Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-19882-01-01 according to DIN EN ISO/IEC 17025:2018[1]

Valid from: **11.07.2022**

Date of issue: 28.09.2022

Holder of certificate:

Keysight Technologies Deutschland GmbH
Hardware Test Center Europe
Herrenberger Straße 130, 71034 Böblingen

Field:	Medical devices
Testing fields/test items:	Safety tests and compatibility tests with regard to electromagnetic disturbances (EMC) of active medical devices and IVD devices

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 can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH (DAkkS) at https://www.dakks.de/en/accredited-bodies-search.html

Abbreviations used: see last page

Scope

Testing field	**Test item** **Product(category)**	**Type of testing** **Test**	**Regulation** **Test method**
Safety tests	In-vitro Diagnostic-(IVD-) Medical equipment	Compliance Tests for Basic Safety and Essential Performance	DIN EN 61010-2-101 IEC 61010-2-101
EMC	Medical devices, active	Compliance Tests - Emissions - Immunity	DIN EN 60601-1-2 IEC 60601-1-2
	Information provided by the manufacturer - Markings - Designations - user manual / accompanying documents	Compliance Tests	<u>Applicable:</u> IEC/TR 60601-4-2
	Care ventilators; Oxygen therapy-(including. Hyperbaric Therapy chamber) and Inhalation anesthesia equipment - anaesthetic workstation - respiratory gas monitors	Compliance Tests for Basic Safety and Essential Performance	DIN EN ISO 80601-2-13 DIN EN ISO 80601-2-55
	Surgical equipment and surgical auxiliary equipment - High frequency surgical equipment and accessories	Compliance Tests for Basic Safety and Essential Performance	DIN EN 60601-2-2 IEC 60601-2-2

Testing field	Test item Product(category)	Type of testing Test	Regulation Test method
EMC	Imaging equipment with non-ionizing radiation - Ultrasonic medical diagnostic and monitoring equipment	Compliance Tests for Basic Safety and Essential Performance	DIN EN 60601-2-37 IEC 60601-2-37
	Equipment for monitoring - Multifunction patient monitoring equipment	Compliance Tests for Basic Safety and Essential Performance	DIN EN IEC 80601-2-49 DIN EN 60601-2-49⊗ IEC 60601-2-49⊗
	Equipment for monitoring of non-vital Physiological parameters - Electroencephalo-graphs - Transcutaneous partial pressure monitoring equipment - Clinical thermometers for body temperature measurement	Compliance Tests for Basic Safety and Essential Performance	DIN EN 60601-2-26 IEC 80601-2-26 IEC 60601-2-26 DIN EN 60601-2-23 IEC 60601-2-23 DIN EN ISO 80601-2-56
	Equipment for monitoring of vital parameters - automated noninvasive sphygmomano-meters - Invasive blood pressure	Compliance Tests for Basic Safety and Essential Performance	DIN EN IEC 80601-2-30 DIN EN 60601-2-34 IEC 60601-2-34

Testing field	Test item Product(category)	Type of testing Test	Regulation Test method
	monitoring equipment		
EMC	Equipment for monitoring of vital parameters - Electro-cardiographs - Pulse oximeter equipment	Compliance Tests for Basic Safety and Essential Performance	DIN EN 60601-2-25 IEC 60601-2-25 DIN EN 60601-2-27 IEC 60601-2-27 DIN EN ISO 80601-2-61
	Devices for Radiation and Thermo-therapy Equipment with non-ionizing radiation - Ultrasonic Physiotherapy equipment	Compliance Tests for Basic Safety and Essential Performance	DIN EN 60601-2-5 IEC 60601-2-5
	In-vitro Diagnostic-(IVD-) Medical equipment	Compliance Tests - Emissions - Immunity	DIN EN 61326-2-6 IEC 61326-2-6
	Information provided by the manufacturer - Markings - Designations - user manual / accompanying documents	Compliance Tests	

If exclusions of partial tests exist they are not listed in the scope of the accreditation. The test lab has to notify the client of those exclusions while clarifying an order.

The assessment for accreditation was performed taking into account the normative references of the European standards (DIN EN). The normative references of the international standards (IEC, ISO) have not been taken into account unless the referenced international versions of the standards are explicitly listed in the annex to the notice.

Regulations:

DIN EN 60601-1-2 : 2016-05	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests (IEC 60601-1-2:2014); German version EN 60601-1-2:2015 VDE 0750-1-2:2016-05 DIN EN 60601-1-2 : 2007-12⊗ - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2007, modified); German version EN 60601-1-2:2007 VDE 0750-1-2:2007-12
DIN EN 60601-2-5 : 2016-08	Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment (IEC 60601-2-5:2009); German version EN 60601-2-5:2015 VDE 0750-2-5:2016-08
DIN EN 60601-2-23 : 2016-08	Medical electrical equipment - Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment (IEC 60601-2-23:2011); German version EN 60601-2-23:2015 VDE 0750-2-23 : 2016-08 DIN EN 60601-2-23 : 2000-11⊗ - Medical electrical equipment - Part 2-23: Particular requirements for the safety, including essential performance, of transcutaneous partial pressure monitoring equipment (IEC 60601-2-23:1999); German version EN 60601-2-23:2000 VDE 0750-2-23:2000-11⊗
DIN EN 60601-2-25 : 2016-08	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs (IEC 60601-2-25:2011); German version EN 60601-2-25:2015 VDE 0750-2-25:2016-08 DIN EN 60601-2-25 : 2001-04⊗ - Medical electrical equipment - Part 2-25: Particular requirements for the safety of electrocardiographs (IEC 60601-2-25:1993 + A1:1999); German version EN 60601-2-25:1995 + A1:1999 VDE 0750-2-25:2001-04⊗

DIN EN 60601-2-26 : 2016-02	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs (IEC 60601-2-26:2012); German version EN 60601-2-26:2015 VDE 0750-2-26:2016-02 DIN EN 60601-2-26 : 2004-01⊗ - Medical electrical equipment - Part 2-26: Particular requirements for the safety of electroencephalographs (IEC 60601-2-26:2002); German version EN 60601-2-26:2003 VDE 0750-2-26:2004-01⊗
DIN EN 60601-2-27 : 2015-04	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment (IEC 60601-2-27:2011 + Cor.:2012); German version EN 60601-2-27:2014 VDE 0750-2-27:2015-04 DIN EN 60601-2-27 : 2006-08⊗ - Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment (IEC 60601-2-27:2005); German version EN 60601-2-27:2006 + Corrigendum 1 : 2007-05⊗ VDE 0750-2-27:2007-05⊗
DIN EN 60601-2-34 : 2015-01	Medical electrical equipment - Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment (IEC 60601-2-34:2011); German version EN 60601-2-34:2014 VDE 0750-2-34:2015-01 DIN EN 60601-2-34 : 2001-11⊗ - Medical electrical equipment - Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment (IEC 60601-2-34:2000); German version EN 60601-2-34:2000 VDE 0750-2-34:2001-11⊗

DIN EN 60601-2-37 : 2016-11	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment (IEC 60601-2-37:2007 + A1:2015); German version EN 60601-2-37:2008 + A11:2011 + A1:2015 VDE 0750-2-37:2016-11 DIN EN 60601-2-37 : 2012-05⊗ - Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment (IEC 60601-2-37:2007); German version EN 60601-2-37:2008 + A11:2011 VDE 0750-2-37:2012-05⊗
DIN EN 60601-2-49 : 2016-10⊗	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment (IEC 60601-2-49:2011); German version EN 60601-2-49:2015 VDE 0750-49 : 2016-10⊗ DIN EN 60601-2-49 : 2002-12⊗ - Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment (IEC 60601-2-49:2001); German version EN 60601-2-49:2001 VDE 0750-2-49:2002-12⊗
DIN EN 61010-2-101 : 2017-10	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment (IEC 61010-2-101:2015); German version EN 61010-2-101:2017 VDE 0411-2-101:2017-10 (in connection with DIN EN 61010-1 : 2011-07, as long as there is a valid accreditation for this) DIN EN 61010-2-101 : 2003-09⊗ - Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment (IEC 61010-2-101:2002, modified); German version EN 61010-2-101:2002 VDE 0411-2-101:2003-09⊗ (in connection with DIN EN 61010-1 : 2002-08, as long as there is a valid accreditation for this)

DIN EN 61326-2-6 : 2013-09	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment (IEC 61326-2-6:2012); German version EN 61326-2-6:2013 VDE 0843-20-2-6:2013-09 (in connection with DIN EN 61326-1 : 2013-07, as long as there is a valid accreditation for this)
DIN EN ISO 80601-2-13 : 2013-03	Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation (ISO 80601-2-13:2011 + A1:2015 + A2:2018); German version EN ISO 80601-2-13:2012 + A1:2019 + A2:2019 VDE 0750-2-13:2013-03 + Amendment 1 : 2020-06 + Amendment 2 : 2020-06
DIN EN IEC 80601-2-30 : 2020-03	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers (IEC 80601-2-30:2018); German version EN IEC 80601-2-30:2019 DIN EN 80601-2-30 : 2016-02⊗ - Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers (IEC 80601-2-30:2009 + Corrigendum Jan. 2010 + A1:2013); German version EN 80601-2-30:2010 + A1:2015 VDE 0750-2-30 : 2016-02⊗ DIN EN 80601-2-30 : 2011-05⊗ - Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated type non-invasive sphygmomanometers (IEC 80601-2-30:2009 + Cor. :2010); German version EN 80601-2-30:2010 VDE 0750-2-30:2011-05⊗
DIN EN IEC 80601-2-49 : 2020-10	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment (IEC 80601-2-49:2018); German version EN IEC 80601-2-49:2019 VDE 0750-49 : 2020-10

DIN EN ISO 80601-2-55 : 2019-03	Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 80601-2-55:2018); German version EN ISO 80601-2-55:2018 DIN EN ISO 80601-2-55 : 2012-03⊗ - Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 80601-2-55:2011); German version EN ISO 80601-2-55:2011 VDE 0750-2-55:2012-03⊗
DIN EN ISO 80601-2-56 : 2020-08	Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement (ISO 80601-2-56:2017 + Amd1:2018); German version EN ISO 80601-2-56:2017 + A1:2020 DIN EN ISO 80601-2-56 : 2018-02⊗ - Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement (ISO 80601-2-56:2017); German version EN ISO 80601-2-56:2017 DIN EN ISO 80601-2-56 : 2013-02⊗ - Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement (ISO 80601-2-56:2009); German version EN ISO 80601-2-56:2012
DIN EN ISO 80601-2-61 : 2019-09	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment (ISO 80601-2-61:2017, Corrected version 2018-02); German version EN ISO 80601-2-61:2019 DIN EN ISO 80601-2-61 : 2012-01⊗ - Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment (ISO 80601-2-61:2011); German version EN ISO 80601-2-61:2011 VDE 0750-2-61:2012-01⊗

IEC 60601-1-2 : 2014-02	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests + Amendment 1 : 2020-09 IEC 60601-1-2 : 2007-03⊗ - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-2-5 : 2009-07	Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment
IEC 60601-2-23 : 2011-02	Medical electrical equipment - Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment
IEC 60601-2-25 : 2011-10	Medical electrical equipment - Part 2-25: Particular requirements for basic safety and essential performance of electrocardiographs
IEC 60601-2-26 : 2012-05⊗	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
IEC 60601-2-27 : 2011-03	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
IEC 60601-2-34 : 2011-05	Medical electrical equipment - Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment
IEC 60601-2-37 : 2007-08	Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment + Amendment 1 : 2015-07
IEC 60601-2-49 : 2011-02⊗	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
IEC TR 60601-4-2 : 2016-05	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

IEC 61010-2-101 : 2018-10	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical Equipment IEC 61010-2-101 : 2015-01⊗ - Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment (in conjunction with IEC 61010-1 : 2010-06 as long as a valid accreditation therefor exists) IEC 61010-2-101 : 2002-01⊗ - Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment (in conjunction with IEC 61010-1 : 2001-02⊗, as long as a valid accreditation therefor exists)
IEC 61326-2-6 : 2020-10	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment IEC 61326-2-6 : 2012-07⊗ - Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment (in conjunction with IEC 61326-1 : 2012-07, as long as a valid accreditation therefor exists)
IEC 80601-2-26 : 2019-05	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs

Abbreviations used:

DIN	German Institute for Standardization (Deutsches Institut für Normung)
EN	European standard
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
Medical devices, active	Medical electrical equipment, medical electrical systems and components
⊗	Withdrawn standards from standardization in the field of active medical devices that are still in use due to existing regulatory requirements outside Europe

[1] DIN EN ISO/IEC 17025:2018: General requirements for the competence of testing and calibration laboratories