Deutsche Akkreditierungsstelle GmbH

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

Valid from: **29.04.2021**

Date of issue: 09.06.2021

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

Tests 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

The management system requirements of DIN EN ISO/IEC 17025 are written in the language relevant to the operations of testing laboratories. Laboratories that conform to the requirements of this standard, operate generally in accordance with the principles of DIN EN ISO 9001.

The certificate together with the annex reflects the status as indicated by the date of issue.
The current status of any given scope of accreditation may be found respectively in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH https://www.dakks.de/en/content/accredited-bodies-dakks.

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

The testing laboratory is permitted, without being required to inform and obtain prior approval from DAkkS, to use standards or equivalent testing methods listed here with different issue dates.

The testing laboratory maintains a current list of all testing methods within the flexible scope of accreditation.

Within the given testing field marked with *), the testing laboratory is permitted, without being required to inform and obtain prior approval from DAkkS, the following:
1) the free choice of standard or equivalent testing methods.

The listed testing methods are exemplary. The testing laboratory maintains a current list of all testing methods within the flexible scope of accreditation.

Flexible area Page 2-13
Not flexible area Page 14

Category III

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 +A2:2019	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
EMC	DIN EN 55011:2018-05+A2:2020;VDE 0875-11:2018-05+A2:2020	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

Subject area	Standard / internal method / version	Title of the standard or internal procedure (specify deviations from /modifications of standard procedures)	Testing area / restrictions
EMC	BS EN 55011 2016+A11:2020	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
EMC	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	
EMC	DIN EN 55016-2-1:2019-11;VDE 0877-16-2-1:2019-11	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 + A1:2017); German version EN 55016-2-1:2014 + A1:2017	
EMC	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	
EMC	IEC CISPR 22 2008 mod.	Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement.	
EMC	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

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 16-2-3 2016+A1:2019	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
EMC	BS EN 55016-2-3:2017+A1:2019	Specification for radio disturbance and immunity measuring apparatus and methods. Methods of measurement of disturbances and immunity. Radiated disturbance measurements	only clause 7.4
EMC	DIN EN 55016-2-3:2019-06; VDE 0877-16-2-3:2019-06	Specification for radio disturbance and immunity measuring apparatus and methods - Part 2-3: Methods of measurement of disturbances and immunity - Radiated disturbance measurements (CISPR 16-2-3:2016); German version EN 55016-2-3:2017	only clause 7.4
EMC	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
EMC	IEC 61000-3-2:2018 + A1:2020	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16A per phase)	Single phase only
EMC	BS EN IEC 61000-3-2:2019-03-05	Electromagnetic compatibility (EMC). Limits. Limits for harmonic current emissions (equipment input current =16 A per phase)	Single phase only

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EMC	DIN EN IEC 61000-3-2:2019-12; VDE 0838-2:2019-12	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase) (IEC 61000-3-2:2018); German version EN IEC 61000-3-2:2019	Single phase only
EMC	DIN EN 61000-3-2: 2015-03⊗	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase) (IEC 61000-3-2:2014); German version EN IEC 61000-3-2:2014	Single phase only
EMC	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 ≤ 16 A per phase and not subject to conditional connection	Single phase only
EMC	BS EN 61000-3-3:2013+A1:2019	Electromagnetic compatibility (EMC). Limits. Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection	Single phase only
EMC	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 ≤ 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
EMC	IEC 61000-4-2 2008	Electromagnetic compatibility (EMC)- Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test	
EMC	IEC 61000-4-2 2008	Electromagnetic compatibility (EMC)- Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test	

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 61000-4-3 2020	Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	
EMC	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	
EMC	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	
EMC	IEC 61000-4-4 2012	Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient / burst immunity test	
EMC	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	
EMC	IEC 61000-4-5 2014+AMD1:2017	Electromagnetic compatibility (EMC)- Part 4-5: Testing and measurement techniques - Surge immunity test	without waveform of 10/700 µs / 5/320 µs
EMC	DIN EN 61000-4-5:2019-03;VDE 0847-4-5:2019-03	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 + A1:2017	without waveform of 10/700 µs / 5/320 µs
EMC	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	

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 61000-4-6 2013	Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields	
EMC	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	
EMC	IEC 61000-4-8 2009	Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test	
EMC	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	
EMC	IEC 61000-4-11 2020	Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests for equipment with input current up to 16 A per phase	Single phase only
EMC	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
EMC	DIN EN 61000-4-11:2019-06;VDE 0847-4-11:2019-06	Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests (IEC 61000-4-11:2004 + A1:2017); German version EN 61000-4-11:2004 + A1:2017	Single phase only

Subject area	Standard / internal method / version	Title of the standard or internal procedure (specify deviations from /modifications of standard procedures)	Testing area / restrictions
EMC	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
EMC	IEC 61000-4-39 2017	Electromagnetic compatibility (EMC) - Part 4-39: Testing and measurement techniques - Radiated fields in close proximity - Immunity test	magnetic field immunity (9 KHz – 26 MHz) only
EMC	IEC 61000-6-1:2016	Electromagnetic compatibility (EMC) - Part 6-1: Generic standards - Immunity standard for residential, commercial and light-industrial environments	
EMC	DIN EN IEC 61000-6-1:2019-11;VDE 0839-6-1:2019-11	Electromagnetic compatibility (EMC) - Part 6-1: Generic standards - Immunity standard for residential, commercial and light-industrial environments (IEC 61000-6-1:2016); German version EN IEC 61000-6-1:2019	
EMC	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	
EMC	IEC 61000-6-2:2016	Electromagnetic compatibility (EMC) - Part 6-2: Generic standards - Immunity standard for industrial environments	
EMC	DIN EN IEC 61000-6-2:2019-11;VDE 0839-6-2:2019-11	Electromagnetic compatibility (EMC) - Part 6-2: Generic standards - Immunity standard for industrial environments (IEC 61000-6-2:2016); German version EN IEC 61000-6-2:2019	
EMC	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	

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 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
EMC	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
EMC	IEC 61000-6-4:2018	Electromagnetic compatibility (EMC) - Part 6-4: Generic standards - Emission standard for industrial environments	FAR only
EMC	BS EN IEC 61000-6-4:2019-09-30	Electromagnetic compatibility (EMC). Generic standards. Emission standard for industrial environments	FAR only
EMC	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
EMC	IEC 61326-1:2012	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements	Without radio interference field strength
EMC	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
EMC	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

Subject area	Standard / internal method / version	Title of the standard or internal procedure (specify deviations from /modifications of standard procedures)	Testing area / restrictions
EMC	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
EMC	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

Subject area	Standard / internal method / version	Title of the standard or internal procedure (specify deviations from / modifications of standard procedres)	Testing area / restrictions
Environ-mental simulation	IEC 60068-2-1 2007	Environmental testing - Part 2-1: Tests - Test A: Cold	
Environ-mental simulation	IEC 60068-2-2 2007	Environmental testing - Part 2-2: Tests - Test B: Dry heat	
Environ-mental simulation	IEC 60068-2-13 1983	Basic environmental testing procedures - Part 2-13: Tests - Test M: Low air pressure	
Environ-mental simulation	IEC 60068-2-14 2009	Environmental testing - Part 2-14: Tests - Test N: Change of temperature	
Environ-mental simulation	IEC 60068-2-78 2012 2001	Environmental testing - Part 2-78: Tests - Test Cab: Damp heat, steady state	
Environ-mental simulation	IEC 60529 1989+A1:1999 +A2:2013+Cor1:2019	Degrees of protection provided by enclosures (IP Code)	IP x1 to IP x4, IP1x to IP4x
Environ-mental simulation	IEC 60068-2-6 2007	Environmental testing - Part 2-6: Tests - Tests Fc: Vibration Sinusoidal Tests Fc: Vibration Sinusoidal	
Environ-mental simulation	IEC 60068-2-27 2008	Environmental testing. Part 2-27: Tests - Test Ea and guidance: Shock	
Environ-mental simulation	IEC 60068-2-64 2008 + A1:2019	Environmental testing - Part 2-64: Tests - Tests Fh: Vibration Broad-band random and guidance Tests Fh: Vibration Broad-band random and guidance	
Environ-mental simulation	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	

Subject area	Standard / internal method / version	Title of the standard or internal procedure (specify deviations from / modifications of standard procedres)	Testing area / restrictions
Environ-mental 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	
Environ-mental simulation (acoustics)	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	

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⊗
	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)	IEC 60068-2-14
Air pressure	Ambient air pressure	10 kPa – 120 kPa	+/- 0,9 kPa	IEC 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	Acceleration	1 – 1000 m/s^2;	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 + A1:2019
	Frequency range	5 Hz – 2000 Hz	Sinus, Schock: ± 50 ppm from the setpoint; Sough: ± 0,125 Hz	

Not flexible area (Page 14)

Subject area	Standard / internal method / version	Title of the standard or internal procedure (specify deviations from / modifications of standard procedres)	Testing area / restrictions
Environmental simulation	DMS IN9030 2015	Climatic and thermal compatibility of medical devices and modules	
	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⊗ 2015	Analysis of impurities by plastics in anesthetics	boiling range 50-300°C

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