibility (EMC) - Part 6-2: Generic standards - Immunity for industrial environments (IEC 61000-6-2:2005); German version EN 61000-6-2:2005	
	IEC 61000-6-3: 2006+AMD1:2010	Electromagnetic compatibility (EMC) - Part 6-3: Generic standards - Emission standard for residential, commercial and light-industrial environments	FAR only

**-Translation-**

Abbreviations used: see last page

**Valid from: 11.11.2019**

Date of issue: 11.11.2019

**Annex to the accreditation certificate D-PL-11250-01-02**

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	DIN EN 61000-6-3: 2011-09	Electromagnetic compatibility (EMC) - Part 6-3: Generic standards - Emission standard for residential, commercial and light-industrial environments (IEC 61000-6-3:2006 + A1:2010); German version EN 61000-6-3:2007 + A1:2011	FAR only
	IEC 61000-6-4:2018	Electromagnetic compatibility (EMC) - Part 6-4: Generic standards - Emission standard for industrial environments	FAR only
	DIN EN 61000-6-4:2011-09	Electromagnetic compatibility (EMC) - Part 6-4: Generic standards - Emission standard for industrial environments (IEC 61000-6-4:2006 + A1:2010); German version EN 61000-6-4:2007 + A1:2011	FAR only
	IEC 61326-1:2012	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements	Without radio interference field strength
	DIN EN 61326-1: 2013-07	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements (IEC 61326-1:2012); German version EN 61326-1:2013	Without radio interference field strength
	IEC 61326-2-1:2012	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-1: Particular requirements - Test configurations, operational conditions and performance criteria for sensitive test and measurement equipment for EMC unprotected applications	Without radio interference field strength
	DIN EN 61326-2-1: 2013-08	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-1: Particular requirements - Test configurations, operational conditions and performance criteria for sensitive test and measurement equipment for EMC unprotected applications (IEC 61326-2-1:2012); German version EN 61326-2-1:2013	Without radio interference field strength

**-Translation-**

Abbreviations used: see last page

**Valid from: 11.11.2019**

Date of issue: 11.11.2019

**Annex to the accreditation certificate D-PL-11250-01-02**

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	DIN EN 50270:2015-10; & Corrigendum 1: 2016-11	Electromagnetic compatibility - Electrical apparatus for the detection and measurement of combustible gases, toxic gases or oxygen; German version EN 50270:2015,	For radio interference field strength FAR only Without EN 61000-4-29

**-Translation-**

Abbreviations used: see last page

**Valid from: 11.11.2019**

Date of issue: 11.11.2019

**Annex to the accreditation certificate D-PL-11250-01-02**

Subject area	Standard / internal method / version	Title of the standard or internal procedure (specify deviations from / modifications of standard procedures)	Testing area / restrictions
Environmental simulation	IEC 60068-2-1 2007	Environmental testing - Part 2-1: Tests - Test A: Cold	
	IEC 60068-2-2 2007	Environmental testing - Part 2-2: Tests - Test B: Dry heat	
	IEC 60068-2-13 1983	Basic environmental testing procedures - Part 2-13: Tests - Test M: Low air pressure	
	IEC 60068-2-14 2009	Environmental testing - Part 2-14: Tests - Test N: Change of temperature	
	IEC 60068-2-78 2012 2001	Environmental testing - Part 2-78: Tests - Test Cab: Damp heat, steady state	
	IEC 60529 1989+A1:1999 +A2:2013	Degrees of protection provided by enclosures (IP Code)	IP x1 to IP x4, IP1x to IP4x
	IEC 60068-2-6 2007	Environmental testing - Part 2-6: Tests - Tests Fc: Vibration Sinusoidal  Tests Fc: Vibration Sinusoidal	
IEC 60068-2-27 2008	Environmental testing. Part 2-27: Tests - Test Ea and guidance: Shock		
IEC 60068-2-64 2008	Environmental testing - Part 2-64: Tests - Tests Fh: Vibration Broad-band random and guidance  Tests Fh: Vibration Broad-band random and guidance		
RTCA DO 160 G:2010+Change1:2014 F:2007	Environmental conditions and test procedures for airborne equipment - Section 7 Operational Shocks and Crash Safety - Section 8 Vibration		

**-Translation-**

Abbreviations used: see last page

**Valid from: 11.11.2019**

Date of issue: 11.11.2019



**Annex to the accreditation certificate D-PL-11250-01-02**

Subject area	Standard / internal method / version	Title of the standard or internal procedure (specify deviations from / modifications of standard procedures)	Testing area / restrictions
Environmental simulation (acoustics)	ISO 3744 2010	Acoustics -- Determination of sound power levels and sound energy levels of noise sources using sound pressure -- Engineering methods for an essentially free field over a reflecting plane	
	ISO 3746 2010	Acoustics -- Determination of sound power levels and sound energy levels of noise sources using sound pressure -- Survey method using an enveloping measurement surface over a reflecting plane	
Electrical equipment	IEC 60598-2-9 1987+A1:1993	Luminaires. Part 2: Particular requirements. Section Nine: Photo and film luminaires (non-professional)	

**Flexible Accreditation according to Category I \***

Type of test	Measured variable / Test parameters	Measuring and testing area	Measurement uncertainty* (k=2)	Characteristic test methods
Chemical-biological review	Gaseous organic emissions	Boiling range 50–300°C	On demand (substance-dependent)	DMS TC5019
	Vaporizable contaminants in anesthetics	Boiling range 50–300°C	On demand (substance-dependent)	DMS TC5023 DMS TC5062 <sup>⊗</sup>
	Determination of the mass of emitted particles (weighing)	particle size > 0,2µm diameter	On demand	DMS TC5022

Type of test	Measured variable / Test parameters	Measuring and testing area	Measurement uncertainty* (k=2)	Characteristic test methods
Temperature	Temperature of surfaces & air	-40°C – 180°C  180°C – 450°C	+/- 0,6 K (Pt100), +/- 1,6 K (thermocouple) +/- 2,6 K (thermocouple)	60068-2-14

**-Translation-**

Abbreviations used: see last page

**Valid from: 11.11.2019**

Date of issue: 11.11.2019

**Annex to the accreditation certificate D-PL-11250-01-02**

Type of test	Measured variable / Test parameters	Measuring and testing area	Measurement uncertainty * (k=2)	Characteristic test methods
Air pressure	Ambient air pressure	10 kPa – 120 kPa	+/- 0,9 kPa	60068-2-13
Climate compatibility	Relative humidity	5 % – 10 % r.h. (30°C – 75°C), 10 % – 95 % r.h. (20°C – 75°C)	± 5 % r.h. Humidity-constant in time;; ± 3 % r.h. Nominal humidity	IEC 60068-2-78
	Temperature / temperature changes	-40°C – +180°C	max. ± 1,25 K Temperature homogeneity spatially, ± 0,5 K temporal	IEC 60068-2-1, IEC 60068-2-2, IEC 60068-2-14
	Vacuum	10 kPa – 120 kPa	≥ 20 kPa: ± 10 % v. setpoint; 10-20 kPa: ± 18 % f. setpoint	IEC 60068-2-13
Protection against water	Flow	1 – 6 mm/min; 10 l/min	-0/+0,5 mm/min; ± 0,5 l/min	IEC 60529 (IP x1 – x2) IEC 60529 (IP x3 – x4)
Mechanical security, dynamic tests	Quickening	1 – 1000 m/s <sup>2</sup> ;	Sinus, Shock: ± 5% from the setpoint; Sough: ± 1,2 dB at 120 DOF	IEC 60068-2-6 IEC 60068-2-27 IEC 60068-2-64
	Frequency range	5 Hz – 2000 Hz	Sinus, Schock: ± 50 ppm from the setpoint; Sough: ± 0,125 Hz	

**-Translation-**

Abbreviations used: see last page

**Valid from: 11.11.2019**

Date of issue: 11.11.2019

**Not flexible area (Page 11)**

Subject area	Standard / internal method / version	Title of the standard or internal procedure (specify deviations from / modifications of standard procedures)	Testing area / restrictions
Environment simulation	DMS IN9030 2015	Climatic and thermal compatibility of medical devices and modules	
	DMS IN9040 2015	Test specification for mechanical safety and environmental tests	
	DMS IN9080 2015 2010	Combustion safety in normal and oxygenized Atmospheres	
Chemical-biological tests	DMS TC5019 2019 2017 2015	Integral testing - biocompatibility	VOC Boiling range 50-300°C
	DMS TC5021 2015	Luminescent bacteria test - biocompatibility	
	DMS TC5023 2019 2015	Anesthetic agent changes - biocompatibility	
	DMS TC5062 <sup>⊗</sup> 2015	Analysis of impurities by plastics in anesthetics	boiling range 50-300°C

**-Translation-**

Abbreviations used: see last page

**Valid from: 11.11.2019**

Date of issue: 11.11.2019

**Abbreviations used:**

AAMI	Association for the Advancement of Medical Instrumentation
ABNT NBR	Associação Brasileira de Normas Técnicas
ANSI	American National Standards Institute
AS/NZS	Australian Standard / New Zealand Standard
ASTM	American Society for Testing Materials
CAN	Canadian
CISPR	Comité International Spécial Des Perturbations Radioélectriques
CSA	Canadian Standard Association
DIN	Deutsches Institut für Normung
DMS IN	Dräger SOP
DMS TC	Dräger SOP Testing & Calibration
EN	Europäische Norm
EUROCAE	European Organization for Civil Aviation Equipment
GB	Guobiao (PR China)
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
JIS	Japanese Industrial Standards
MIL-STD	Military Standard (USA)
RTCA	Radio Technical Commission for Aeronautics
UL	Underwriters Laboratories
YY	Code for Medical Industrial Standards (PR China)
⊗	Standards withdrawn from standardization

**-Translation-**

Abbreviations used: see last page

**Valid from: 11.11.2019**

Date of issue: 11.11.2019