Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-IS-11250-01-01 according to DIN EN ISO/IEC 17020:2012[1]

Valid from: 08.11.2019

Date of issue: 08.11.2019

Holder of certificate:

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

for its inspection body Type C

At the location:
Drägerwerk AG & Co. KGaA
Product Qualification, Inspektionsstelle
Finkenstraße 5, 23558 Lübeck

Inspections in the fields:

Inspection of medical devices and determination of their conformity - based on expert judgment - with general requirements

according to the following inspection instructions

DCS TC3600 Inspection

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

Abbreviations used: see last page

in the following scope

Inspection area	Produkt category	Inspection activity	Regulations inspection instructions
Biocompatibility	Medical devices according to the following MD codes: - MD 0101 - MD 0104 - MD 1101 - MD 1102 - MD 1103 - MD 1108 - MD 1109 - MD 1112 - MD 1202 - MD 1301 - MD 1302 - MD 1402	Determination of compliance with general requirements	DIN EN ISO 10993-1 ISO 10993-1 ISO 18562-1 Applicable: DCS IN8190 DMS TC5019 DMS TC5021 DMS TC5022 DMS TC5023
Safety checks (without process tests)	Medical devices according to the following MD codes / for the following products:	Determination of compliance with general requirements	DIN EN 60601-1 IEC 60601-1 *incl. collateral norms*
	- MD 1112 - MD 1202		DIN EN ISO 11197 ISO 11197
	- Luminaires		DIN EN 60601-2-41 IEC 60601-2-41
	- MD 0101		DIN EN ISO 80601-2-13 ISO 80601-2-13
	- MD 1102		DIN EN ISO 80601-2-13 ISO 80601-2-13 DIN EN 60601-2-13⊗ IEC 60601-2-13⊗

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Inspection area	Produkt category	Inspection activity	Regulations inspection instructions
			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 DIN EN ISO 80601-2-55 ISO 80601-2-55 DIN EN ISO 21647⊗ ISO 21647⊗
	- MD 1109		DIN EN 80601-2-35 IEC 80601-2-35 DIN EN 60601-2-35⊗ IEC 60601-2-35⊗
	- MD 1301 - MD 1302		DIN EN 60601-2-49 IEC 60601-2-49⊗ IEC 80601-2-49 DIN EN ISO 80601-2-55 ISO 80601-2-55 DIN EN ISO 21647⊗ ISO 21647⊗
	- MD 1402		DIN EN 60601-2-19 IEC 60601-2-19 DIN EN 60601-2-21 IEC 60601-2-21 DIN EN 80601-2-35 IEC 80601-2-35 DIN EN 60601-2-35⊗ IEC 60601-2-35⊗

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Inspection area	Produkt category	Inspection activity	Regulations inspection instructions
			Applicable: EUROCAE ed-14 #7-8 RTCA DO 160 #7-8 DMS IN9040 DMS IN9080
Security check (with process checks)	Medical devices according to the following MD codes: - MD 1102 - MD 1109 - MD 1111 - MD 1112 - MD 1202 - MD 1301 - MD 1302 - MD 1402	Determination of compliance with general requirements	DIN EN 62304 IEC 62304
	Medical devices, active according to the following MD codes: - MD 0101 - MD 1102 - MD 1109 - MD 1111 - MD 1112 - MD 1202 - MD 1301 - MD 1302 - MD 1402	Determination of compliance with general requirements	DIN EN 62366-1 IEC 62366-1 DIN EN 62366⊗ IEC 62366⊗

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Inspection area	Produkt category	Inspection activity	Regulations inspection instructions
Electromagnetic compatibility	Medical devices, active according to the following MD codes: - MD 1102 - MD 1109 - MD 1112 - MD 1202 - MD 1301 - MD 1302 - MD 1402	Determination of compliance with general requirements	DIN EN 60601-1-2 IEC 60601-1-2 Applicable: IEC TR 60601-4-2

Regulations[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 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 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 60601-1-2 : 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 60601-2-12 : 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~~13 (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 basic safety and essential performance of infant incubators (IEC 60601-2-19:2009); 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 the safety of baby 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

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	VDE 0750-2-21:2010-01 DIN EN 60601-2-21 : 1998-01⊗ - Medical electrical equipment - Part 2: Particular requirements for the 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⊗
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 the 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 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 62304:2016-10	Medical device software - Software life-cycle processes (IEC 62304:2006 + A1:2015); German version EN 62304:2006 + Cor.:2008 + A1:2015 VDE 0750-101:2016-10 DIN EN 62304 : 2007-03⊗ Medical device software - Software life-cycle processes (IEC 62304:2006); German version EN 62304:2006

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	VDE 0750-101:2007-03⊗
DIN EN 62366-1 : 2017-07	Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015 + COR1:2016); German version EN 62366-1:2015 + AC:2015 DIN EN 62366 : 2008-09⊗ - Medical devices - Application of usability engineering to medical devices (IEC 62366:2007); German version EN 62366:2008 + A1 : 2016-05 VDE 0750-241:2008-09
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 VDE 0750-2-35:2010-08
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

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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 + 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 0601-1:2017 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 60601-1-2 : 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 NO. 60601-1-2:16 JIS T 0601-1-2:2018 KS C IEC 60601-1-2 : 2017-12 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

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	ABNT NBR IEC 60601-1-2:2010 ANSI/AAMI/IEC 60601-1-2:2007 AS/NZS 3200.1.2:2005⊗ 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 KS C IEC 60601-1-2 : 2007-11 JIS T 0601-1-2:2012 YY 0505—2012
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⊗
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

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	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
	ANSI/AAMI/IEC 60601-2-19:2009
	ABNT NBR IEC 60601-2-19:2014 + Cor.1:2014
	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
	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

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	JIS T 0601-2-21:2005
	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
	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

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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 62304 : 2006-05	Medical device software - Software life cycle processes + Amendment 1 : 2015-06 JIS T 2304 : 2017-03 IEC 62304 : 2006-05 - Medical device software - Software life cycle processes ANSI/AAMI/IEC 62304 : 2006 + A1:2016 CAN/CSA IEC 62304 : 2014 JIS T 2304 : 2012 YY/T 0664 - 2008
IEC 62366 : 2007-10 ⊗	Medical devices - Application of usability engineering to medical devices + Amendment 1 : 2014-01 ANSI/AAMI/IEC 62366 : 2007 +A1:2013 ABNT NBR IEC 62366 : 2010 +A1:2016 IEC 62366 : 2007-10 - Medical devices - Application of usability engineering to medical devices ANSI/AAMI/IEC 62366 : 2007 CAN/CSA IEC 62366 : 2014
IEC 62366-1 : 2015-02	Medical devices - Part 1: Application of usability engineering to medical devices + Technical Corrigendum 1 : 2016-07 Medical devices - Part 1: Application of usability engineering to medical devices ANSI/AAMI/IEC 62366-1 : 2015 CAN/CSA IEC 62366-1 : 2015
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

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	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	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 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 11197 : 2016-02	Medical supply units
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 21647 : 2004-11⊗	Medical electrical equipment - Particular requirements for the basic safety and essential performance of respiratory gas monitors + Corrigendum 1 : 2005-07

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	CAN/CSA-Z21647-07 KS P ISO 21647 : 2010-12 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
EUROCAE ed-14G : 2011-05	Environmental Conditions and Test Procedures for Airborne Equipment + Change 1 : 2015-01 Sections 7-8: Temperature and Altitude, Temperature Variation, Humidity, Operational Shocks and Crash Safety, Vibration EUROCAE ed-14 F : 2008. Sections 7-8
RTCA DO-160G : 2010-08	Environmental Conditions and Test Procedures for Airborne Equipment + Change 1 : 2014-12

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	Sections 7-8: Temperature and Altitude, Temperature Variation, Humidity, Operational Shocks and Crash Safety, Vibration RTCA DO 160 F : 2007, Sections 7-8 RTCA DO 160 E : 2004, Sections 7-8
DMS IN9040	Test specification for mechanical safety and environmental tests
DCS IN8190	Biocompatibility of medical devices, modules and accessories
DMS IN9080	Combustion safety in normal and oxygenized atmospheres
DCS TC3600	Inspection
DMS TC5019	Integral testing- Biocompatibility
DMS TC5021	Luminescent bacteria test - Biocompatibility
DMS TC5022	Particle emissions - Biocompatibility
DMS TC5023	Anesthetic agent changes - biocompatibility

Abbreviations used:

ABNT NBR	Associação Brasileira de Normas Técnicas
ANSI/AAMI	American National Standards Institute/Association for the Advancement of Medical Instrumentation
AS/NZS	Australian Standard / New Zealand Standard
BS	British Standard
CAN/CSA	Canadian Standards Association
DIN	Deutsches Institut für Normung
DMS IN	Dräger Medical SOP
DCS TC / DMS TC	Dräger SOP Testing & Calibration
EN	Europäische Norm
EUROCAE	European Organization for Civil Aviation Equipment
IEC	International Electrical Committee
GB	Guobiao (PR China)
ISO	International Organization for Standardization
JIS	Japanese Industrial Standards
KS	Korean Standard
Medical devices, active	medical electrical equipment, medical electrical systems and components
RTCA	Radio Technical Commission for Aeronautics
UL	Underwriters Laboratories
VDE	Vorschriftenwerk Verband der Elektrotechnik Elektronik Informationstechnik e.V.
YY	Code for Medical Industrial Standards (PR China)
⊗	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 17020:2012-07 – Conformity assessment - Requirements for the operation of various types of bodies performing inspection

[2] For the transition periods, see the list of harmonized standards on the EU homepage.

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