

## Deutsche Akkreditierungsstelle

### Annex to the Accreditation Certificate D-PL-12092-01-01 according to DIN EN ISO/IEC 17025:2018

**Valid from:** 09.03.2026

**Date of issue:** 09.03.2026

**This annex is part of the Accreditation Certificate D-PL-12092-01-00.**

Holder of the Accreditation Certificate:

**Eurofins Product Service GmbH  
Storkower Straße 38 C, 15526 Reichenwalde b. Berlin**

with the location

**Eurofins Product Service GmbH  
Storkower Straße 38 C, 15526 Reichenwalde b. Berlin**

The testing laboratory meets the requirements of DIN EN ISO/IEC 17025:2018 to carry out the conformity assessment activities listed in this annex. The testing laboratory meets additional legal and normative requirements, if applicable, including those in relevant sectoral schemes, provided that these are explicitly confirmed below.

The management system requirements of DIN EN ISO/IEC 17025 are written in the language relevant to the operations of testing laboratories and they conform to the principles of DIN EN ISO 9001.

**Safety tests and compatibility tests with regard to electromagnetic disturbances (EMC) of active medical devices and IVD devices**

outside of a recognition according to § 18 of the Medical Device Law Implementation Act.

*This annex to the certificate was issued by the Deutsche Akkreditierungsstelle GmbH (DAkkS) and is digitally sealed.  
This annex to the certificate is only valid together with the written accreditation certificate and reflects the status as indicated by the date of issue. The current status of any valid and surveyed accreditation can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH ([www.dakks.de](http://www.dakks.de)).*

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Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
Safety tests	Medical devices, active	<p>Compliance Tests</p> <p>Components and ME systems</p> <ul style="list-style-type: none"> <li>- Without tests on lithium batteries</li> <li>- Electrical tests and protection against electrical hazards</li> <li>- Without tests on CF application parts</li> </ul> <p>Mechanical strength and protection against mechanical hazards</p> <ul style="list-style-type: none"> <li>- Without laser and LED tests</li> </ul> <p>Protection against excessive temperatures including fire prevention</p> <ul style="list-style-type: none"> <li>- Without spark ignition tests according to appendix G</li> </ul> <p>Environmental simulation tests</p> <ul style="list-style-type: none"> <li>- Without resistance tests on natural latex</li> </ul>	<p>DIN EN 60601-1 IEC 60601-1</p> <p>DIN EN 60601-1-1<sup>⊗</sup> IEC 60601-1-1<sup>⊗</sup></p>
	Information provided by the manufacturer	<ul style="list-style-type: none"> <li>- Compliance tests</li> </ul>	
	<ul style="list-style-type: none"> <li>- For components and assemblies</li> <li>- For biocompatibility</li> <li>- User manual / accompanying documents</li> <li>- Usability file</li> </ul>		

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Safety tests	<ul style="list-style-type: none"> <li>- For programmable electrical medical systems (PEMS)</li> <li>- Risk management file</li> <li>- For radiation, ionizing / non-ionizing</li> </ul>		DIN EN 60601-1-4 <sup>⊗</sup> IEC 60601-1-4 <sup>⊗</sup>
	<ul style="list-style-type: none"> <li>- Medical devices, active</li> </ul>	Compliance tests <ul style="list-style-type: none"> <li>- Visual alarms</li> <li>- Acoustic slarms</li> </ul>	DIN EN 60601-1-8 IEC 60601-1-8
	Information provided by the manufacturer <ul style="list-style-type: none"> <li>- User manual / accompanying documents / technical descriptions</li> <li>- Risk management file</li> </ul>		
Safety tests	Information provided by the manufacturer regarding physiologic closed-loop controllers <ul style="list-style-type: none"> <li>- User manual / accompanying documents</li> <li>- Usability file</li> <li>- Risk managment file</li> <li>- For programmable electrical medical systems (PEMS)</li> </ul>	Compliance tests	DIN EN 60601-1-10 IEC 60601-1-10
	Medical devices, active, for use in the home healthcare environment	Compliance tests  Mechanical strength and protection against mechanical hazards	DIN EN 60601-1-11 IEC 60601-1-11
			Protection against excessive temperatures including fire prevention

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		Environmental simulation tests	
	Information provided by the manufacturer - User manual / accompanying documents - Usability file - Risk management file		
	- Medical devices, active, for use in the emergency medical services environment	Compliance tests  Environmental simulation tests	DIN EN 60601-1-12 IEC 60601-1-12
	Medical devices, active, general  Hearing aid	Test of proof for compliance	DIN EN IEC 60601-2-66 IEC 60601-2-66 <sup>⊗</sup>
	Equipment for stimulation or inhibition - Nerve and muscle stimulators - External cardiac pacemakers with internal power source	Compliance tests for general and special specifications	DIN EN 60601-2-10 IEC 60601-2-10 DIN EN IEC 60601-2-31 IEC 60601-2-31
	- Sterilizers and washer-disinfectors	Compliance tests for general and special specifications	DIN EN IEC 61010-2-040 IEC 60601-2-040
	Surgical equipment and auxiliary surgical equipment - Endoscopic equipment  - HF surgical equipment and accessories	Compliance tests for general and special specifications	DIN EN 60601-2-18 IEC 60601-2-18  DIN EN 60601-2-2 IEC 60601-2-2

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Safety tests	Patient positioning and transport equipment - Medical beds  - Operating tables	Compliance tests for general and special specifications	DIN EN 60601-2-52 IEC 60601-2-52 DIN EN 50637 DIN EN 60601-2-46 IEC 60601-2-46
	Equipment for monitoring  - Multifunction patient monitoring equipment	Compliance tests for general and special specifications	DIN EN IEC 80601-2-49 DIN EN 60601-2-49 <sup>⊗</sup> IEC 60601-2-49 <sup>⊗</sup>
	Equipment for monitoring non-vital physiological parameters  - Electroencephalographs  - Electromyographs and evoked response equipment Equipment for monitoring vital parameters  - Ambulatory electrocardiographic systems  - Recording and analysing single-channel and multichannel electrocardiographs  - Automatic, cyclical, non-invasive blood pressure monitoring equipment	Compliance tests for general and special specifications	DIN EN IEC 80601-2-26 DIN EN 60601-2-26 <sup>⊗</sup> IEC 60601-2-26 <sup>⊗</sup> DIN EN 60601-2-40 IEC 60601-2-40  DIN EN 60601-2-47 IEC 60601-2-47  DIN EN 60601-2-51 <sup>⊗</sup> IEC 60601-2-51 <sup>⊗</sup>  DIN EN IEC 80601-2-30 DIN EN 60601-2-30 <sup>⊗</sup> IEC 60601-2-30 <sup>⊗</sup>

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Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
Safety tests	- Electrocardiographs		DIN EN 60601-2-25 IEC 60601-2-25  DIN EN 60601-2-27 IEC 60601-2-27
	- Pulse oximetry devices		DIN EN ISO 80601-2-61
	- In vitro diagnostic (IVD) medical equipment	Compliance tests for general and special specifications	DIN EN IEC 61010-2-101

Any existing exclusions of partial tests of a test are not listed in the scope of accreditation and must be communicated to the client by the laboratory during the contract test.

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.

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Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
EMC	Medical devices, active	Compliance tests - Emission - Immunity	DIN EN 60601-1-2 IEC 60601-1-2
	Information provided by the manufacturer - Markings - Designations - User manual / accompanying documents	Compliance tests	Applicable: IEC/TS 60601-4-2 IEC/TR 60601-4-2 <sup>⊗</sup>
	Equipment for stimulation or inhibition - Equipment for stimulation of nerves and muscles - External cardiac pacemakers with internal power source	Compliance tests for general and specific requirements	DIN EN 60601-2-10 IEC 60601-2-10  DIN EN IEC 60601-2-31 IEC 60601-2-31
	Surgical equipment and auxiliary surgical equipment - Endoscopic equipment - HF surgical devices and accessories	Compliance tests for general and specific requirements	DIN EN 60601-2-18 IEC 60601-2-18  DIN EN 60601-2-2 IEC 60601-2-2
	Patient positioning and transport facilities - Medical beds	Compliance tests for general and specific requirements	DIN EN 60601-2-52 IEC 60601-2-52

EMC	Equipment for monitoring	Compliance tests for general and specific requirements	
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Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
	- multifunction patient monitoring equipment		DIN EN IEC 80601-2-49 DIN EN 60601-2-49 <sup>⊗</sup> IEC 60601-2-49 <sup>⊗</sup>
	Equipment for monitoring non-vital physiological parameters		
	- Electroencephalographs		DIN EN IEC 80601-2-26 DIN EN 60601-2-26 <sup>⊗</sup> IEC 60601-2-26 <sup>⊗</sup>
	- Electromyographs and evoked response equipment		DIN EN 60601-2-40 IEC 60601-2-40
	- Equipment for monitoring vital parameters		
	- Ambulant electrocardiographic systems		DIN IEC 60601-2-47 IEC 60601-2-47
	- Automatic, cyclical, non-invasive blood pressure monitoring equipment		DIN EN IEC 80601-2-30 DIN EN 60601-2-30 <sup>⊗</sup> IEC 60601-2-30 <sup>⊗</sup>
EMC	- Electrocardiographs	Compliance tests for general and specific requirements	DIN EN 60601-2-25 IEC 60601-2-25 DIN EN 60601-2-27 IEC 60601-2-27
	In vitro diagnostic (IVD) medical devices	Compliance tests - Emission - Immunity	DIN EN IEC 61326-2-6 IEC 61326-2-6

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Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
	Information provided by the manufacturer - User manual/ accompanying documents	Compliance tests	

Any existing exclusions of partial tests of a test are not listed in the scope of accreditation and must be communicated to the client by the laboratory during the contract test.

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.

**List of sources for regulations/test procedures:**

DIN EN 50637 : 2018-07	Medical electrical equipment - Particular requirements for the basic safety and essential performance of medical beds for children; German version EN 50637:2017
DIN EN 60601-1 : 2022-11	<p>Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 + Cor1:2006 + Cor2:2007 + A1:2012 + A1:2012/Cor1:2014 + A2:2020);</p> <p>VDE 0750-1:2022-11</p> <p>German version EN 60601-1:2006 + Cor.:2010 + A1:2013 + AC:2014 + A1:2013/AC:2014 + A12:2014 + A2:2021</p> <p>DIN EN 60601-1 : 2013-12<sup>⊗</sup> - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 + Cor. :2006 + Cor. :2007 + A1:2012); German version EN 60601-1:2006 + Cor. :2010 + A1:2013</p> <p>VDE 0750-1:2013-12<sup>⊗</sup></p> <p>DIN EN 60601-1 : 2007-07<sup>⊗</sup> - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005); German version EN 60601-1:2006</p> <p>VDE 0750-1:2007-07<sup>⊗</sup></p> <p>DIN EN 60601-1 : 1996-03<sup>⊗</sup> - Medical electrical equipment - Part 1: General requirements for safety (IEC 60601-1 : 1988 +A1 : 1991 +A2 : 1995); German version EN 60601-1 : 1990 + A1 : 1993 + A2 : 1995</p> <p>VDE 0750-1:1996-03</p>
DIN EN 60601-1-1 : 2002-08 <sup>⊗</sup>	<p>Medical electrical equipment - Part 1-1: General requirements for safety; Collateral standard: Safety requirements for medical electrical systems (IEC 60601-1-1 : 2000); German version EN 60601-1-1 : 2001</p> <p>VDE 0750-1-1:2002-08<sup>⊗</sup></p>
DIN EN 60601-1-2 : 2022-01	<p>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 + A1:2020); German version EN 60601-1-2:2015 + A1:2021</p> <p>VDE 0750-1-2:2022-01</p> <p>DIN EN 60601-1-2 : 2016-05<sup>⊗</sup> - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential</p>

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	<p>performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (IEC 60601-1-2:2014); German version EN 60601-1-2:2015</p> <p>VDE 0750-1-2:2016-05<sup>⊗</sup></p> <p>DIN EN 60601-1-2 : 2007-12<sup>⊗</sup> - 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</p> <p>VDE 0750-1-2:2007-12<sup>⊗</sup></p>
DIN EN 60601-1-4 : 2001-04 <sup>⊗</sup>	<p>Medical electrical equipment - Part 1-4: General requirements for safety; Collateral standard: Programmable electrical medical systems (IEC 60601-1-4:1996 + A1:1999); German version EN 60601-1-4:1996 + A1:1999</p> <p>VDE 0750-1-4:2001-04<sup>⊗</sup></p>
DIN EN 60601-1-8 : 2021-12	<p>Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (IEC 60601-1-8:2006 + A1:2012 + A2:2020); German version EN 60601-1-8:2007 + Cor.:2010 + A1:2013 + A1:2013/AC:2014 + A11:2017 + A2:2021</p> <p>VDE 0750-1-8:2021-12</p> <p>DIN EN 60601-1-8/A11: 2018-02<sup>⊗</sup> - Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems; German version EN 60601-1-8:2007/A11:2017</p> <p>VDE 0750-1-8:2014-04<sup>⊗</sup></p>
DIN EN 60601-1-10 : 2021-11	<p>Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers (IEC 60601-1-10:2007 + A1:2013 + A2:2020); German version EN 60601-1-10:2008 + A1:2015 + A2:2021</p> <p>VDE 0750-1-10:2021-11</p> <p>DIN EN 60601-1-10 : 2016-04<sup>⊗</sup> - Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers (IEC 60601-1-</p>

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	10:2007 + A1:2013); German version EN 60601-1-10:2008 + A1:2015
DIN EN 60601-1-11 : 2021-12	<p>Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC 60601-1-11:2015 + A1:2020); German version EN 60601-1-11:2015 + A1:2021</p> <p>VDE 0750-1-11:2021-12</p> <p>DIN EN 60601-1-11 : 2011-03<sup>⊗</sup> - Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC 60601-1-11:2010); German version EN 60601-1-11:2010</p> <p>VDE 0750-1-11:2011-03<sup>⊗</sup></p>
DIN EN 60601-1-12 : 2022-02	<p>Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment (IEC 60601-1-12:2014 + A1:2020); German version EN 60601-1-12:2015 + A1:2020</p> <p>VDE 0750-1-12:2022-02</p> <p>DIN EN 60601-1-12 : 2016-01<sup>⊗</sup> - Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment (IEC 60601-1-12:2014); German version EN 60601-1-12:2015</p>
DIN EN IEC 60601-2-2 : 2018-12	<p>Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories (IEC 60601-2-2:2017); German version EN IEC 60601-2-2:2018</p> <p>VDE 0750-2-2:2018-12</p> <p>DIN EN 60601-2-2 : 2010-01<sup>⊗</sup> - Medical electrical equipment - Part 2-2: Particular requirements for basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories (IEC 60601-2-2:2009); German version EN 60601-2-2:2009</p> <p>VDE 0750-2-2:2010-01<sup>⊗</sup></p> <p>DIN EN 60601-2-2 : 2007-09<sup>⊗</sup> - Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency</p>

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	<p>surgical equipment (IEC 60601-2-2:2006); German version EN 60601-2-2:2007</p> <p>VDE 0750-2-2:2007-09<sup>⊗</sup></p>
DIN EN 60601-2-10 : 2017-09	<p>Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators (IEC 60601-2-10:2012 + A1:2016); German version EN 60601-2-10:2015 + A1:2016</p> <p>VDE 0750-2-10:2017-09</p> <p>DIN EN 60601-2-10 : 2015-11<sup>⊗</sup> - Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators (IEC 60601-2-10:2012); German version EN 60601-2-10:2015</p> <p>VDE 0750-2-10:2015-11<sup>⊗</sup></p> <p>DIN EN 60601-2-10 : 2003-04<sup>⊗</sup> - Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators (IEC 60601-2-10:1987 + A1:2001-09 + Corrigendum 1:2002); German version EN 60601-2-10:2000 + A1:2001</p> <p>VDE 0750-2-10:2003-04<sup>⊗</sup></p>
DIN EN 60601-2-18 : 2016-10	<p>Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment (IEC 60601-2-18:2009); German version EN 60601-2-18:2015</p> <p>VDE 0750-2-18:2016-10</p> <p>DIN EN 60601-2-18 : 2001-12<sup>⊗</sup> - Medical electrical equipment - Part 2-18: Particular requirements for the safety of endoscopic equipment (IEC 60601-2-18:1996 + A1:2000); German version EN 60601-2-18:1996 + A1:2000</p> <p>VDE 0750-2-18:2001-12<sup>⊗</sup></p>
DIN EN 60601-2-25 : 2016-08	<p>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</p> <p>VDE 0750-2-25:2016-08</p> <p>DIN EN 60601-2-25 : 2001-04<sup>⊗</sup> - 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</p> <p>VDE 0750-2-25:2001-04<sup>⊗</sup></p>
DIN EN 60601-2-26 : 2016-02 <sup>⊗</sup>	<p>Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of</p>

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	<p>electroencephalographs (IEC 60601-2-26:2012); German version EN 60601-2-26:2015</p> <p>VDE 0750-2-26:2016-02</p> <p>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</p> <p>VDE 0750-2-26:2004-01<sup>⊗</sup></p>
DIN EN 60601-2-27 : 2015-04	<p>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</p> <p>VDE 0750-2-27:2015-04</p> <p>DIN EN 60601-2-27 : 2006-08<sup>⊗</sup> - 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</p> <p>+ Corrigendum 1 : 2007-05<sup>⊗</sup></p> <p>VDE 0750-2-27:2007-05<sup>⊗</sup></p>
DIN EN IEC 60601-2-31 : 2021-07	<p>Medical electrical equipment - Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source (IEC 60601-2-31:2020); German version EN IEC 60601-2-31:2020</p> <p>VDE 0750-2-31:2021-07</p> <p>DIN EN 60601-2-31 : 2012-04<sup>⊗</sup> - Medical electrical equipment - Part 2-31: Particular requirements for basic safety and essential performance of external cardiac pacemakers with internal power source (IEC 60601-2-31:2008 + A1:2011); German version EN 60601-2-31:2008 + A1:2011</p> <p>VDE 0750-2-31:2012-04<sup>⊗</sup></p> <p>DIN EN 60601-2-31 : 1999-05<sup>⊗</sup> - Medical electrical equipment - Part 2-31: Particular requirements for the safety of external cardiac pacemakers with internal power source; Amendment A1 (IEC 60601-2-31/A1:1998); German version EN 60601-2-31:1996/A1:1998</p>
DIN EN 60601-2-40 : 2019-04	<p>Medical electrical equipment - Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment (IEC 60601-2-40:2016); German version EN 60601-2-40:2019</p> <p>VDE 0750-2-40:2019-04</p> <p>DIN EN 60601-2-40 : 1998-12<sup>⊗</sup> - Medical electrical equipment - Part 2-40: Particular requirements for the safety of</p>

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	<p>electromyographs and evoked response equipment (IEC 60601-2-40:1998); German version EN 60601-2-40:1998 VDE 0750-2-40:1998-12<sup>⊗</sup></p>
DIN EN IEC 60601-2-46 : 2020-04	<p>Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables (IEC 60601-2-46:2016); German version EN IEC 60601-2-46:2019 VDE 0750-2-46:2020-04</p> <p>DIN EN 60601-2-46 : 2011-12<sup>⊗</sup> - Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables (IEC 60601-2-46:2010); German version EN 60601-2-46:2011</p>
DIN EN 60601-2-47 : 2016-02	<p>Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems (IEC 60601-2-47:2012); German version EN 60601-2-47:2015 VDE 0750-2-47:2016-02</p> <p>DIN EN 60601-2-47 : 2002-11<sup>⊗</sup> - Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems (IEC 60601-2-47:2001); German version EN 60601-2-47:2001 VDE 0750-2-47:2002-11<sup>⊗</sup></p>
DIN EN 60601-2-51 : 2004-02 <sup>⊗</sup>	<p>Medical electrical equipment - Part 2-51: Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs (IEC 60601-2-51:2003); German version EN 60601-2-51:2003 VDE 0750-2-51:2004-02</p>
DIN EN 60601-2-52 : 2016-04	<p>Medical electrical equipment - Part 2-52: Particular requirements for basic safety and essential performance of medical beds (IEC 60601-2-52:2009 + Cor.:2010 + A1:2015); German version EN 60601-2-52:2010 + AC:2011 + A1:2015 VDE 0750-2-52:2016-04</p> <p>DIN EN 60601-2-52 : 2010-12<sup>⊗</sup> - Medical electrical equipment - Part 2-52: Particular requirements for basic safety and essential performance of medical beds (IEC 60601-2-52:2009); German version EN 60601-2-52:2010 VDE 0750-2-52:2010-12<sup>⊗</sup></p>
DIN EN IEC 60601-2-66 : 2020-09	<p>Medical electrical equipment - Part 2-66: Particular requirements for the basic safety and essential performance of hearing aids and hearing aid systems (IEC 60601-2-66:2019); German version EN IEC 60601-2-66:2020</p>

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	VDE 0750-2-66:2020-09
	Medical electrical equipment - Part 2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems (IEC 60601-2-66:2012); German version EN 60601-2-66:2013
	VDE 0750-2-66:2015-08 <sup>⊗</sup>
DIN EN IEC 61010-2-040 : 2023-02	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials (IEC 61010-2-040:2020); German version EN IEC 61010-2-040:2021
	VDE 0411-2-040:2023-02
	(in conjunction with DIN EN 61010-1 : 2020-03, as long as a valid accreditation therefor exists)
	(in conjunction with IEC 61010-1 : 2016-12, as long as a valid accreditation therefor exists)
	DIN EN 61010-2-040 : 2016-06 <sup>⊗</sup> - Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials (IEC 61010-2-040:2015); German version EN 61010-2-040:2015
	(in conjunction with DIN EN 61010-1 : 2011-07, as long as a valid accreditation therefor exists)
DIN EN IEC 61010-2-101 : 2023-12	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Safety requirements for in vitro diagnostic (IVD) medical equipment (IEC 61010-2-101:2018, modified); German version EN IEC 61010-2-101:2022 + A11:2022
	(in conjunction with DIN EN 61010-1 : 2020-03, as long as a valid accreditation therefor exists)
	(in conjunction with IEC 61010-1 : 2016-12, as long as a valid accreditation therefor exists)
	DIN EN 61010-2-101 : 2003-09 <sup>⊗</sup> - 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
	(in conjunction with DIN EN 61010-1 : 2002-08, as long as a valid accreditation therefor exists)
DIN EN IEC 61326-2-6 : 2022-11	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In

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- vitro diagnostic (IVD) medical equipment (IEC 61326-2-6:2020);  
German version EN IEC 61326-2-6:2021  
VDE 0843-20-2-6:2022-11  
(in conjunction with DIN EN IEC 61326-1 : 2022-11, as long as a  
valid accreditation therefor exists)  
(in conjunction with IEC 61326-1 : 2020-10, as long as a valid  
accreditation therefor exists)
- DIN EN 61326-2-6 : 2013-09<sup>⊗</sup> - Electrical equipment for  
measurement, control and laboratory use - EMC requirements -  
Part 2-6: Particular requirements - In vitro diagnostic (IVD)  
medical equipment (IVD) (IEC 61326-2-6:2012); German version  
EN 61326-2-6:2013  
VDE 0843-20-2-6 : 2013-09<sup>⊗</sup>  
(in conjunction with DIN EN 61326-1 : 2013-07, as long as a valid  
accreditation therefor exists)
- DIN EN 61326-2-6 : 2006-10<sup>⊗</sup> - Electrical equipment for  
measurement, control and laboratory use - EMC requirements -  
Part 2-6: Particular requirements - In vitro diagnostic (IVD)  
medical equipment (IEC 61326-2-6:2005); German version EN  
61326-2-6:2006  
VDE 0843-20-2-6 : 2006-10<sup>⊗</sup>  
(in conjunction with DIN EN 61326-1 : 2013-07, as long as a valid  
accreditation therefor exists)
- DIN EN IEC 80601-2-26 : 2025-01 Medical electrical equipment - Part 2-26: Particular requirements  
for the basic safety and essential performance of  
electroencephalographs (IEC 80601-2-26:2019 + COR1:2021 +  
AMD1:2024); German version EN IEC 80601-2-26:2020 + AC:2021  
+ A1:2024
- 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  
VDE 0750-2-30:2020-03  
DIN EN 80601-2-30 : 2016-02<sup>⊗</sup> - Medizinische elektrische Geräte -  
Teil 2-30: Besondere Festlegungen für die Sicherheit einschließlich  
der wesentlichen Leistungsmerkmale von automatisierten nicht-  
invasiven Blutdruckmessgeräten (IEC 80601-2-30:2009 +  
Corrigendum Jan. 2010 + A1:2013); Deutsche Fassung EN 80601-  
2-30:2010 + A1:2015  
VDE 0750-2-30:2016-02<sup>⊗</sup>  
DIN EN 80601-2-30 : 2011-05<sup>⊗</sup> - Medical electrical equipment -  
Part 2-30: Particular requirements for the basic safety and

	<p>essential performance of automated non-invasive sphygmomanometers (IEC 80601-2-30:2009 + Cor. :2010); Deutsche Fassung EN 80601-2-30:2010 VDE 0750-2-30:2011-05<sup>⊗</sup></p> <p>Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment (IEC 60601-2-30:1999); German version EN 60601-2-30:2000 VDE 0750-2-30 (2000-12)<sup>⊗</sup></p>
DIN EN IEC 80601-2-49:2020-10	<p>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</p> <p>DIN EN 60601-2-49 : 2016-10<sup>⊗</sup> - 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 0750-2-49:2016-10<sup>⊗</sup></p> <p>DIN EN 60601-2-49 : 2002-12<sup>⊗</sup> - 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<sup>⊗</sup></p>
DIN EN ISO 80601-2-61 : 2019-09	<p>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</p>
IEC 60601-1 : 2005-12	<p>Medical electrical equipment - Part 1: General requirements for basic safety and essential performance + Corrigendum 1 : 2006-12 + Corrigendum 2 : 2007-12 + Amendment 1 : 2012-07 + Amendment 2 : 2020-08 IEC 60601-1 : 1988<sup>⊗</sup> - Medical electrical equipment; part 1: general requirements for safety + Amendment 1 : 1991-11 + Amendment 2 : 1995-03</p>
IEC 60601-1-1 : 2000-12 <sup>⊗</sup>	<p>Medical electrical equipment - Part 1-1: General requirements for safety; Collateral standard: Safety requirements for medical electrical systems</p>

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IEC 60601-1-2 : 2014-02	<p>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</p> <p>IEC 60601-1-2 : 2007-03<sup>⊗</sup> - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests +Amendment 1:2020-09</p>
IEC 60601-1-4 : 1996-05 <sup>⊗</sup>	<p>Medical electrical equipment - Part 1: General requirements for safety - 4. Collateral standard: Programmable electrical medical systems + Amendment 1 : 1999-10</p>
IEC 60601-1-8 : 2006-10	<p>Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems + Amendment 1 : 2012-11 + Amendment 2 : 2020-07</p>
IEC 60601-1-10 : 2007-11	<p>Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral standard: Requirements for the development of physiologic closed-loop controllers + Amendment 1: 2013-11 + Amendment 2 : 2020-07</p>
IEC 60601-1-11 : 2015-01	<p>Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment</p> <p>IEC 60601-1-11 : 2010-04<sup>⊗</sup> - Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment + Amendment 1 : 2020-07</p>
IEC 60601-1-12 : 2014-06	<p>Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment + Amendment 1 : 2020-07</p>

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IEC 60601-2-2 : 2017-03	<p>Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories</p> <p>IEC 60601-2-2 : 2009-02<sup>⊗</sup> - Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories</p> <p>+ Corrigendum 1 : 2014-02</p> <p>IEC 60601-2-2 : 2006-07<sup>⊗</sup> - Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment</p>
IEC 60601-2-10 : 2012-06	<p>Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators</p> <p>+ Amendment 1 : 2016-04</p> <p>+ Amendment 2 : 2023-01</p> <p>IEC 60601-2-10 : 1987<sup>⊗</sup> - Medical electrical equipment; part 2: particular requirements for the safety of nerve and muscle stimulators</p> <p>+ Amendment 1 : 2001-09</p> <p>Corrigendum 1 : 2002-02</p>
IEC 60601-2-18 : 2009-08	<p>Medical electrical equipment - Part 2-18: Particular requirements for basic safety and essential performance of endoscopic equipment</p> <p>IEC 60601-2-18 : 1996-08<sup>⊗</sup> - Medical electrical equipment - Part 2: Particular requirements for the safety of endoscopic equipment</p> <p>+ Amendment 1 : 2000-07</p>
IEC 60601-2-25 : 2011-10	<p>Medical electrical equipment - Part 2-25: Particular requirements for basic safety and essential performance of electrocardiographs</p> <p>IEC 60601-2-25 : 1993-03<sup>⊗</sup> - Medical electrical equipment; part 2: particular requirements for the safety of electrocardiographs</p> <p>+ Amendment 1 : 1999-05</p>
IEC 60601-2-26 : 2012-05 <sup>⊗</sup>	<p>Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs</p> <p>IEC 60601-2-26 : 2002-11<sup>⊗</sup> - Medical electrical equipment - Part 2-26: Particular requirements for the safety of electroencephalographs</p>
IEC 60601-2-27 : 2011-03	<p>Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment</p>

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	+ Corrigendum 1 : 2012-05
	IEC 60601-2-27 : 2005-08 <sup>⊗</sup> - Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment
IEC 60601-2-31 : 2020-01	Medical electrical equipment - Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source
	IEC 60601-2-31 : 2008-03 <sup>⊗</sup> - Medical electrical equipment - Part 2-31: Particular requirements for basic safety and essential performance of external cardiac pacemakers with internal power source
	+ Amendment 1 : 2011-06
	IEC 60601-2-31 : 1994-10 <sup>⊗</sup> - Medical electrical equipment - Part 2-31: Particular requirements for the safety of external cardiac pacemakers with internal power source
	+ Amendment 1 : 1998-01 <sup>⊗</sup>
IEC 60601-2-40 : 2016-08	Medical electrical equipment - Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment
	IEC 60601-2-40 : 1998-02 <sup>⊗</sup> - Medical electrical equipment - Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment
IEC 60601-2-46 : 2023-05	Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables
	IEC 60601-2-46 : 2016-08 <sup>⊗</sup> Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables
IEC 60601-2-47 : 2012-02	Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
	IEC 60601-2-47 : 2001-07 <sup>⊗</sup> - Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
IEC 80601-2-49 : 2011-02 <sup>⊗</sup>	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
	IEC 60601-2-49 : 2011-02 <sup>⊗</sup> - Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment

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	IEC 60601-2-49 : 2001-07 <sup>⊗</sup> - Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
IEC 60601-2-51 : 2003-02 <sup>⊗</sup>	Medical electrical equipment - Part 2-51: Particular requirements for the safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs
IEC 60601-2-52 : 2009-12	Medical electrical equipment - Part 2-52: Particular requirements for basic safety and essential performance of medical beds + Amendment 1: 2015-03
IEC 60601-2-66 : 2015-06 <sup>⊗</sup>	Medical electrical equipment - Part 2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems  IEC 60601-2-66 : 2012-10 <sup>⊗</sup> Medical electrical equipment - Part 2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems
IEC TS 60601-4-2 : 2024-03	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems  IEC/TR 60601-4-2 : 2016-05 <sup>⊗</sup> - Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
IEC 61010-2-040 : 2015-07 <sup>⊗</sup>	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials  (in conjunction with IEC 61010-1 : 2010-06 <sup>⊗</sup> , as long as a valid accreditation therefor exists)
IEC 61010-2-101 : 2015-01 <sup>⊗</sup>	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 <sup>⊗</sup>  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 <sup>⊗</sup> , as long as a valid accreditation therefor exists)

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IEC 61326-2-6 : 2025-06

Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical electrical equipment

(in conjunction with IEC 61326-1 : 2020-10, as long as a valid accreditation therefor exists)

IEC 61326-2-6 : 2012-07<sup>⊗</sup> - 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 61326-2-6 : 2005-12<sup>⊗</sup> - Electrical equipment for measurement, control and laboratory use, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

(in conjunction with IEC 61326-1, as long as a valid accreditation therefor exists)

IEC 80601-2-30 : 2009-01<sup>⊗</sup>

Medical electrical equipment - Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers

+ Corrigendum 1 : 2010-01

IEC 60601-2-30 : 1999-12<sup>⊗</sup> - Medical electrical equipment - Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment

## **Abbreviations**

DIN	German Institute for Standardization (Deutsches Institut für Normung)
EMC	Electromagnetic compatibility
EN	European Standard
IEC	International Electrical Committee
ISO	International Organization for Standardization
Medical devices, active	Medical electrical equipment, medical electrical systems and components
VDE	Association for Electrical, Electronic & Information Technologies
⊗	Regulations withdrawn from standardization in the field of active medical devices that are still in use due to existing non-European regulatory requirements.