Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-11250-01-01 according to DIN EN ISO/IEC 17025:2018[1]

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:

Area: Medical devices

Biological and chemical tests of medical devices as well as safety tests and compatibility tests with regard to electromagnetic disturbances (EMC) of active medical devices

Scope:

1) Safety tests and biological and chemical tests

Test field	Test item Product (category)	Type of testing Test	Regulation Test method
Biological tests	Medical devices, general	Toxicity testing of emitted substances Luminescent bacteria test	DMS TC5021 (DIN EN ISO 11348-2)

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

Abbreviations used: see last page

The certificate together with its annex reflects the status at the time of the date of issue. The current status of the scope of accreditation can be found in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH. https://www.dakks.de/en/content/accredited-bodies-dakks

Test field	Test item Product (category)	Type of testing Test	Regulation Test method
Chemical tests	Medical devices, general	Chemical characterization of materials	DIN EN ISO 10993-18 ISO 10993-18 applicable: DIN EN ISO 10993-1 ISO 10993-1 DIN EN ISO 10993-12 ISO 10993-12 DCS IN8190
		Testing of product properties Tests for particle emissions Tests for emissions of volatile organic compounds (VOCs) Tests for leachable substances in condensates	 ISO 18562-2 ISO 18562-3 ISO 18562-4 applicable: ISO 18562-1
		Testing of product properties Determination of the mass of emitted particles (weighing)	 DMS TC5022
Safety tests	Medical devices, active	Verification of compliance Components and ME systems Electrical tests and protection against electrical hazards	DIN EN 60601-1 IEC 60601-1 DIN EN 60601-1-1⊗ IEC 60601-1-1⊗

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Abbreviations used: see last page

Valid from: 11.11.2019
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Test field	Test item Product (category)	Type of testing Test	Regulation Test method
Safety tests	Medical devices, active	mechanical strength and protection against mechanical hazards Protection against hazards caused by unwanted / excessive radiation Microwave radiation tests only Protection against excessive temperatures including fire prevention Environmental simulation tests	DIN EN 60601-1 IEC 60601-1 DIN EN 60601-1-1⊗ IEC 60601-1-1⊗
	Information provided by the manufacturer on components and assemblies on biocompatibility instructions for use/accompanying documents usability file on programmable electrical medical systems (PEMS) risk management file on radiation, ionizing/non-ionizing	Verification of compliance	DIN EN 60601-1-4⊗ IEC 60601-1-4⊗

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Abbreviations used: see last page

Valid from: 11.11.2019
Date of issue: 11.11.2019

Test field	Test item Product (category)	Type of testing Test	Regulation Test method
Safety tests	Medical products, active Information provided by the manufacturer usability file	Verification of compliance	DIN EN 60601-1-6 IEC 60601-1-6
	Medical products, active	Verification of compliance visual alarms acoustic alarms	DIN EN 60601-1-8 IEC 60601-1-8
	Information provided by the manufacturer Instructions for use/accompanying documents/technical description risk management file	Verification of compliance	
	Information on physiological closed control loops provided by the manufacturer Instructions for use/accompanying documents usability file risk management file on programmable electrical medical systems (PEMS)	Verification of compliance	DIN EN 60601-1-10 IEC 60601-1-10

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Abbreviations used: see last page

Valid from: 11.11.2019
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Test field	Test item Product (category)	Type of testing Test	Regulation Test method
Safety tests	Medical products, active, in the area for emergency use	Verification of compliance Environmental Simulation tests	DIN EN 60601-1-12 IEC 60601-1-12
	Ventilation, oxygen therapy (including hyperbaric therapy chambers) and inhalation anaesthesia devices	Verification of compliance with general and particular requirements	
	Anaesthesia workstations		DIN EN ISO 80601-2-13 ISO 80601-2-13 DIN EN 60601-2-13⊗ IEC 60601-2-13⊗
	Ventilators		DIN EN ISO 80601-2-12 ISO 80601-2-12 DIN EN ISO 60601-2-12⊗ IEC 60601-2-12⊗ DIN EN 794-3 ISO 10651-3
	Respiratory gas monitors		DIN EN ISO 80601-2-55 ISO 80601-2-55 DIN EN ISO 21647⊗ ISO 21647⊗
	Gas mixers for medical use		ISO 11195
	Surgical equipment and auxiliary surgical equipment	Verification of compliance with general and particular requirements	
	- Luminaires		DIN EN 60601-2-41 IEC 60601-2-41
	- Medical care units	Verification of compliance with general and particular requirements	DIN EN ISO 11197

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Abbreviations used: see last page

Test field	Test item Product (category)	Type of testing Test	Regulation Test method
Safety tests	Devices for patient positioning and transport	Verification of compliance with general and particular requirements	
	Blankets, pads and mattresses		DIN EN 80601-2-35 IEC 80601-2-35 DIN EN 60601-2-35⊗ IEC 60601-2-35⊗
	Infant incubators		DIN EN 60601-2-19 IEC 60601-2-19
	Monitoring devices	Verification of compliance with general and particular requirements	
	multifunctional patient monitoring devices		DIN EN 60601-2-49 IEC 60601-2-49⊗ IEC 80601-2-49
	Equipment for radiation and thermotherapy	Verification of compliance with general and particular requirements	
	infant radiant warmers		DIN EN 60601-2-21 IEC 60601-2-21

Any exclusions of partial tests for a test are not specified within the scope of accreditation and must be reported to the client by the laboratory during order verification.

The accreditation assessment was conducted with reference to the normative references of European regulations (DIN EN). Where the referenced International versions of the standards are not explicitly listed in the appendix to the notice, the normative references of international regulations (IEC, ISO) were not taken into account.

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Abbreviations used: see last page

2) EMC

Test field	Test item Product (category)	Type of testing Test	Regulation Test method
EMC	Medical devices, active	Test for verification of compliance conducted emission radiated emissions in the frequency range 30 MHz to 1 GHZ (IEC 60601-1-2:2007 only) Interference immunity	DIN EN 60601-1-2 IEC 60601-1-2 applicable: IEC TR 60601-4-2
EMC	Information provided by the manufacturer Labels Inscriptions instructions for use/accompanying documents	Verification of compliance	DIN EN 60601-1-2 IEC 60601-1-2 applicable: IEC TR 60601-4-2
	Ventilation, oxygen therapy (including hyperbaric therapy chambers) and inhalation anaesthesia devices Ventilators Respiratory gas monitors	Verification of compliance with general and particular requirements	 DIN EN ISO 80601-2-12 ISO 80601-2-12 DIN EN 794-3 ISO 10651-3 DIN EN ISO 80601-2-55 ISO 80601-2-55 DIN EN ISO 21647⊗ ISO 21647⊗
	Devices for patient positioning and transport	Verification of compliance with general and particular requirements	

Test field	Test item Product (category)	Type of testing Test	Regulation Test method
	Blankets, pads and mattresses Infant incubators		DIN EN 80601-2-35 IEC 80601-2-35 DIN EN 60601-2-35⊗ IEC 60601-2-35⊗ DIN EN 60601-2-19 IEC 60601-2-19
EMC	Monitoring devices multifunctional patient monitoring devices	Verification of compliance with general and particular requirements	 DIN EN 60601-2-49 IEC 60601-2-49
	Equipment for radiation and thermotherapy Devices with non-ionizing beams infant radiant warmers	Verification of compliance with general and particular requirements	 DIN EN 60601-2-21 IEC 60601-2-21

Any exclusions of partial tests for a test are not specified within the scope of accreditation and must be reported to the client by the laboratory during order verification.

The accreditation assessment was conducted with reference to the normative references of European regulations (DIN EN). Where the referenced International versions of the standards are not explicitly listed in the appendix to the notice, the normative references of international regulations (IEC, ISO) were not taken into account.

Standards[2]

DIN EN 794-3 : 2009-12	Lung ventilators - Part 3: Particular requirements for emergency and transport ventilators; German version EN 794-3:1998 + A1:2005 + A2:2009
DIN EN ISO 10993-1 : 2010-04	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system (ISO 10993-1:2009); German version EN ISO 10993-1:2009
	DIN EN ISO 10993-1 : 2003-12⊗ - Biological evaluation of medical devices - Part 1: Evaluation and testing (ISO 10993-1:2003); German version EN ISO 10993-1:2003
DIN EN ISO 10993-12 : 2012-10	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2012); German version EN ISO 10993-12:2012
DIN EN ISO 10993-18 : 2009-08	Biological evaluation of medical devices - Part 18: Chemical characterization of materials (ISO 10993-18:2005); German version EN ISO 10993-18:2009
DIN EN ISO 11348-2 : 2009-05	Water quality - Determination of the inhibitory effect of water samples on the light emission of Vibrio fischeri (Luminescent bacteria test) - Part 2: Method using liquid-dried bacteria (ISO 11348-2:2007); German version EN ISO 11348-2:2008
ISO 11195:2018-01	Gas mixers for medical use - Stand-alone gas mixers
DIN EN ISO 11197:2016-08	Medical supply units (ISO 11197:2016); German version EN ISO 11197:2016
DIN EN ISO 21647 : 2009-09⊗	Medical electrical equipment - Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 21647:2004, including Cor 1:2005); German version EN ISO 21647:2009
DIN EN 60601-1 : 2013-12	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
	VDE 0750-1:2013-12
	DIN EN 60601-1 : 2007-07⊗ - Medical electrical equipment - Part 1: General requirements for basic safety and essential

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Abbreviations used: see last page

	performance (IEC 60601-1:2005); German version EN 60601-1 : 2006; including AC:2010 DIN EN 60601-1 : 1996-10⊗ - Medical electrical equipment - Part 1: General requirements for safety; German version EN 60601-1:1990/A13:1996; VDE 0750-1/A13:1996-10 DIN EN 60601-1 : 1996-03⊗ - 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; VDE 0750-1:1996-03
DIN EN 60601-1-1 : 2002-08⊗	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 VDE 0750-1-1:2002-08
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 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 60601-1-2 : 2006-10⊗ - Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2001 + A1:2004); German version EN 60601-1-2:2001 + A1:2006
DIN EN 60601-1-4 : 2001-04⊗	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 VDE 0750-1-4:2001-04⊗
DIN EN 60601-1-6 : 2016-02	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard:

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Abbreviations used: see last page

	Usability (IEC 60601-1-6:2010 + A1:2013); German version EN 60601-1-6:2010 + A1:2015
	DIN EN 60601-1-6 : 2010-10⊗ - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601-1-6:2010); German version EN 60601-1-6 : 2010
	VDE 0750-1-6:2010-10
	DIN EN 60601-1-6 : 2008-02⊗ - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability (IEC 60601-1-6:2006); German version EN 60601-1-6:2007
	DIN EN 60601-1-6 : 2005-06⊗ - Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability (IEC 60601-1-6:2004); German version EN 60601-1-6:2004
	VDE 0750-1-6:2005-06⊗
DIN EN 60601-1-8 : 2014-04	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); German version EN 60601-1-8:2007 + Cor.:2010 + A1:2013; VDE 0750-1-8:2014-04
	DIN EN 60601-1-8 : 2010-05⊗ - 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); German version EN 60601-1-8:2007, Corrigendum to DIN EN 60601-1-8 (VDE 0750-1-8):2008-02; German version CENELEC-Cor. :2010 to EN 60601-1-8:2007; VDE 0750-1-8:2010-05⊗
	DIN EN 60601-1-8 : 2006-11⊗ - Medical electrical equipment - Part 1-8: General requirements for safety - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (IEC 60601-1-8:2003 + A1:2006); German version EN 60601-1-8:2004 + A1:2006
	DIN EN 60601-1-8 : 2004-09⊗ - Medical electrical equipment - Part 1-8: General requirements for safety - Collateral standard: General requirements, tests and guidance for alarm systems in

	medical electrical equipment and medical electrical systems (IEC 60601-1-8:2003); German version EN 60601-1-8:2004 VDE 0750-1-8:2004-09⊗
DIN EN 60601-1-10 : 2016-04	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); German version EN 60601-1-10:2008 + A1:2015 DIN EN 60601-1-10⊗ : 2008-11 - 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); German version EN 60601-1-10:2008 VDE 0750-1-10:2008-11
DIN EN 60601-1-12 : 2016-01	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
DIN EN 60601-2-12 : 2007-03⊗	Medical electrical equipment - Part 2-12: Particular requirements for the safety of lung ventilators - Critical care ventilators (IEC 60601-2-12:2001); German version EN 60601-2-12:2006 VDE 0750-2-12 (2007-03)⊗
DIN EN 60601-2-13 : 2007-05⊗	Medical electrical equipment - Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems (IEC 60601-2-13:2003 + A1:2006); German version EN 60601-2-13:2006 + A1:2007; VDE 0750-2-12 (2007-05)⊗
DIN EN 60601-2-19 : 2017-09	Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators (IEC 60601-2-19:2009 + Cor.:2012 + A1:2016); German version EN 60601-2-19:2009 + A11:2011 + A1:2016 VDE 0750-2-19:2017-09 DIN EN 60601-2-19 : 2010-01⊗ Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators (IEC60601-2-19:2009); German Version EN 60601-2-19:2009 VDE 0750-2-19:2010-01 DIN EN 60601-2-19 : 1998-01⊗ - Medical electrical equipment - Part 2: Particular requirements for basic safety of infant

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	incubators (IEC 60601-2-19:1990 + A1:1996); German version EN 60601-2-19:1996 + A1:1996; VDE 0750-2-19:1998-01⊗
DIN EN 60601-2-21 : 2017-09	Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers (IEC 60601-2-21:2009 + Cor.:2013 + A1:2016); German version EN 60601-2-21:2009 + A11:2011 + A1:2016 VDE 0750-2-21:2017-09 DIN EN 60601-2-21 : 2010-01 ⊗ Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers (IEC 60601-2-21:2009); German version EN 60601-2-21:2009; VDE 0750-2-21:2010-01 DIN EN 60601-2-21 : 1998-01⊗ - Medical electrical equipment - Part 2: Particular requirements for basic safety of infant radiant warmers (IEC 60601-2-21:1994 + A1:1996); German version EN 60601-2-21:1994 + A1 : 1996; VDE 0750-2-21:1998-01⊗
DIN EN 60601-2-35 : 1997-12⊗	Medical electrical equipment - Part 2: Particular requirements for the safety of blankets, pads and mattresses, intended for heating in medical use (IEC 60601-2-35:1996); German version EN 60601-2-35:1996; VDE 0750-2-35 : 1997-12⊗ Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use (IEC 80601-2-35:2009); German version EN 80601-2-35:2009
DIN EN 60601-2-41 : 2016-02	Medical electrical equipment - Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis (IEC 60601-2-41:2009 + A1:2013); German version EN 60601-2-41:2009 + A1:2015 DIN EN 60601-2-41 : 2010-05⊗ - Medical electrical equipment - Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis (IEC 60601-2-41:2009); German version EN 60601-2-41:2009 VDE 0750-2-41:2010-05 DIN EN 60601-2-41 : 2001-11⊗ - Medical electrical equipment - Part 2-41: Particular requirements for basic safety of surgical luminaires and luminaires for diagnosis (IEC 60601-2-41:2000); German version EN 60601-2-41:2000 VDE 0750-2-41:2001-11⊗
DIN EN 60601-2-49:2016-10	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction

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Abbreviations used: see last page

	patient monitoring equipment (IEC 60601-2-49:2011); German version EN 60601-2-49:2015 VDE 0750-2-49:2016-10 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 ISO 80601-2-12 : 2012-02	Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators (ISO/IEC 80601-2-12:2011 + Cor. :2011); German version EN ISO 80601-2-12:2011 + AC:2011; VDE 0750-2-12:2012-02
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); German version EN ISO 80601-2-13:2012; VDE 0750-2-13:2013-03
DIN EN IEC 80601-2-35 : 2017-11	Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use (IEC 80601-2-35:2009 + Cor.:2012 + Cor.:2015 + A1:2016); German version EN 80601-2-35:2009 + A11:2011 + AC:2015 + A1:2016 VDE 0750-2-35:2017-11
DIN EN IEC 80601-2-35 : 2010-08⊗	Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use (IEC 80601-2-35:2009); German version EN 80601-2-35:2009
DIN EN ISO 80601-2-55 : 2018-07	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
IEC 60601-1 : 2005-12	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance + Corrigendum 1 : 2006-12 + Corrigendum 2 : 2007-12

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Abbreviations used: see last page

	+ Amendment 1 : 2012-07
	ABNT NBR IEC 60601-1:2010 + A1 IEC 60601-1:2012
	ANSI/AAMI ES60601-1 : 2005 & C1:2009 & A2:2010 & A1:2012
	AS/NZS IEC 60601.1:2015
	CAN/CSA-C22.2 NO. 60601-1:14
	JIS T 0601-1:2012/AMENDMENT 1:2014
	IEC 60601-1 : 2005-12 - Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
	KS C IEC 60601-1 : 2011-12
	IEC 60601-1 : 1988⊗ - Medical electrical equipment; part 1: general requirements for safety
	+ Amendment 1 : 1991-11
	+ Amendment 2 : 1995-03
	ABNT NBR IEC 60601-1:1994
	AS/NZS 3200.1.0:1998
	CAN/CSA-C22.2 NO. 601.1-M90 + 601.1S1-94 + 601.1B-98
	GB 9706.1 – 2007
	JIS T 0601-1:1999
	KS C IEC 60601-1 : 2008
	UL 60601-1 (2003-04)
IEC 60601-1-1 : 2000-12⊗	Medical electrical equipment - Part 1-1: General requirements for safety; Collateral standard: Safety requirements for medical electrical systems
	ABNT NBR IEC 60601-1-1:2004
	CSA C22.2 NO 60601-1-1-02
	GB 9706.15—2008
	JIS T 0601-1-1:2005
	KS C IEC 60601-1-1 : 2002-06⊗
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
	ABNT NBR IEC 60601-1-2:2017
	ANSI/AAMI/IEC 60601-1-2:2014
	AS IEC 60601.1.2:2017-06
	CAN/CSA C22.2 60601-1-2 : 2016
	JIS T 0601-1-2:2018
	KS C IEC 60601-1-2 : 2017-12

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Abbreviations used: see last page

	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
	ABNT NBR IEC 60601-1-2:2010
	ANSI/AAMI/IEC 60601-1-2:2007
	CAN/CSA-C22.2 NO. 60601-1-2-08
	KS C IEC 60601-1-2 : 2012-12⊗
	IEC 60601-1-2 : 2001-09⊗ - Medical electrical equipment - Part 1-2: General requirements for safety; Collateral standard: Electromagnetic compatibility; Requirements and tests
	+ Amendment 1 : 2004-09
	AS/NZS 3200.1.2:2005⊗
	CAN/CSA-C22.2 NO. 60601-1-2-03 + A1:2006
	JIS T 0601-1-2:2012
	KS C IEC 60601-1-2 : 2007-11
	YY 0505—2012
IEC 60601-1-4 : 1996-05⊗	Medical electrical equipment - Part 1: General requirements for safety - 4. Collateral standard: Programmable electrical medical systems
	+ Amendment 1 : 1999-10
	ABNT NBR IEC 60601-1-4:2004⊗
	CAN/CSA-C22.2 NO. 60601-1-4-02
	KS C IEC 60601-1-4 : 2002-06⊗
	YY/T 0708 – 2009
IEC 60601-1-6 : 2010-01	Medical electrical equipment - General requirements for basic safety and essential performance - Collateral Standard: Usability
	+ Amendment 1 : 2013-10
	AS IEC 60601.1.6:2017-06
	CAN/CSA-C22.2 NO. 60601-1-6:11 + A1:2015
	IEC 60601-1-6 : 2010-01 - Medical electrical equipment - General requirements for basic safety and essential performance - Collateral Standard: Usability
	ABNT NBR IEC 60601-1-6:2011
	KS C IEC 60601-1-6 : 2012-01
	IEC 60601-1-6 : 2006-12⊗ - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability

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Abbreviations used: see last page

	CAN/CSA-C22.2 No. 60601-1-6-08 IEC 60601-1-6 : 2004-06⊗ - Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability CAN/CSA-C22.2 No. 60601-1-6-05
IEC 60601-1-8 : 2006-10	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 ABNT NBR IEC 60601-1-8:2014 ANSI/AAMI IEC 60601-1-8:2006 +A1:2012 AS IEC 60601.1.8:2017-06 CAN/CSA C22.2 60601-1-8:2008 +A1:2014 KS C IEC 60601-1-8:2017-12 IEC 60601-1-8 : 2006-10 - 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 ABNT NBR IEC 60601-1-8:2010 CAN/CSA-C22.2 NO. 60601-1-8-08
	IEC 60601-1-8 : 2003-08⊗ - Medical electrical equipment - Part 1-8: General requirements for safety; Collateral standard; General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems + Amendment 1 : 2006-03⊗ JIS T 60601-1-8:2012 IEC 60601-1-8 : 2003-08⊗ - Medical electrical equipment - Part 1-8: General requirements for safety; Collateral standard; General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems AS/NZS 3200.1.8:2005⊗ CAN/CSA-C22.2 NO. 60601-1-8-05 KS C IEC 60601-1-8 : 2005-09⊗ YY 0709 — 2009
IEC 60601-1-10 : 2007-11	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

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Abbreviations used: see last page

	+ Amendment 1 : 2013-11 ABNT NBR IEC 60601-1-10:2010 + A1:2017 AS IEC 60601.1.10:2017-06 CAN/CSA-C22.2 NO. 60601-1-10-09 + A1:2014 KS C IEC 60601-1-10 : 2017-12 IEC 60601-1-10 : 2007-11 - 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 ABNT NBR IEC 60601-1-10:2010 KS C IEC 60601-1-10 : 2012-01⊗
IEC 60601-1-12 : 2014-06	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 CAN/CSA C22.2 60601-1-12:15 ANSI/AAMI/IEC 60601-1-12 : 2016 AS IEC 60601.1.12:2017-06
IEC 60601-2-12 : 2001-10⊗	Medical electrical equipment - Part 2-12: Particular requirements for the safety of lung ventilators; Critical care ventilators ABNT NBR IEC 60601-2-12:2004⊗ CAN/CSA-C22.2 No. 60601-2-12-03 GB 9706.28—2006 KS C IEC 60601-2-12 : 2011-12
IEC 60601-2-13 : 2003-05	Medical electrical equipment - Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems + Amendment 1 : 2006-05 CAN/CSA C22.2 60601-2-13:2007 IEC 60601-2-13 : 2003-05 - Medical electrical equipment - Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems ABNT NBR IEC 60601-2-13:2004⊗ AS/NZS 3200.2.13: 2005 GB 9706.29—2006 KS C IEC 60601-2-13 : 2011-12⊗ KS P IEC 60601-2-13 : 2009-12⊗ KS P IEC 60601-2-13 : 2014-12⊗

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IEC 60601-2-19 : 2009-02	Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators + Corrigendum 1 : 2012-02 + Amendment 1 : 2016-04 ANSI/AAMI/IEC 60601-2-19 2009 +A1:2016 AS 60601.2.19:2018 KS C IEC 60601-2-19 : 2017-09 IEC 60601-2-19 : 2009-02 - Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators + Corrigendum 1 : 2012-02 ABNT NBR IEC 60601-2-19:2014 + Cor.1:2014 ANSI/AAMI/IEC 60601-2-19:2009 CAN/CSA-C22.2 NO. 60601-2-19-09 KS C IEC 60601-2-19 : 2011-12⊗ IEC 60601-2-19 : 1990-12⊗ - Medical electrical equipment; part 2: particular requirements for safety of baby incubators + Amendment 1 : 1996-10 ABNT NBR IEC 60601-2-19:1997 + A1:2000 CAN/CSA-C22.2 NO. 601.2.19-92 GB 11243—2008
IEC 60601-2-21 : 2009-02	Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers + Corrigendum 1 : 2013-02 + Amendment 1 : 2016-04 ANSI/AAMI/IEC 60601-2-21:2009 + A1:2016 KS C IEC 60601-2-21 : 2017-09 IEC 60601-2-21 : 2009-02 - Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers + Corrigendum 1 : 2013-02 ABNT NBR IEC 60601-2-21 : 2013-06 ANSI/AAMI/IEC 60601-2-21:2009 AS/NZS IEC 60601-2-21 : 2015 CAN/CSA-C22.2 NO. 60601-2-21-10

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	KS C IEC 60601-2-21 : 2011-12
	IEC 60601-2-21 : 1994-02⊗ - Medical electrical equipment; part 2: particular requirements for the safety of infant radiant warmers
	+ Amendment 1 :1996-10
	ABNT NBR IEC 60601-2-21:1997 + A1:2000
	AS/NZS 3200.2.21:1994 + A1:1998
	JIS T 0601-2-21:2005
	IEC 60601-2-21 : 1994-02⊗ - Medical electrical equipment; part 2: particular requirements for the safety of infant radiant warmers YY 0455 — 2011
IEC 60601-2-35 : 1996-10⊗	Medical electrical equipment - Part 2: Particular requirements for the safety of blankets, pads and mattresses, intended for heating in medical use
	ABNT NBR IEC 60601-2-35:2006
	AS/NZS 3200.2.35:1999
	JIS T 0601-2-35:2005
IEC 60601-2-41 : 2009-08	Medical electrical equipment - Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis
	+ Amendment 1 : 2013-10
	ABNT NBR IEC 60601-2-41:2012 + A1:2014
	CAN/CSA-C22.2 NO. 60601-2-41:11 +A1:2015
	KS C IEC 60601-2-41 :2017-09
	IEC 60601-2-41 : 2009-08 - Medical electrical equipment - Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis
	ABNT NBR IEC 60601-2-41:2012
	CAN/CSA-C22.2 NO. 60601-2-41:11
	KS C IEC 60601-2-41 : 2011-12⊗
	IEC 60601-2-41 : 2000-02⊗ - Medical electrical equipment - Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnostic
	AS/NZS 3200.2.41:2002
	YY 0627—2008
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

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	ABNT NBR IEC 60601-2-49 : 2014
	CAN/CSA-C22.2 NO. 60601-2-49:11
	KS C IEC 60601-2-49 : 2011-12
	IEC 60601-2-49 : 2001-07⊗ - Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
	ABNT NBR IEC 60601-2-49:2003
	YY 0668 - 2008
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 80601-2-35 : 2009-10	Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use
	+ Corrigendum 1 : 2012-03
	+ Amendment 1 : 2016-04
	ANSI/AAMI/ISO 80601-2-35:2009 + A1:2016
	KS C IEC 60601-2-35 : 2017-09
	IEC 80601-2-35 : 2009-10 - Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use
	+ Corrigendum 1 : 2012-03
	ABNT NBR IEC 80601-2-35:2013
	ANSI/AAMI/ISO 80601-2-35:2009
	CAN/CSA-C22.2 NO. 80601-2-35:12
	JIS T0601-2-35:2015
	KS C IEC 60601-2-35 : 2011-12⊗
IEC 80601-2-49 : 2018-03	IEC 80601-2-49 : 2018-03 Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors
ISO 10651-3 : 1997-01	Lung ventilators for medical use -- Part 3: Particular requirements for emergency and transport ventilators
	ABNT NBR ISO 10651-3 : 2014
	AS ISO 10651.3-2004
	CAN/CSA Z10651.3:1998 (R2013)
	KS P ISO 10651-3 : 2008-11

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	YY 0600.3—2007
ISO 10993-1 : 2018-08	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process ISO 10993-1 : 2009-10⊗ - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process ANSI/AAMI/ISO 10993-1:2009/(R)2013 GB/T 16886.1—2011 JIS T 0993-1:2012 ABNT NBR ISO 10993-1 : 2013-06 ISO 10993-1 : 2003-08⊗ - Biological evaluation of medical devices - Part 1: Evaluation and testing KS P ISO 10993-1 : 2007-11 AS ISO 10993.1-2002
ISO 10993-12 : 2012-07	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials ANSI/AAMI ISO 10993-12:2012 KS P ISO 10993-12:2014
ISO 10993-18 : 2005-07	Biological evaluation of medical devices - Part 18: Chemical characterization of materials GB/T 16886.18—2011 KS P ISO 10993-18 : 2009-12
ISO 11197:2016-02	Medical supply units
ISO 11348-2 : 2007-12	Water quality - Determination of the inhibitory effect of water samples on the light emission of Vibrio fischeri (Luminescent bacteria test) - Part 2: Method using liquid-dried bacteria
ISO 18562-1 : 2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process
ISO 18562-2 : 2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 2: Tests for emissions of particulate matter
ISO 18562-3 : 2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 3: Tests for emissions of volatile organic compounds (VOCs)

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ISO 18562-4 : 2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 4: Tests for leachables in condensate
ISO 21647 : 2004-11⊗	Medical electrical equipment - Particular requirements for the basic safety and essential performance of respiratory gas monitors + Corrigendum 1 : 2005-07 CAN/CSA-Z21647-07 KS P ISO 21647 : 2010-10 YY 0601—2009
ISO 80601-2-12 : 2011-04	Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators + Technical Corrigendum 1 : 2011-10 ABNT NBR ISO 80601-2-12:2014 CAN/CSA-C22.2 NO. 80601-2-12:12
ISO 80601-2-13 : 2011-08	Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation + Amendment 1 : 2015-03 CAN/CSA-C22.2 NO. 80601-2-13 : 2015 ABNT NBR ISO 80601-2-13: 2017-01 + Amendment 2 : 2018-07 ISO 80601-2-13 : 2011-08 - Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation KS C ISO 80601-2-13 : 2017-09
ISO 80601-2-55 : 2018-02	Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors ISO 80601-2-55 : 2011-12⊗ - Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors ABNT NBR ISO 80601-2-55 : 2014 CAN/CSA-C22.2 NO. 80601-2-55:2014 JIS T 80601-2-55 : 2014
DMS TC5021	Luminescent bacteria test - Biocompatibility
DMS TC5022	Particle emission - Biocompatibility

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DMS IN9050	Biocompatibility of medical devices, modules and accessories

Abbreviations used:

ANSI/AAMI	American National Standards Institute/Association for the Advancement of Medical Instrumentation
CAN/CSA	Canadian Standards Association
DIN	Deutsches Institut für Normung [German Institute for Standardisation]
DMS/DMS TC / IN	Dräger Standard Operating Procedure
EN	Europäische Norm [European Standard]
IEC	International Electrical Committee
ISO	International Organization for Standardization
Medical devices, active	Medical electrical devices, medical electrical systems and components
VDE	Vorschriftenwerk Verband der Elektrotechnik Elektronik Informationstechnik e.V. [Association for Electrical, Electronic and Information Technologies]
⊗	Standards withdrawn 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

[2] For transition periods, see list of harmonised standards on the EU website