医療関係IEC規格　（平成24年9月3日現在）　European Norm（CENELEC）　調査日：2012-09-25　2012-08-30発行のOJ（2012-09-01時点で有効なもの）　（2012-09-12時点のDB）

規格番号	規格名称	規格名称（仮邦訳）	TC	Reference	Date	Title		EU Harmonised Standards ○：最新版 ●：旧版等 ISO /IEC standard	MDD	AIMD	IVD	FDA Recognized Consensus Standards（経過措置終了日）	○：最新版	●：旧版等
IEC 60601-1-8 Ed. 2.0:2006	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	医用電気機器－第1-8部：基礎安全及び基本性能に関する一般要求事項－副通則：医用電気機器及び医用電気システムの警報システムの一般要求事項，試験及び指針	TC 62A	EN 60601-1-8:2007	2007-07-31	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	CLC/TC 62	EN 60601-1-8:2007 (IEC 60601-1-8:2006) EN 60601-1-8:2007/ AC:2010	○[1]			IEC 60601-1-8 Ed. 1	General	● (2013-06-30)
												IEC 60601-1-8 Ed. 2:2006-10	General	○
IEC 60601-1-9 Ed. 1.0:2007	Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious	医用電気機器－第1-9部：基礎安全及び基本性能に関する一般要求事項－副通則：環境配慮設計の要求事項	TC 62A	EN 60601-1-9:2008	2008-04-29	Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious	CLC/TC 62							
IEC 60601-1-10 Ed. 1.0:2007	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	医用電気機器－第1-10部：基礎安全及び基本性能に関する一般要求事項－副通則：生理的閉ループ制御器の開発に関する要求事項	TC 62A	EN 60601-1-10:2008	2008-04-24	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	CLC/TC 62	EN 60601-1-10:2008 (IEC 60601-1-10:2007)	○[1]			IEC 60601-1-10 Ed. 1.0:2007	General	○[5]
IEC 60601-1-11 Ed. 1.0:2010 IEC 60601-1-11 Ed. 1.0 Cor.1:2011	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	医用電気機器－第1-11部：基礎安全及び基本性能に関する一般要求事項－副通則：家庭ヘルスケア環境で使用する医用電気機器及び医用電気システムに対する要求事項	TC 62A	EN 60601-1-11:2010	2010-06-04	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	CLC/TC 62	EN 60601-1-11:2010 (IEC 60601-1-11:2010)	●[1]			IEC 60601-1-11 Edition 1.0:2010 IEC 60601-1-11 (First edition – 2010) April 2011/Cor 1	General	○[1]
IEC 60601-1-SER Ed. 1.0:2011	Medical electrical equipment – ALL PARTS	医用電気機器－すべての部	TC 62A											
IEC 60601-2-1 Ed. 3.0:2009	Medical electrical equipment – Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV	医用電気機器－第2-1部：1 MeV～50 MeVの範囲の電子加速装置の基礎安全及び基本性能の特定要求事項	TC 62C	EN 60601-2-1:1998 EN 60601-2-1:1998/A1:2002	1998-08-14 2002-06-07	Medical electrical equipment – Part 2-1: Particular requirements for the safety of electron accelerators in the range of 1 MeV to 50 MeV	CLC/TC 62	EN 60601-2-1:1988 (IEC 60601-2-1:1998) EN 60601-2-1:1998/ A1:2002 (IEC 60601-2-1:1998/ A1:2002)	●			IEC 60601-2-1 (1998) Amendment 1: 2002	Radiology	●
												IEC 60601-2-1 Edition 3.0 2009-10	Radiology	○
IEC 60601-2-2 Ed. 5.0:2009	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	医用電気機器－第2-2部：高周波外科用器具及び高周波外科用附属品の基礎安全及び基本性能の特定要求事項	TC 62D	EN 60601-2-2:2009 EN 60601-2-2:2009/A11:2011	2009-05-20 2011-10-14	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	CLC/TC 62	EN 60601-2-2:2009 (IEC 60601-2-2:2009)	○[1]			IEC 60601-2-2 2006 IEC 60601-2-2- 2006	GPS/GH OBGYN/GU	● (2013-06-30)
												IEC 60601-2-2 Edition 5.0 2009-02 AAMI ANSI IEC 60601-2-2:2009 (IEC 60601-2-2:2009)	GPS/GH OBGYN/GU	○
IEC 60601-2-3 Ed. 3.0:2012	Medical electrical equipment – Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment	医用電気機器－第2-3部：短波治療機器の基礎安全及び基本性能の特定要求事項	TC 62D	EN 60601-2-3:1993 EN 60601-2-3:1993/A1:1998	1993-04-22 1998-11-06	Medical electrical equipment – Part 2: Particular requirements for the safety of short-wave therapy equipment	CLC/TC 62	EN 60601-2-3:1993 (IEC 60601-2-3:1991) EN 60601-2-3:1993/ A1:1988 (IEC 60601-2-3:1993/ Amd.1:1988)	●[1][*]					
~~IEC 60601-2-4 ed2.0:2002~~	~~Medical electrical equipment – Part 2-4: Particular requirements for the safety of cardiac defibrillators~~		TC 62D	EN 60601-2-4:2003	2003-01-31	Medical electrical equipment – Part 2-4: Particular requirements for the safety of cardiac defibrillators	CLC/TC 62	EN 60601-2-4:2003 (IEC 60601-2-4:2002)	●[1]					
IEC 60601-2-4 Ed. 3.0:2010	Medical electrical equipment – Part 2-4: Particular requirements for the basic safety and essential performance of cardiac	医用電気機器－第2-4部：細動除去器の基礎安全及び基本性能に関する特定要求事項		EN 60601-2-4:2011	2011-08-19	Medical electrical equipment – Part 2-4: Particular requirements for the basic safety and essential performance of cardiac								
IEC 60601-2-5 Ed. 3.0:2009	Medical electrical equipment – Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment	医用電気機器－第2-5部：超音波物理療法機器の基礎安全及び基本性能の特定要求事項	TC 62D	EN 60601-2-5:2000	2000-12-19	Medical electrical equipment – Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment	CLC/TC 62	EN 60601-2-5:2000 (IEC 60601-2-5:2000)	●[1]			IEC 60601-2-5:(2000)	Radiology	● (2013-06-30)
												IEC 60601-2-5: Edition 3.0 2009-07	Radiology	○
IEC 60601-2-6 Ed. 2.0:2012	Medical electrical equipment – Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment	医用電気機器－第2部：マイクロ波治療機器の安全性の特定要求事項	TC 62D											
IEC 60601-2-7 Ed. 2.0:1998	Medical electrical equipment – Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators	医用電気機器－第2-7部：診断用X線発生器の高電圧発生器の安全性の特定要求事項	TC 62B					EN 60601-2-7:1998 (IEC 60601-2-7:1998)	○[1]			IEC 60601-2-7 (1998)	Radiology	○
IEC 60601-2-8 Ed. 2.0:2010	Medical electrical equipment – Part 2-8: Particular requirements for basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1	医用電気機器－第2-8部：動作範囲が10 kV から1 MVの治療用X線機器の基礎安全及び基本性能の特定要求事項	TC 62C	EN 60601-2-8:1997 EN 60601-2-8:1997/A1:1997	1997-09-09 1997-09-09	Medical electrical equipment – Part 2: Particular requirements for the safety of therapeutic X-ray equipment operating in the range 10 kV to 1 MV	CLC/TC 62	EN 60601-2-8:1997 (IEC 60601-2-8:1987) EN 60601-2-8:1997/ A1:1997 (IEC 60601-2-8:1987/ A1:1997)	●[1]			IEC 60601-2-8(1999-04)	Radiology	●
IEC 60601-2-10 Ed. 2.0:2012	Medical electrical equipment – Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators	医用電気機器－第2-10部：神経及び筋刺激装置の基礎安全及び基本性能の特定要求事項	TC 62D	EN 60601-2-10:2000 EN 60601-2-10:2000/A1:2001	2000-11-13 2001-11-09	Medical electrical equipment – Part 2-10: Particular requirements for the safety of nerve and muscle stimulators	CLC/TC 62	EN 60601-2-10:2000 (IEC 60601-2-10:1987 EN 60601-2-10:2000/ A1:2001 (IEC 60601-2-10:1987/ A1:2001)	●[1][*]			IEC 60601-2-10 1987/Amendment 1 2001	Neur	●
IEC 60601-2-11 Ed. 2.0:1997 IEC 60601-2-11 Amd.1 Ed.2.0:2004	Medical electrical equipment – Part 2: Particular requirements for the safety of gamma beam therapy equipment	医用電気機器－第2部：ガンマ線治療機器の安全性の特定要求事項	TC 62C	EN 60601-2-11:1997 EN 60601-2-11:1997/A1:2004	1997-09-30 2004-09-21	Medical electrical equipment – Part 2-11: Particular requirements for the safety of gamma beam therapy equipment	CLC/TC 62	EN 60601-2-11:1997 (IEC 60601-2-11:1997) EN 60601-2-11:1997/ A1:2004 (IEC 60601-2-11:1997/ Amd.1:2004)	●[1]			IEC 60601-2-11 (1997)(2004)	Radiology	○
~~IEC 60601-2-12 Ed. 2.0:2001~~	~~Medical electrical equipment – Part 2-12: Particular requirements for the safety of lung ventilators – Critical care ventilators~~	医用電気機器－第2-12部：肺ベンチレータの安全性に関する特定要求事項－臨床看護ベンチレータ	TC 62D	EN 60601-2-12:2006	2006-06-28	Medical electrical equipment – Part 2-12: Particular requirements for the safety of lung ventilators – Critical care ventilators	CLC/TC 62	EN 60601-2-12:2006 (IEC 60601-2-12:2001)	●[1]			IEC 60601-2-12:(2001-10)	Anesthesia	●[1]
IEC 60601-2-13 Ed. 3.1:2009	Medical electrical equipment – Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems	医用電気機器－第2-13部：麻酔システムの安全性及び基本性能の特定要求事項	TC 62D	EN 60601-2-13:2006 EN 60601-2-13:2006/A1:2007	2006-06-28 007-03-16	Medical electrical equipment – Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems	CLC/TC 62	EN 60601-2-13:2006 (IEC 60601-2-13:2003) EN 60601-2-13:2006/ A1:2007 (IEC 60601-2-13:2003/ A1:2006)	●[1]			IEC 60601-2-13(2003-05)	Anesthesia	●[1] (2013-06-30)
												IEC 60601-2-13 Edition 3.1 2009-08	Anesthesia	○

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規格番号	規格名称	規格名称（仮邦訳）	TC	Reference	Date	Title		EU Harmonised Standards ○：最新版 ●：旧版等 ISO /IEC standard	MDD	AIMD	IVD	FDA Recognized Consensus Standards（経過措置終了日）	○：最新版	●：旧版等
~~IEC 60601-2-16 Ed. 3.0:2008~~ ~~IEC 60601-2-16 Ed. 3.0 Cor.1:2008~~ IEC 60601-2-16 Ed. 4.0:2012	Medical electrical equipment – Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment	医用電気機器－第2-16部：血液透析，濾過透析及び血液ろ過機器の基礎安全及び基本性能の特定要求事項	TC 62D	EN 60601-2-16:1998	1998-04-09	Medical electrical equipment – Part 2-16: Particular requirements for the safety of haemodialysis, haemodiafiltration and haemofiltration equipment	CLC/TC 62	EN 60601-2-16:1998 (IEC 60601-2-16:1998) EN 60601-2-16:1998/ AC:1999	●[1]			IEC 60601-2-16 (1998)	OBGYN/GU	● (2013-06-30)
												IEC 60601-2-16 Edition 3.0 2008-04 IEC 60601-2-16 (Third edition – 2008)/Cor 1 AAMI ANSI ISO 60601-2-16:2008 (IEC 60601-2-16:2008)	OBGYN/GU	●
IEC 60601-2-17 Ed. 2.0:2004	Medical electrical equipment – Part 2-17: Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment	医用電気機器－第2-17部：自動制御近接照射療法アフタローディング機器の安全性の特定要求事項	TC 62C	EN 60601-2-17:2004	2004-04-06	Medical electrical equipment – Part 2-17: Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment	CLC/TC 62	EN 60601-2-17:2004 (IEC 60601-2-17:2004)	○[1]			IEC 60601-2-17 (2004)	Radiology	○
IEC 60601-2-18 Ed. 3.0:2009	Medical electrical equipment – Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment	医用電気機器－第2-18部：内視鏡機器の基礎安全及び基本性能の特定要求事項	TC 62D	EN 60601-2-18:1996 EN 60601-2-18:1996/A1:2000	1996-09-30 2000-12-22	Medical electrical equipment – Part 2: Particular requirements for the safety of endoscopic equipment	CLC/TC 62	EN 60601-2-18:1996 (IEC 60601-2-18:1996) EN 60601-2-18:1996/ A1:2000 (IEC 60601-2-18:1996/ A1:2000)	●[1]			IEC 60601-2-18 (1996) Amendment 1 2000	Dental/ENT OBGYN/GU	●[3] (2013-06-13)
												IEC 60601-2-18 Edition 3.0 2009-08	Dental/ENT OBGYN/GU	○
IEC 60601-2-19 Ed. 2.0:2009 IEC 60601-2-19 Ed. 2.0 Cor.1:2012	Medical electrical equipment – Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators	医用電気機器－第2-19部：早産児保育器の基礎安全及び基本性能の特定要求事項	TC 62D	EN 60601-2-19:2009 EN 60601-2-19:2009/A11:2011	2009-05-20 2011-10-14	Medical electrical equipment – Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators	CLC/TC 62	IEC 60601-2-19:2009	●[1][*]			IEC 60601-2-19 1996-10/Amd 1	GPS/GH	● (2013-06-30)
												AAMI ANSI IEC 60601-2-19:2009 (IEC 60601-2-19:2009) IEC 60601-2-19 (Second edition – 2009)/Cor 1	GPS/GH	○
IEC 60601-2-20 Ed. 2.0:2009 IEC 60601-2-20 Ed. 2.0 Cor.1:2012	Medical electrical equipment – Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators	医用電気機器－第2-20部：搬送保育器の基礎安全及び基本性能の特定要求事項	TC 62D	EN 60601-2-20:2009 EN 60601-2-20:2009/A11:2011	2009-11-26 2011-10-14	Medical electrical equipment – Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators	CLC/TC 62	EN 60601-2-20:2009 (IEC 60601-2-20:2009)	●[1][*]			IEC 60601-2-20 1996 IEC 60601-2-20:1996/Amd 1	GPS/GH	● (2013-06-30)
												AAMI ANSI IEC 60601-2-20:2009 (IEC 60601-2-20:200) IEC 60601-2-20 (Second edtion – 2009)/Cor 1	GPS/GH	○
IEC 60601-2-21 Ed. 2.0:2009	Medical electrical equipment – Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers	医用電気機器－第2-21部：乳幼児放射ウォーマーの基礎安全及び基本性能の特定要求事項	TC 62D	EN 60601-2-21:2009 EN 60601-2-21:2009/A11:2011	2009-05-20 2011-10-14	Medical electrical equipment – Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers	CLC/TC 62	EN 60601-2-21:2009 (IEC 60601-2-21:2009)	○[1]			IEC 60601-2-21:1996/Amd 1:2000 AAMI ANSI IEC 60601-2-21 and 60601-2-21 Amendment 1:2000	GPS/GH	● (2013-06-30)
												IEC 60601-2-21 AAMI ANSI IEC 60601-2-21:2009 (IEC 60601-2-21:2009)	GPS/GH	○
IEC 60601-2-22 Ed. 3.0:2007	Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment	医用電気機器－第2-22部：外科，美容用治療，及び診断用レーザ機器の基礎安全及び基本性能に関する特定要求事項	TC 76	EN 60601-2-22:1996	1996-01-08	Medical electrical equipment – Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment		EN 60601-2-22:1996 (IEC 60601-2-22:1995)	●[1]			IEC 60601-2-22 (1995)	Radiology	● (2013-06-30)
												IEC 60601-2-22 Third Edition 2007-05	Radiology	○
IEC 60601-2-23 Ed. 3.0:2011	Medical electrical equipment – Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment	医用電気機器－第2-23部：経皮分圧監視機器の基礎安全及び基本性能に関する特定要求事項	TC 62D	EN 60601-2-23:2000	2000-03-15	Medical electrical equipment – Part 2-23: Particular requirements for the safety, including essential performance, of transcutaneous partial pressure monitoring	CLC/TC 62	EN 60601-2-23:2000 (IEC 60601-2-23:1999)	●[1]			IEC 60601-2-23 Edition 3.0 2011-02	Anesthesia	○
IEC 60601-2-24 Ed. 1.0:1998	Medical electrical equipment – Part 2-24: Particular requirements for the safety of infusion pumps and controllers	医用電気機器－第2-24部：薬物注入ポンプ及びコントローラの安全性の特定要求事項	TC 62D	EN 60601-2-24:1998	1998-04-14	Medical electrical equipment – Part 2-24: Particular requirements for the safety of infusion pumps and controllers	CLC/TC 62	EN 60601-2-24:1998 (IEC 60601-2-24:1998)	○[1]					
~~IEC 60601-2-25 Ed. 1.0:1993~~ ~~IEC 60601-2-25 Amd.1 Ed. 1.0:1999~~ IEC 60601-2-25 Ed. 2.0:2011	Medical electrical equipment – Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs	医用電気機器－第2-25部：心電計の基礎安全及び基本性能の特定要求事項	TC 62D	EN 60601-2-25:1995 EN 60601-2-25:1995/A1:1999	1995-11-30 1999-06-03	Medical electrical equipment – Part 2-25: Particular requirements for the safety of electrocardiographs	CLC/TC 62	EN 60601-2-25:1995 (IEC 60601-2-25:1993) EN 60601-2-25:1995/A1:1999 (IEC 60601-2-25:1993/A1:1999)	●[1]			IEC 60601-2-25 Amendment 1 (1999)	Card	●[1][3]
~~IEC 60601-2-26 Ed. 3.0:2012~~	Medical electrical equipment – Part 2-26: Particular requirements for the basic safety and essential performance of	医用電気機器－第2-26部：脳波計の基礎安全及び基本性能に関する特定要求事項	TC 62D	EN 60601-2-26:2003	2003-07-31	Medical electrical equipment – Part 2-26: Particular requirements for the safety of electroencephalographs	CLC/TC 62	~~EN 60601-2-26:2003~~ ~~(IEC 60601-2-26:2002)~~	●[1][*]					
IEC 60601-2-27 Ed. 3.0:2011 IEC 60601-2-27 Ed. 3.0 Cor.1:2012	Medical electrical equipment – Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment	医用電気機器－第2-27部：心電計監視装置の基礎安全及び基本性能に関する特定要求事項	TC 62D	EN 60601-2-27:2006	2006-04-05	Medical electrical equipment – Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment	CLC/TC 62	EN 60601-2-27:2006 (IEC 60601-2-27:2005) EN 60601-2-27:2006/ AC:2006	●[1]			~~IEC 60601-2-27: (2005-08)~~	Card	●[1][3] (2013-06-30)
												IEC 60601-2-27 Edition 3.0 2011-03 AAMI ANSI ISO 60601-2-27:2011 (IEC 60601-2-27:2011)	Card	●[1]
~~IEC 60601-2-28 ed1.0:1993~~	~~Medical electrical equipment – Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis~~		TC 62B	EN 60601-2-28:1993	1993-05-28	Medical electrical equipment – Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis	CLC/TC 62	EN 60601-2-28:1993 (IEC 60601-2-28:1993) IEC 60601-2-28:2010 (IEC 60601-2-28:2010)	●[1] (2013-03-31) ○[1]			IEC 60601-2-28: 1993	Radiology	● (2013-06-30)
IEC 60601-2-28 Ed. 2.0:2010	Medical electrical equipment – Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis	医用電気機器－第2-28部：医用診断のためのX線管装置の基礎安全及び基本性能の特定要求事項		EN 60601-2-28:2010	2010-05-07	Medical electrical equipment – Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis						IEC 60601-2-28 Edition 2.0 2010-03	Radiology	○

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IEC 60601-2-29 Ed. 3.0:2008	Medical electrical equipment – Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators	医用電気機器－第2-29部：放射線療法シミュレータの基礎安全及び基本性能の特定要求事項	TC 62C	EN 60601-2-29:2008 EN 60601-2-29:2008/A11:2011	2008-11-28 2011-10-14	Medical electrical equipment – Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators	CLC/TC 62	EN 60601-2-29:2008 (IEC 60601-2-29:2008)	○[1]			IEC 60601-2-29 (1999) IEC 60601-2-29 Edition 3.0 2008-06	Radiology Radiology	● (2013-06-30) ○
~~IEC 60601-2-30:1999~~	~~Medical electrical equipment – Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment~~		TC 62D	EN 60601-2-30:2000	2000-05-18	Medical electrical equipment – Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment	CLC/TC 62	EN 60601-2-30:2000 (IEC 60601-2-30:1999)	●[1]					
IEC 60601-2-31 Ed. 2.0:2008 IEC 60601-2-31 Amd.1 Ed. 2.0:2011 IEC 60601-2-31 Ed. 2.1:2011	Medical electrical equipment – Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source	医用電気機器－第2-31部：内部電源を持つ外部心臓ペースメーカの基礎安全及び基本性能の特定要求事項	TC 62D	EN 60601-2-31:2008 EN 60601-2-31:2008/A1:2011	2008-07-25 2011-08-12	Medical electrical equipment – Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source	CLC/TC 62	~~EN 60601-2-31:1995~~ ~~(IEC 60601-2-31:1994)~~ ~~EN 60601-2-31:199/ A1:1998~~ ~~(IEC 60601-2-31:1994/ A1:1998)~~	~~●[1]~~			IEC 60601-2-31 Edition 2.1 2011-09	Card	○[3]
IEC 60601-2-32 Ed. 1.0:1994	Medical electrical equipment – Part 2: Particular requirements for the safety of associated equipment of X-ray equipment	医用電気機器－第2部：X線機器附属機器の安全性の特定要求事項	TC 62B					EN 60601-2-32:1994 (IEC 60601-2-32:1994)	○[1]			IEC 60601-2-32: 1994	Radiology	○
~~IEC 60601-2-33 ed2.0:2002~~ ~~IEC 60601-2-33-am1 ed2.0:2005~~ ~~IEC 60601-2-33-am2 ed2.0:2007~~ IEC 60601-2-33 Ed. 3.0:2010 ~~IEC 60601-2-33 Ed. 3.0 Cor.1:2012~~	~~Medical electrical equipment – Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis~~ Medical electrical equipment – Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis	医用電気機器－第2-33部：医療診断用のMR装置の基礎安全及び基本性能の特定要求事項	TC 62B	EN 60601-2-33:2002 EN 60601-2-33:2002/A1:2005 EN 60601-2-33:2002/A2:2008 EN 60601-2-33:2010 EN 60601-2-33:2010/A11:2011	2002-10-08 2005-11-30 2008-03-05 2010-10-15 2011-10-14	Medical electrical equipment – Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis Medical electrical equipment – Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis	CLC/TC 62	EN 60601-2-33:2002 (IEC 60601-2-33:2002) EN 60601-2-33:2002/ A1:2005 (IEC 60601-2-33:2002/ A1:2005) EN 60601-2-33:2002/ A2:2008 (IEC 60601-2-33:2002/ A2:2007) EN 60601-2-33:2002/ A2:2008/AC:2008	●[1][*]			IEC 60601-2-33 (2008) ed 2.2 IEC 60601-2-33 Edition 3.0 2010-03	Radiology Radiology	●[1] (2013-06-20) ●[1]
IEC 60601-2-34 Ed. 3.0:2011	Medical electrical equipment – Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment	医用電気機器－第2-34部：侵襲性血圧監視機器の重要性能を含む安全性の特定要求事項	TC 62D	EN 60601-2-34:2000	2000-12-19	Medical electrical equipment – Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment	CLC/TC 62	IEC 60601-2-34:2000 (IEC 60601-2-34:2000)	●[1]			IEC 60601-2-34 (2000-10)	Card	●[3]
~~IEC 60601-2-35:1996~~	~~Medical electrical equipment – Part 2: Particular requirements for the safety of blankets, pads and mattresses, intended for heating in medical use~~ IEC 80601-2-35に移行(2009-10-20)		TC 62D	EN 60601-2-35:1996	1996-12-13	Medical electrical equipment – Part 2: Particular requirements for the safety of blankets, pads and mattresses, intended for heating in medical use	CLC/TC 62	EN 60601-2-35:1996 (IEC 60601-2-35:1996)	●[1]					
IEC 60601-2-36 Ed. 1.0:1997	Medical electrical equipment – Part 2: Particular requirements for the safety of equipment for extracorporeally induced	医用電気機器－第2部：体外誘導砕石術のための機器の安全性の特定要求事項	TC 62D	EN 60601-2-36:1997	1997-05-07	Medical electrical equipment – Part 2: Particular requirements for the safety of equipment for extracorporeally induced	CLC/TC 62	EN 60601-2-36:1997 (IEC 60601-2-36:1997)	○[1]			IEC 60601-2-36 (1997)	OBGYN/GU	○
IEC 60601-2-37 Ed. 2.0:2007	Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment	医用電気機器－第2-37部：超音波医用診断及び監視機器の基礎安全及び基本性能の特定要求事項	TC 62B	EN 60601-2-37:2008 EN 60601-2-37:2008/A11:2011	2008-01-31 2011-10-14	Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment	CLC/TC 62	IEC 60601-2-37:2007	○[1]			IEC 60601-2-37 (2004) (2005) Amendment 2 IEC 60601-2-37 Edition 2.0 2007-08	Radiology Radiology	● (2013-06-30) ○
~~IEC 60601-2-38:1996~~ ~~IEC 60601-2-38:1996/A1:1999~~	~~Medical electrical equipment – Part 2-38: Particular requirements for the safety of electrically operated hospital beds~~IEC 60601-2-52に移行(2009-12-14)		TC 62D	EN 60601-2-38:1996 EN 60601-2-38:1996/A1:2000	1996-12-16 2000-03-20	Medical electrical equipment – Part 2-38: Particular requirements for the safety of electrically operated hospital beds	CLC/TC 62	EN 60601-2-38:1996 (IEC 60601-2-38:1996) EN 60601-2-38:1996/ A1:2000 (IEC 60601-2-38:1996/ A1:1999)	●[1]			IEC 60601-2-38 1996/ Amendment 1:1999	GPS/GH	●[1] (2013-06-30)
IEC 60601-2-39 Ed. 2.0:2007	Medical electrical equipment – Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment	医用電気機器－第2-39部：腹膜透析機器の基礎安全及び基本性能に関する特定要求事項	TC 62D	EN 60601-2-39:2008 EN 60601-2-39:2008/A11:2011	2008-04-24 2011-10-14	Medical electrical equipment – Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment	CLC/TC 62	EN 60601-2-39:2008 (IEC 60601-2-39:2007)	○[1]					
IEC 60601-2-40 Ed. 1.0:1998	Medical electrical equipment – Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment	医用電気機器－第2-40部：筋電計及び誘発反応機器の安全性の特定要求事項	TC 62D	EN 60601-2-40:1998	1998-04-14	Medical electrical equipment – Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment	CLC/TC 62	EN 60601-2-40:1998 (IEC 60601-2-40:1998)	○[1]					
~~IEC 60601-2-43 ed1.0:2000~~ IEC 60601-2-41 Ed. 2.0:2009	~~Medical electrical equipment – Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures~~ Medical electrical equipment – Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis	医用電気機器－第2-41部：無影照明器具及び診断のための照明器具の基礎安全及び基本性能の特定要求事項	TC 62D	EN 60601-2-41:2000 EN 60601-2-41:2009 EN 60601-2-41:2009/A11:2011	2000-06-14 2009-12-23 2011-10-14	Medical electrical equipment – Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis Medical electrical equipment – Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis	CLC/TC 62	EN 60601-2-41:2000 (IEC 60601-2-41:2000) EN 60601-2-41:2009 (IEC 60601-2-41:2009)	●[1] (2012-10-31) ○[1]					
~~IEC 60601-2-43 ed1.0:2000~~ IEC 60601-2-43 Ed. 2.0:2010	~~Medical electrical equipment – Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures~~ Medical electrical equipment – Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures	医用電気機器－第2-43部：インタベンショナル処置のためのX線装置の基礎安全及び基本性能の特定要求事項	TC 62B	EN 60601-2-43:2000 EN 60601-2-43:2010	2000-12-19 2010-06-11	Medical electrical equipment – Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures Medical electrical equipment – Part 2-43: Particular requirements for basic safety and essential performance of X-ray equipment for interventional procedures	CLC/TC 62	EN 60601-2-43:2000 (IEC 60601-2-43:2000) EN 60601-2-43:2010 (IEC 60601-2-43:2010)	●[1] (2013-05-31) ○[1]			IEC 60601-2-43 – Ed. 1.0 IEC 60601-2-43 – Ed. 2.0 2010-03	Radiology Radiology	● (2013-06-30) ○
IEC 60601-2-44 Ed. 3.0:2009 IEC 60601-2-44 Ed. 3.0 Cor.1:2010 ~~IEC 60601-2-44 Amd.1 Ed. 3.0:2012~~	Medical electrical equipment – Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography	医用電気機器－第2-44部：コンピュータ断層撮影用X線機器の基礎安全及び基本性能の特定要求事項	TC 62B	EN 60601-2-44:2009 EN 60601-2-44:2009/A11:2011	2009-05-20 2011-10-14	Medical electrical equipment – Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography	CLC/TC 62	EN 60601-2-44:2009 (IEC 60601-2-44:2009)	●[1][*]			IEC 60601-2-44 (2002-11) IEC 60601-2-44 Edition 3.0 2009-02 IEC 60601-2-44 (Third edition – 2009)/Cor 1	Radiology Radiology	● (2013-06-30) ●

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規格番号	規格名称	規格名称（仮邦訳）	TC	Reference	Date	Title		EU Harmonised Standards ○：最新版 ●：旧版等 ISO /IEC standard	MDD	AIMD	IVD	FDA Recognized Consensus Standards （経過措置終了日）	○：最新版	●：旧版等
~~IEC 60601-2-45 ed2.0:2001~~	~~Medical electrical equipment – Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices~~			EN 60601-2-45:2001	2001-07-30	Medical electrical equipment – Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices		EN 60601-2-45:2001 (IEC 60601-2-45:2001)	●[1]			IEC 60601-2-45 Ed. 2.0, (2001)	Radiology	● (2013-06-30)
IEC 60601-2-45 Ed. 3.0:2011	Medical electrical equipment – Part 2-45: Particular requirements for basic safety and essential performance of mammographic X-ray equipment and mammomagraphic stereotactic devices	医用電気機器－第2-45部：乳房用X線機器及び定位乳房撮影装置の基礎安全及び基本性能の特定要求事項	TC 62B	EN 60601-2-45:2011	2011-03-18	Medical electrical equipment – Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices	CLC/TC 62					IEC 60601-2-45 Edition 3.0 2011-02	Radiology	○
~~IEC 60601-2-46 ed1.0:1998~~	~~Medical electrical equipment – Part 2-46: Particular requirements for the safety of operating tables~~			EN 60601-2-46:1998	1998-08-14	Medical electrical equipment – Part 2-46: Particular requirements for the safety of operating tables		EN 60601-2-46:1998 (IEC 60601-2-46:1998)	●[1]					
IEC 60601-2-46 Ed. 2.0:2010	Medical electrical equipment – Part 2-46: Particular requirements for basic safety and essential performance of operating tables	医用電気機器－第2-46部：手術台の基礎安全及び基本性能に関する特定要求事項	TC 62D	EN 60601-2-46:2011	2011-08-19	Medical electrical equipment – Part 2-46: Particular requirements for the basic safety and essential performance of operating tables	CLC/TC 62							
~~IEC 60601-2-47 Ed. 1.0:2001~~ IEC 60601-2-47 Ed. 2.0:2012	Medical electrical equipment – Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems	医用電気機器－第2-47部：移動式心電計システムの基礎安全及び基本性能に関する特定要求事項	TC 62D	EN 60601-2-47:2001	2001-10-26	Medical electrical equipment – Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems	CLC/TC 62	EN 60601-2-47:2001 (IEC 60601-2-47:2001)	●[1][*]					
IEC 60601-2-49 Ed. 2.0:2011	Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment	医用電気機器－第2-49部：多機能患者監視機器の基礎安全及び基本性能に関する特定要求事項	TC 62D	EN 60601-2-49:2001	2001-10-26	Medical electrical equipment – Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment	CLC/TC 62	EN 60601-2-49:2001 (IEC 60601-2-49:2001)	●[1]					
IEC 60601-2-50 Ed. 2.0:2009 IEC 60601-2-50 Ed. 2.0 Cor.1:2010	Medical electrical equipment – Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment	医用電気機器－第2-50部：乳幼児の光線療法機器の基礎安全及び基本性能の特定要求事項	TC 62D	EN 60601-2-50:2009 EN 60601-2-50:2009/A11:2011	2009-05-20 2011-10-14	Medical electrical equipment – Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment	CLC/TC 62	EN 60601-2-50:2009 (IEC 60601-2-50:2009)	●[1]			IEC 60601-2-50 Edition 2.0 2009-03 AAMI ANSI IEC 60601-2-50:2009 (IEC 60601-2-50:2009)	GPS/GH	●
~~IEC 60601-2-51 Ed. 1.0:2003~~	~~Medical electrical equipment – Part 2-51: Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs~~ IEC 0601-2-25に移行(2011-10-19)	~~医用電気機器－第2-51部：単チャネル及び多チャネル心電計の記録並びに分析の必須能力を含む安全性の特定要求事項~~	TC 62D	EN 60601-2-51:2003	2003-07-31	Medical electrical equipment – Part 2-51: Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs	CLC/TC 62	EN 60601-2-51:2003) (IEC 60601-2-51:2003)	●[1]					
IEC 60601-2-52 Ed. 1.0:2009 IEC 60601-2-52 Ed. 1.0 Cor.1:2010	Medical electrical equipment – Part 2-52: Particular requirements for the basic safety and essential performance of medical beds	医用電気機器－第2-52部：医療用ベッドの基礎安全及び基本性能の特定要求事項	TC 62D	EN 60601-2-52:2010 EN 60601-2-52:2010/AC:2011	2010-04-09 2011-04-01	Medical electrical equipment – Part 2-52: Particular requirements for basic safety and essential performance of medical beds	CLC/TC 62	EN 60601-2-52:2010 (IEC 60601-2-52:2009) EN 60601-2-52:2010/ AC:2011	●[1]			IEC 60601-2-52 Edition 1.0 2009-12	GPS/GH	●
IEC 60601-2-54 Ed. 1.0:2009 IEC 60601-2-54 Ed. 1.0 Cor.1:2010 IEC 60601-2-54 Ed. 1.0 Cor.2:2011	Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy	医用電気機器－第2-54部：X線撮影及び透視用機器の基礎安全及び基本性能の特定要求事項	TC 62B	EN 60601-2-54:2009	2009-09-18	Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy	CLC/TC 62	EN 60601-2-54:2009 (IEC 60601-2-54:2009)	●[1]			IEC 60601-2-54 Edition 1.0 2009-06	Radiology	●
IEC 60601-2-57 Ed. 1.0:2011	Medical electrical equipment – Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and	医用電気機器－第2-57部：治療，診断，監視及び整形/審美用途の非レーザ光線源機器の基礎安全及び基本性能の特定要求事項	TC 76	EN 60601-2-57:2011	2011-04-08	Medical electrical equipment – Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic						IEC 60601-2-57 Edition 1.0 2011-01	Radiology	○[1]
IEC 60601-3-1 Ed. 1.0:1996	Medical electrical equipment – Part 3-1: Essential performance requirement for transcutaneous oxygen and carbon dioxide partial pressure monitoring equipment	医用電気機器－第3-1部：経皮的酸素及び二酸化炭素分圧監視機器の重要性能要求事項	TC 62D	EN 60601-3-1:1996	1996-12-16	Medical electrical equipment – Part 3-1: Essential performance requirements for transcutaneous oxygen and carbon dioxide partial pressure monitoring equipment	CLC/TC 62							
IEC 60613 Ed. 3.0:2010	Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis	医療診断のためのX線管アセンブリの電気及び負荷特性	TC 62B	EN 60613:1990 EN 60613:2010	1990-12-06 2010-04-16	Electrical, thermal and loading characteristics of rotating anode X-ray tubes for medical diagnosis Electrical and loading characteristics of X-ray	CLC/TC 62							
IEC 60627 Ed. 2.0:2001	Diagnostic X-ray imaging equipment – Characteristics of general purpose and mammographic anti-scatter grids	診断X線影像装置－汎用及び乳房撮影散乱線除去グリッドの特性	TC 62B	EN 60627:2001	2001-11-12	Diagnostic X-ray imaging equipment – Characteristics of general purpose and mammographic anti-scatter grids	CLC/TC 62	EN 60627:2001 (IEC 60627:2001) EN 60627:2001/ AC:2002	○[1]					
IEC 60645-1 Ed. 3.0:2012	Electroacoustics – Audiometric equipment – Part 1: Equipment for pure-tone audiometry	電子音響学－聴覚機器－第1部：純音オージオメータ	TC 29	EN 60645-1:2001	2001-10-24	Electroacoustics – Audiological equipment – Part 1: Pure-tone audiometers	CLC/TC 29	EN 60645-1:2001 (IEC 60645-1:2001)	●[1][*]					
IEC 60645-2 Ed. 1.0:1993	Audiometers – Part 2: Equipment for speech audiometry	オージオメーター第2部：語音聴力測定機器	TC 29	EN 60645-2:1997	1997-01-24	Audiometers – Part 2: Equipment for speech audiometry	CLC/TC 29	EN 60645-2:1997 (IEC 60645-2:1993)	○[1]					
IEC 60645-3 Ed. 2.0:2007	Electroacoustics – Audiometric equipment – Part 3: Test signals of short duration	電気音響－聴覚検査機器－第3部：短期聴覚試験信号	TC 29	EN 60645-3:2007	2007-07-20	Electroacoustics – Audiometric equipment – Part 3: Test signals of short duration	CLC/TC 29	EN 60645-3:2007 (IEC 60645-3:2007)	○[1]					
~~IEC 60645-4:1994~~	~~Audiometers – Part 4: Equipment for extended high-frequency audiometry~~ IEC 60645-1に移行(2012-02-16)		TC 29					EN 60645-4:1995 (IEC 60645-4:1994)	●[1]					
IEC 60645-5 Ed. 1.0:2004	Electroacoustics – Audiometric equipment – Part 5: Instruments for the measurement of aural acoustic impedance/admittance	電子音響学－聴覚機器－第5部：聴覚音響インピーダンス/アドミタンスの測定のための計器	TC 29	EN 60645-5:2005	2005-01-07	Electroacoustics – Audiometric equipment – Part 5: Instruments for the measurement of aural acoustic impedance/admittance	CLC/TC 29							
IEC 60645-6 Ed. 1.0:2009	Electroacoustics – Audiometric equipment – Part 6: Instruments for the measurement of otoacoustic emissions	電子音響学－聴覚機器－第6部：耳音響放射の測定用計器	TC 29	EN 60645-6:2010	2010-01-08	Electroacoustics – Audiometric equipment – Part 6: Instruments for the measurement of otoacoustic emissions	CLC/TC 29							
IEC 60645-7 Ed. 1.0:2009	Electroacoustics – Audiometric equipment – Part 7: Instruments for the measurement of auditory brainstem responses	電子音響学－聴覚機器－第7部：聴性脳幹反応の測定用計器	TC 29	EN 60645-7:2010	2010-01-08	Electroacoustics – Audiometric equipment – Part 7: Instruments for the measurement of auditory brainstem responses	CLC/TC 29							

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規格番号	規格名称	規格名称(仮邦訳)	TC	Reference	Date	Title		EU Harmonised Standards ○:最新版 ●:旧版等 ISO /IEC standard	MDD	AIMD	IVD	FDA Recognized Consensus Standards (経過措置終了日)	○:最新版	●:旧版等
~~IEC 60731 ed2.0:1997~~ ~~IEC 60731-am1 ed2.0:2002~~ IEC 60731 Ed. 3.0:2011	~~Medical electrical equipment – Dosimeters with ionization chambers as used in radiotherapy~~ Medical electrical equipment – Dosimeters with ionization chambers as used in	医用電気機器－放射線療法で用いるイオン化室を持った線量計	TC 62C	EN 60731:1997 EN 60731:1997/A1:2002 EN 60731:2012	1997-10-17 2002-09-13 2012-04-06	Medical electrical equipment – Dosimeters with ionization chambers as used in radiotherapy Medical electrical equipment – Dosimeters with ionization chambers as used in radiotherapy	CLC/TC 62					IEC 60731 Edition 3.0 2011-02	Radiology	○
IEC/TR 60788 Ed. 2.0:2004	Medical electrical equipment – Glossary of defined terms	医用電気機器－定義済み用語の用語集	TC 62											
IEC 60789 Ed. 3.0:2005 IEC 60789 Ed. 3.0 Cor.1:2009	Medical electrical equipment – Characteristics and test conditions of radionuclide imaging devices – Anger type gamma cameras	医用電気機器－RI撮像装置の特性及び試験条件－Angerタイプガンマカメラ	TC 62C	EN 60789:2005	2005-12-01	Medical electrical equipment – Characteristics and test conditions of radionuclide imaging devices – Anger type gamma cameras	CLC/TC 62							
IEC 60806 Ed. 1.0:1984	Determination of the maximum symmetrical radiation field from a rotating anode X-ray tube for medical diagnosis	医療診断用の回転陽極式X線管からの最大対称放射域の決定	TC 62B	EN 60806:2004	2004-06-03	Determination of the maximum symmetrical radiation field from a rotating anode X-ray tube for medical diagnosis	CLC/TC 62					IEC 60806 (R1984)	Radiology	○
IEC 60812 Ed. 2.0:2006	Analysis techniques for system reliability – Procedure for failure mode and effects analysis (FMEA)	システム信頼性の解析技法－故障モード影響解析(FMEA)の手順	TC 56	EN 60812:2006	2006/5/17	Analysis techniques for system reliability – Procedure for failure mode and effects analysis (FMEA)	CLC/TC 56					IEC 60812 Second edition 2006-01	General	○
IEC 60825-1 Ed. 2.0:2007 IEC 60825-1 Ed. 2.0 Cor.1:2008	Safety of laser products – Part 1: Equipment classification and requirements	レーザ製品の安全性－第1部：機器の分類及び要求事項	TC 76	EN 60825-1:2007	2007-10-17	Safety of laser products – Part 1: Equipment classification and requirements	CLC/TC 76					IEC 60825-1 (2007) Second Edition IEC 60825-1 (Second edition – 2007)/Cor 1	Radiology	○
IEC 60825-1ISH 11 Ed. 2.0:2009	Interpretation sheet – Safety of laser products – Part 1: Equipment classification and requirements	解説シート－レーザ製品の安全性－第1部：機器の分類及び要求事項	TC 76									IEC 60825-1 (Second edition – 2007)/ISH 1	Radiology	○
IEC 60825-1ISH 12 Ed. 2.0:2011	Interpretation sheet 2 – Safety of laser products – Part 1: Equipment classification and requirements	解説シート2－レーザ製品の安全性－第1部：機器の分類及び要求事項	TC 76									IEC 60825-1 Ed. 2.0 (2007)/ISH 2	Radiology	○
IEC/TR 60825-8 Ed. 2.0:2006	Safety of laser products – Part 8: Guidelines for the safe use of laser beams on humans	レーザ製品の安全性－第8部：レーザビームの人への安全使用の指針	TC 76											
IEC/TR 60854 Ed. 1.0:1986	Methods of measuring the performance of ultrasonic pulse-echo diagnostic equipment	超音波パルス反射診断機器の性能測定方法	TC 87											
IEC/TR 60878 Ed. 2.0:2003	Graphical symbols for electrical equipment in medical practice	医療に用いる電気機器用図記号	TC 62A											
IEC/TR 60930 Ed. 2.0:2008	Guidelines for administrative, medical and nursing staff concerned with the safe use of medical electrical equipment and medical electrical systems	医用電気機器及び医用電気システムの安全使用の管理，医用及び看護スタッフに対する指針	TC 62A											
IEC 60976 Ed. 2.0:2007	Medical electrical equipment – Medical electron accelerators – Functional performance characteristics	医用電気機器－医用電子加速装置－機能性能特性	TC 62C	EN 60976:2007	2007-12-07	Medical electrical equipment – Medical electron accelerators – Functional performance characteristics	CLC/TC 62							
IEC/TR 60977 Ed. 2.0:2008	Medical electrical equipment – Medical electron accelerators – Guidelines for functional performance characteristics	医用電気機器－医用電子加速装置－機能的性能特性の指針	TC 62C											
IEC 61010-2-101:2002	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment	計測，制御及び試験所用電気機器の安全要求事項－第2-101部：インビトロ診断(IVD)医用機器の特定要求事項	TC 66	EN 61010-2-101:2002	2002-11-15	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment	CLC/TC 66	EN 61010-2-101:2002 (IEC 61010-2-101:2002 Modified)			●			
IEC 61145 Ed. 1.0:1992	Calibration and usage of ionization chamber systems for assay of radionuclides	核種評価のためのイオン化室システムの構成及び用途	TC 45									IEC 61145 (1992-05)	Radiology	○
IEC 61157 Ed. 2.0:2007 IEC 61157 Ed. 2.0 en Cor.1:2008	Standard means for the reporting of the acoustic output of medical diagnostic ultrasonic equipment	医用診断超音波機器の音響出力を報告するための標準手段	TC 87	EN 61157:2007	2007-11-07	Standard means for the reporting of the acoustic output of medical diagnostic ultrasonic equipment	CLC/TC 87							
IEC 61168 Ed. 1.0:1993	Radiotherapy simulators – Functional performance characteristics	放射線療法シミュレーター機能性能特性	TC 62C	EN 61168:1994	1994-02-22	Radiotherapy simulators – Functional performance characteristics	CLC/TC 62					IEC 61168:1993	Radiology	○
IEC/TS 61170 Ed. 1.0:1993	Radiotherapy simulators – Guidelines for functional performance characteristics	放射線治療シミュレーター機能性能特性の指針	TC 62C											
IEC 61205 Ed. 1.0:1993	Ultrasonics – Dental descaler systems – Measurement and declaration of the output characteristics	超音波－歯科デスケーラ装置－出力特性の計測及び告知	TC 87	EN 61205:1994	1994-01-21	Ultrasonics – Dental descaler systems – Measurement and declaration of the output characteristics	CLC/TC 87							
~~IEC 61217 ed1.0:1996~~ ~~IEC 61217-am1 ed1.0:2000~~ ~~IEC 61217-am2 ed1.0:2007~~ IEC 61217 Ed. 2.0:2011	~~Radiotherapy equipment – Coordinates, movements and scales~~ Radiotherapy equipment – Coordinates, movements and scales	放射線治療機器－座標，移動及びスケール	TC 62C	EN 61217:1996 EN 61217:1996/ A1:2001 EN 61217:1996/ A2:2008 EN 61217:2012	1996-09-05 2001-02-22 2008-02-22 2012-04-13	Radiotherapy equipment – Coordinates, movements and scales Radiotherapy equipment – Coordinates, movements and scales	CLC/TC 62	EN 61217:1996 (IEC 61217:1996) EN 61217:1996/ A1:2001 (IEC 61217:1996/ A1:2000) EN 61217:1996/ A2:2008 (IEC 61217:1996/ A2:2007) EN 61217:2012 (IEC 61217:2011)	●[1] ○[1]			IEC 61217 (2008) ed 1.2	Radiology	●[1][2]
IEC/TS 61223-1 Ed. 1.0:1993	Evaluation and routine testing in medical imaging departments – Part 1: General	医用イメージング部の評価及び定期試験－第1部：一般的側面	TC 62B											
IEC/TS 61223-2-1 Ed. 1.0:1993	Evaluation and routing testing in medical imaging departments – Part 2-1: Constancy tests – Film processors	医用イメージング部の評価及び定期試験－第2-1部：恒久性試験－フィルムプロセッサ	TC 62B											
				EN 61223-2-4:1994	1994-06-09	Evaluation and routine testing in medical imaging departments – Part 2-4: Constancy tests – Hard copy cameras	CLC/TC 62							
				EN 61223-2-5:1994	1994-06-09	Evaluation and routine testing in medical imaging departments – Part 2-5: Constancy tests – Image display devices	CLC/TC 62							

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規格番号	規格名称	規格名称（仮邦訳）	TC	Reference	Date	Title		EU Harmonised Standards ○：最新版 ●：旧版等 ISO /IEC standard	MDD	AIMD	IVD	FDA Recognized Consensus Standards （経過措置終了日）	○：最新版	●：旧版等
IEC 61223-2-6 Ed. 2.0:2006	Evaluation and routine testing in medical imaging departments Part 2 6: Constancy tests Imaging performance of computed tomography X-ray equipment	医用イメージング部の評価及び定期試験－第2-6部：恒久性試験－コンピュータ断層撮影法におけるX線機器	TC 62B	EN 61223-2-6:2007	2007-05-09	Evaluation and routine testing in medical imaging departments – Part 2-6: Constancy tests – Imaging performance of computed tomography X-ray equipment	CLC/TC 62					IEC 61223-2-6 Second Edition 2006-11	Radiology	○
IEC 61223-3-2 Ed. 2.0:2007	Evaluation and routine testing in medical imaging departments – Part 3-2: Acceptance tests – Imaging performance of mammographic X-ray equipment	医用イメージング部の評価及び定期試験－第3-2部：検収試験－乳房X線機器のイメージング性能	TC 62B	EN 61223-3-2:2008	2008-07-25	Evaluation and routine testing in medical imaging departments – Part 3-2: Acceptance tests – Imaging performance of mammographic X-ray equipment	CLC/TC 62					IEC 61223-3-2 (2007)	Radiology	○
~~IEC 61223-3-3 ed1.0:1996~~	~~Evaluation and routine testing in medical imaging departments – Part 3-3: Acceptance tests – Imaging performance of X-ray equipment for digital subtraction angiography~~		TC 62B	EN 61223-3-3:1996	1996-12-19	Evaluation and routine testing in medical imaging departments – Part 3-3: Acceptance tests – Imaging performance of X-ray equipment for digital subtraction angiography	CLC/TC 62							
IEC 61223-3-4 Ed. 1.0:2000	Evaluation and routine testing in medical imaging departments – Part 3-4: Acceptance tests – Imaging performance of dental X-ray	医用イメージング部の評価及び定期試験－第3-4部：検収試験－歯科用X線機器のイメージング性能	TC 62B	EN 61223-3-4:2000	2000-09-07	Evaluation and routine testing in medical imaging departments – Part 3-4: Acceptance tests – Imaging performance of dental X-ray	CLC/TC 62					IEC 61223-3-4 First edition 2000-03	Radiology	○
IEC 61223-3-5 Ed. 1.0:2004 IEC 61223-3-5 Ed. 1.0 Cor.1:2006	Evaluation and routine testing in medical imaging departments – Part 3-5: Acceptance tests – Imaging performance of computed tomography X-ray equipment	医用イメージング部の評価及び定期試験－第3-5部：検収試験－コンピュータ断層撮影X線機器のイメージング性能	TC 62B	EN 61223-3-5:2004	2004-09-23	Evaluation and routine testing in medical imaging departments – Part 3-5: Acceptance tests – Imaging performance of computed tomography X-ray equipment	CLC/TC 62					IEC 61223-3-5 First edition 2004-08 IEC 61223-3-5 (First edition – 2004)/Cor 1	Radiology	○
IEC/TR 61258 Ed. 2.0:2008	Guidelines for the development and use of medical electrical equipment educational materials	医療電気機器に関する教育資料の作成・使用のための指針	TC 62A											
IEC 61262-1 Ed. 1.0:1994	Medical electrical equipment – Characteristics of electro-optical X-ray image intensifiers – Part 1: Determination of	医用電気機器－電気光学的X線蛍光倍増管の特性－第1部：入力域サイズの決定	TC 62B	EN 61262-1:1994	1994-09-02	Medical electrical equipment – Characteristics of electro-optical X-ray image intensifiers – Part 1: Determination of the entrance field	CLC/TC 62							
IEC 61262-2 Ed. 1.0:1994	Medical electrical equipment – Characteristics of electro-optical X-ray image intensifiers – Part 2: Determination of	医用電気機器－電気光学的X線蛍光倍増管の特性－第2部：変換係数の決定	TC 62B	EN 61262-2:1994	1994-09-02	Medical electrical equipment – Characteristics of electro-optical X-ray image intensifiers – Part 2: Determination of the conversion factor	CLC/TC 62							
IEC 61262-3 Ed. 1.0:1994	Medical electrical equipment – Characteristics of electro-optical X-ray image intensifiers – Part 3: Determination of the luminance distribution and luminance	医用電気機器－電気光学的X線蛍光倍増管の特性－第3部：輝度分布及び輝度非均一性の決定	TC 62B	EN 61262-3:1994	1994-09-02	Medical electrical equipment – Characteristics of electro-optical X-ray image intensifiers – Part 3: Determination of the luminance distribution and luminance non-uniformity	CLC/TC 62							
IEC 61262-4 Ed. 1.0:1994	Medical electrical equipment – Characteristics of electro-optical X-ray image intensifiers – Part 4: Determination of	医用電気機器－電気光学的X線蛍光倍増管の特性－第4部：イメージ歪みの決定	TC 62B	EN 61262-4:1994	1994-09-09	Medical electrical equipment – Characteristics of electro-optical X-ray image intensifiers – Part 4: Determination of the image distortion	CLC/TC 62							
IEC 61262-5 Ed. 1.0:1994	Medical electrical equipment – Characteristics of electro-optical X-ray image intensifiers – Part 5: Determination of the detective quantum efficiency	医用電気機器－電気光学的X線蛍光倍増管の特性－第5部：欠陥量子効率の決定	TC 62B	EN 61262-5:1994	1994-09-09	Medical electrical equipment – Characteristics of electro-optical X-ray image intensifiers – Part 5: Determination of the detective quantum efficiency	CLC/TC 62							
IEC 61262-6 Ed. 1.0:1994	Medical electrical equipment – Characteristics of electro-optical X-ray image intensifiers – Part 6: Determination of the contrast ratio and veiling glare index	医用電気機器－電気光学的X線蛍光倍増管の特性－第6部：コントラスト比及び膜状眩輝の決定	TC 62B	EN 61262-6:1994	1994-09-02	Medical electrical equipment – Characteristics of electro-optical X-ray image intensifiers – Part 6: Determination of the contrast ratio and veiling glare index	CLC/TC 62							
IEC 61262-7 Ed. 1.0:1995	Medical electrical equipment – Characteristics of electro-optical X-ray image intensifiers – Part 7: Determination of the modulation transfer function	医用電気機器－電気光学的X線蛍光倍増管の特性－第7部：変調移行機能の決定	TC 62B	EN 61262-7:1995	1995-11-24	Medical electrical equipment – Characteristics of electro-optical X-ray image intensifiers – Part 7: Determination of the modulation transfer function	CLC/TC 62							
IEC 61266 Ed. 1.0:1994	Ultrasonics – Hand-held probe Doppler foetal heartbeat detectors – Performance requirements and methods of measurement	超音波－手持ち式プローブドップラー胎児心音検出器	TC 87	EN 61266:1995	1995-04-10	Ultrasonics – Hand-held probe Doppler foetal heartbeat detectors – Performance requirements and methods of measurement	CLC/TC 87							
IEC 61267 Ed. 2.0:2005	Medical diagnostic X-ray equipment – Radiation conditions for use in the determination of characteristics	医用診断X線機器－特性の決定に使用する放射線条件	TC 62C	EN 61267:2006	2006-01-27	Medical diagnostic X-ray equipment – Radiation conditions for use in the determination of characteristics	CLC/TC 62							
IEC/TR 61288-1 Ed. 1.0:1993	Cardiac defibrillators – Cardiac defibrillator-monitors – Part 1: Operation	細動除去器-モニター第1部：操作	TC 62A											
IEC/TR 61288-2 Ed. 1.0:1993	Cardiac defibrillators – Cardiac defibrillators-monitors – Part 2: Maintenance	細動除去器-モニター第2部：保守	TC 62A											
~~IEC/TR 61289-1 Ed. 1.0:1994~~	~~High frequency surgical equipment – Part 1: Operation~~	~~高周波外科手術機器－第1部：操作~~	TC 62D											
~~IEC/TR 61289-2 Ed. 1.0:1994~~	~~High frequency surgical equipment – Part 2: Maintenance~~	~~高周波外科手術機器－第2部：保守~~	TC 62D											
IEC/TR 61289 Ed. 1.0:2011	High frequency surgical equipment – Operation and maintenance	高周波外科手術機器－操作及び保守	TC 62D											
IEC 61303 Ed. 1.0:1994	Medical electrical equipment – Radionuclide calibrators – Particular methods for describing performance	医用電気機器－放射性核種キャリブレーター性能記述のための特定法	TC 62C	EN 61303:1995	1995-01-09	Medical electrical equipment – Radionuclide calibrators – Particular methods for describing performance	CLC/TC 62					IEC 61303 (1994-10)	Radiology	○
IEC 61326-2-6 Ed. 2.0:2012	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD)	計測，制御及び試験所用の電気機器－EMC要求事項－第2-6部：特定要求事項－インビトロ診断(IVD)医用機器	TC 65A	EN 61326-2-6:2006	2006-05-05	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment	CLC/TC 62	EN 61326-2-6:2006 IEC 61326-2-6:2005			●			
IEC 61331-1 Ed. 1.0:1994	Protective devices against diagnostic medical X-radiation – Part 1: Determination of attenuation properties of materials	診断用医用X線に対する保護装置－第1部：材料の減衰特性の決定	TC 62B	EN 61331-1:2002	2002-04-23	Protective devices against diagnostic medical X-radiation – Part 1: Determination of attenuation properties of materials	CLC/TC 62							
IEC 61331-2 Ed. 1.0:1994	Protective devices against diagnostic medical X-radiation – Part 2: Protective glass plates	診断用医用X線に対する保護装置－第2部：保護ガラス板	TC 62B	EN 61331-2:2002	2002-04-23	Protective devices against diagnostic medical X-radiation – Part 2: Protective glass plates	CLC/TC 62							
IEC 61331-3 Ed. 1.0:1998	Protective devices against diagnostic medical X-radiation – Part 3: Protective clothing and protective devices for gonads	診断用医用X線に対する保護装置－第3部：生殖腺保護衣服及び保護装置	TC 62B	EN 61331-3:1999	1999-01-20	Protective devices against diagnostic medical X-radiation – Part 3: Protective clothing and protective devices for gonads	CLC/TC 62							
IEC/TS 61390 Ed. 1.0:1996	Ultrasonics – Real-time pulse-echo systems – Test procedures to determine performance specifications	超音波－リアルタイムパルスエコーシステム－性能仕様を決めるための試験手順	TC 87											
IEC 61391-1 Ed. 1.0:2006	Ultrasonics – Pulse-echo scanners – Part 1: Techniques for calibrating spatial measurement systems and measurement of system point-spread function response	超音波学－パルス反射スキャナ－第1部：空間測定システム及びシステム点像分布関数応答の測定の校正技法	TC 87	EN 61391-1:2006	2006-10-26	Ultrasonics – Pulse-echo scanners – Part 1: Techniques for calibrating spatial measurement systems and measurement of system point-spread function response	CLC/TC 87					IEC 61391-1 First edition 2006-07	Radiology	○[2]

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規格番号	規格名称	規格名称（仮邦訳）	TC	Reference	Date	Title		EU Harmonised Standards ○：最新版 ●：旧版等				FDA Recognized Consensus Standards		
								ISO /IEC standard	MDD	AIMD	IVD	（経過措置終了日）	○：最新版	●：旧版等
IEC 61391-2 Ed. 1.0:2010	Ultrasonics - Pulse-echo scanners - Part 2: Measurement of maximum depth of penetration and local dynamic range	超音波学－パルス反射スキャナー第2部：最大浸透深さ及び局部ダイナミックレンジの測定	TC 87	EN 61391-2:2010	2010-04-23	Ultrasonics - Pulse-echo scanners - Part 2: Measurement of maximum depth of penetration and local dynamic range	CLC/TC 87					IEC 61391-2 Edition 1.0 2010-01	Radiology	○[2]
IEC 61674 Ed. 1.0:1997 IEC 61674 Amd.1 Ed. 1.0:2002	Medical electrical equipment - Dosimeters with ionization chambers and/or semi-conductor detectors as used in X-ray diagnostic imaging	医用電気機器－X線画像診断で使用するイオン化室を持つ線量計及び/又は半導体検出器	TC 62C	EN 61674:1997 EN 61674:1997/ A1:2002	1997-11-28 2002-09-26	Medical electrical equipment - Dosimeters with ionization chambers and/or semi-conductor detectors as used in X-ray diagnostic imaging	CLC/TC 62					IEC 61674(1997)(2002)	Radiology	○
IEC 61675-1 Ed. 1.1:2008 IEC 61675-1 Amd.1 Ed. 1.0:2008	Radionuclide imaging devices - Characteristics and test conditions - Part 1: Positron emission tomographs	放射性核種画像装置－特性及び試験条件－第1部：ポジトロン放射トモグラフ	TC 62C	EN 61675-1:1998 EN 61675-1:1998/ A1:2008	1998-02-23 2008-07-17	Radionuclide imaging devices - Characteristics and test conditions - Part 1: Positron emission tomographs	CLC/TC 62							
IEC 61675-2 Amd.1 Ed. 1.0:2004 IEC 61675-2 Ed. 1.1:2005	Radionuclide imaging devices - Characteristics and test conditions - Part 2: Single photon emission computed tomographs	放射性核種画像装置－特性及び試験条件－第2部：単一光子放射コンピュータ断層撮影	TC 62C	EN 61675-2:1998 EN 61675-2:1998/A1:2005	1998-02-23 2005-02-08	Radionuclide imaging devices - Characteristics and test conditions - Part 2: Single photon emission computer tomographs	CLC/TC 62							
IEC 61675-3 Ed. 1.0:1998	Radionuclide imaging devices - Characteristics and test conditions - Part 3: Gamma camera based wholebody imaging systems	放射性核種画像装置－特性及び試験条件－第3部：ガンマカメラをベースとする全身画像システム	TC 62C	EN 61675-3:1998	1998-04-22	Radionuclide imaging devices - Characteristics and test conditions - Part 3: Gamma camera based wholebody imaging systems	CLC/TC 62							
IEC 61676 Amd.1 Ed. 1.0:2008 IEC 61676 Ed. 1.1:2009	Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology	医用電気機器－診断用放射線医学における管電圧の無侵襲計測に用いる線量算定器	TC 62C	EN 61676:2002 EN 61676:2002/A1:2009	2002-12-17 2009-04-02	Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology	CLC/TC 62	EN 61676:2002 (IEC 61676:2002) EN 61676:2000/ A1:2009 (IEC 61676:2002/ A1:2008)	○[1]					
IEC 61689 Ed. 2.0:2007	Ultrasonics - Physiotherapy systems - Field specifications and methods of measurement in the frequency range 0.5 MHz to 5 MHz	超音波－物理療法－周波数範囲 0.5 MHz～5 MHzの現場仕様及び計測方法	TC 87	EN 61689:2007	2007-11-07	Ultrasonics - Physiotherapy systems - Field specifications and methods of measurement in the frequency range 0.5 MHz to 5 MHz	CLC/TC 87					IEC 61689:2007	Radiology	○
IEC 61846 Ed. 1.0:1998	Ultrasonics - Pressure pulse lithotripters - Characteristics of fields	超音波－圧力パルス破石器－電界特性	TC 87	EN 61846:1998	1998-04-22	Ultrasonics - Pressure pulse lithotripters - Characteristics of fields	CLC/TC 87					IEC 61846 First edition 1998-04	OBGYN/GU	○
IEC 61847 Ed. 1.0:1998	Ultrasonics - Surgical systems - Measurement and declaration of the basic output characteristics	超音波－外科システム－基本出力特性の計測及び表示	TC 87	EN 61847:1998	1998-02-24	Ultrasonics - Surgical systems - Measurement and declaration of the basic output characteristics	CLC/TC 87					IEC 61847: 1998	Radiology	○
IEC/TR 61852 Ed. 1.0:1998	Medical electrical equipment - Digital imaging and communications in medicine (DICOM) - Radiotherapy objects	医用電気機器－医用デジタル画像及び通信(DICOM)－放射線療法対象	TC 62C											
IEC/TR 61859 Ed. 1.0:1997	Guidelines for radiotherapy treatment rooms design	放射線療法処置室設計の指針	TC 62C											
IEC/TS 61895 Ed. 1.0:1999	Ultrasonics - Pulsed Doppler diagnostic systems - Test procedures to determine	超音波－パルス式ドップラー診断システム－性能を求めるための試験方法	TC 87											
IEC/PAS 61910-1 Ed. 1.0:2007	Medical electrical equipment - Radiation dose documentation - Part 1: Equipment for radiography and radioscopy	医用電気機器－放射線量文書－第1部：X線写真及び透視用の機器	TC 62B									IEC PAS 61910-1 First Edition 2007-07	Radiology	○
IEC/TR 61948-1 Ed. 1.0:2001	Nuclear medicine instrumentation - Routine tests - Part 1: Radiation counting systems	核医学計装－定期試験－第1部：放射線計数システム	TC 62C											
IEC/TR 61948-2 Ed. 1.0:2001	Nuclear medicine instrumentation - Routine tests - Part 2: Scintillation cameras and single photon emission computed tomography	核医学計装－定期試験－第2部：シンチレーションカメラ及びシングル光子放出X線断層画像	TC 62C											
IEC/TR 61948-3 Ed. 1.0:2005	Nuclear medicine instrumentation - Routine tests - Part 3: Positron emission tomographs	核医学計装－定期試験－第3部：陽電子放射断層撮影法	TC 62C											
IEC/TR 61948-4 Ed. 1.0:2006	Nuclear medicine instrumentation - Routine tests - Part 4: Radionuclide calibrators	核医学計装－定期試験－第4部：放射性核種校正器	TC 62C											
~~IEC 62083 ed1.0:2000~~	~~Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems~~			EN 62083:2001	2001-02-12	Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems		EN 62083:2001 (IEC 62083:2000)	●[1] (2012-10-31)			IEC 62083 Edition 2.0 2009-09	Radiology	○
IEC 62083 Ed. 2.0:2009	Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems	医用電気機器－放射線療法計画システムの安全要求事項	TC 62C	EN 62083:2009	2009-12-11	Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems	CLC/TC 62	EN 62083:2009 (IEC 62083:2009)	○[1]					
IEC 62127-1 Ed. 1.0:2007 IEC 62127-1 Ed. 1.0 Cor.1:2008	Ultrasonics - Hydrophones - Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz	超音波－ハイドロホン－第1部：40MHz以下の医用超音波界の測定及び特性付け	TC 87	EN 62127-1:2007	2007-10-05	Ultrasonics - Hydrophones - Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz	CLC/TC 87							
IEC 62220-1 Ed. 1.0:2003	Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1: Determination of the detective quantum efficiency	医用電気機器－デジタルエックス線イメージング装置－第1部：検出量子効率の測定	TC 62B	EN 62220-1:2004	2004-01-14	Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1: Determination of the detective quantum efficiency	CLC/TC 62	EN 62220-1:2004 (IEC 62220-1:2003)	○[1]			IEC 62220-1 Edition 1.0 (2003-10)	Radiology	○
IEC 62220-1-2 Ed. 1.0:2007	Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-2: Determination of the detective quantum efficiency - Detectors	医用電気機器－デジタルエックス線イメージング装置の特性－第1-2部：検出量子効率の測定－乳房撮影法で使用する検出器	TC 62B	EN 62220-1-2:2007	2007-09-20	Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-2: Determination of the detective quantum efficiency - Detectors used in mammography	CLC/TC 62	EN 62220-1-2:2007 (IEC 62220-1-2:2007)	○[1]			IEC 62220-1-2 Edition 1.0 (2007-06)	Radiology	○
IEC 62220-1-3 Ed. 1.0:2008	Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-3: Determination of the detective quantum efficiency - Detectors	医用電気機器－デジタルエックス線イメージング装置－第1-3部：検出量子効率の測定－動態イメージングに使用する検出器	TC 62B	EN 62220-1-3:2008	2008-09-03	Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-3: Determination of the detective quantum efficiency - Detectors used in dynamic imaging	CLC/TC 62	EN 62220-1-3:2008 (IEC 62220-1-3:2008)	○[1]			IEC 62220-1-3 Edition 1.0 (2008-06)	Radiology	○
IEC/TR 62266 Ed. 1.0:2002	Medical electrical equipment - Guidelines for implementation of DICOM in radiotherapy	医用電気機器－放射線治療における DICOMの実施の指針	TC 62C											
IEC 62274 Ed. 1.0:2005	Medical electrical equipment - Safety of radiotherapy record and verify systems	医用電気機器－放射線治療記録の安全性及び検証システム	TC 62C	EN 62274:2005	2005-06-15	Medical electrical equipment - Safety of radiotherapy record and verify systems	CLC/TC 62					IEC 62274 First Edition 2005-05	Radiology	○
IEC/TR 62296 Ed. 2.0:2009	Considerations of unaddressed safety aspects in the second edition of IEC 60601-1 and proposals for new requirements	IEC 60601-1の第2版で扱われていない安全面の考察及び新要求事項の提案	TC 62A											
IEC 62304 Ed. 1.0:2006	Medical device software - Software life cycle processes	医療機器ソフトウェアーソフトウェアライフサイクルプロセス	TC 62A	EN 62304:2006	2006-07-12	Medical device software - Software life-cycle processes	CLC/TC 62	EN 62304:2006 (IEC 62304:2006) EN 62304:2006/ AC:2008	○[1]	○[1]	○	IEC 62304 First edition 2006-05 AAMI ANSI IEC 62304:2006 (IEC 62304:2006)	Software	○
IEC/TS 62306 Ed. 1.0:2006	Ultrasonics - Field characterisation - Test objects for determining temperature elevation in diagnostic ultrasound fields	超音波－分野別の特性付け－診断超音波音の分野の温度上昇の測定のための試験対象物	TC 87											

医療関係IEC規格　（平成24年9月3日現在）　European Norm（CENELEC）　調査日：2012-09-25　2012-08-30発行のOJ（2012-09-01時点で有効なもの）　（2012-09-12時点のDB）

規格番号	規格名称	規格名称（仮邦訳）	TC	Reference	Date	Title		EU Harmonised Standards ○：最新版 ●：旧版等 ISO /IEC standard	MDD	AIMD	IVD	FDA Recognized Consensus Standards （経過措置終了日）	○：最新版	●：旧版等
IEC/TR 62348 Ed. 1.0:2006	Mapping between the clauses of the third edition of IEC 60601-1 and the 1988 edition	IEC 60601-1の第3版と修正された1988年版とのマッピング	TC 62A											
IEC 62353 Ed. 1.0:2007	Medical electrical equipment – Recurrent test and test after repair of medical electrical equipment	医用電気機器－医用電気機器の反復試験及び修理後の試験	TC 62A	EN 62353:2008	2008-01-25	Medical electrical equipment – Recurrent test and test after repair of medical electrical equipment	CLC/TC 62							
IEC/TR 62354 Ed. 2.0:2009	General testing procedures for medical electrical equipment	医用電気機器の一般試験手順	TC 62A											
~~IEC 62359 ed1.0:2005~~	~~Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields~~		TC 87	EN 62359:2005	2005-10-14	Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields	CLC/TC 87					IEC 62359 Edition 2.0 2010-10-10 IEC 62359 (Second edition 2010) March 2011/Cor 1	Radiology	○
IEC 62359 Ed. 2.0:2010 IEC 62359 Ed. 2.0 Cor.1:2011	Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields	超音波－音場の特性化－医療診断超音波の分野に関する熱的及び機械的指数の測定のための試験方法		EN 62359:2011	2011-02-11	Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields								
IEC 62366 Ed. 1.0:2007	Medical devices – Application of usability engineering to medical devices	医療機器－医療機器へのユーザビリティエンジニアリングの適用	TC 62A	EN 62366:2008	2008-01-25	Medical devices – Application of usability engineering to medical devices	CLC/TC 62	EN 62366:2008 (IEC 62366:2007)	○[1]		○	IEC 62366:2007 AAMI ANSI IEC 62366:2007 (IEC 62366:2007)	General	○[2]
IEC/TS 62462 Ed. 1.0:2007	Ultrasonics – Output Test – Guide for the maintenance of ultrasound physiotherapy systems	超音波－出力試験－超音波音響理療法システムの保守の手引	TC 87											
IEC 62464-1 Ed. 1.0:2007	Magnetic resonance equipment for medical imaging – Part 1: Determination of essential image quality parameters	医用画像用磁気共鳴装置－第1部：基本画像品質パラメタの測定	TC 62B	EN 62464-1:2007	2007-05-04	Magnetic resonance equipment for medical imaging – Part 1: Determination of essential image quality parameters	CLC/TC 62							
IEC 62464-2 Ed. 1.0:2010	Magnetic resonance equipment for medical imaging – Part 2: Classification criteria for pulse sequences	医用画像用磁気共鳴装置－第2部：パルスシーケンスの分類基準	TC 62B	EN 62464-2:2011	2011-02-11	Magnetic resonance equipment for medical imaging – Part 2: Classification criteria for pulse sequences	CLC/TC 62							
IEC 62471 Ed. 1.0:2006	Photobiological safety of lamps and lamp systems	ランプ及びランプシステムの光生物学的安全性	TC 76	EN 62471:2008	2008-09-12	Photobiological safety of lamps and lamp systems	CLC/TC 76					IEC 62471 First edition 2006-07	Radiology	○[2]
IEC 62467-1 Ed. 1.0:2009	Medical electrical equipment – Dosimetric instruments as used in brachytherapy – Part 1: Instruments based on well-type ionization chambers	医用電気機器－近接照射療法で使用する線量測定計器－第1部：井戸形電離箱に基づく計器	TC 62C											
IEC/TR 62471-2 Ed. 1.0:2009	Photobiological safety of lamps and lamp systems – Part 2: Guidance on manufacturing requirements relating to non-laser optical radiation safety	ランプ及びランプシステムの光生物学的安全性－第2部：非レーザ光学的放射の安全性の手引	TC 76											
IEC 62494-1 Ed. 1.0:2008	Medical electrical equipment – Exposure index of digital X-ray imaging systems – Part 1: Definitions and requirements for general radiography	医用電気機器－デジタルX線映像システムの照射線量指数－第1部：一般撮影の定義及び要求事項	TC 62B	EN 62494-1:2008	2008-11-19	Medical electrical equipment – Exposure index of digital X-ray imaging systems – Part 1: Definitions and requirements for general radiography	CLC/TC 62					IEC 62494-1 Edition 1.0 (2008-08)	Radiology	○
IEC/TS 62558 Ed. 1.0:2011	Ultrasonics – Real-time pulse-echo scanners – Phantom with cylindrical, artificial cysts in tissue-mimicking material and method for evaluation and periodic testing of 3D-distributions of void-detectability ratio (VDR)	超音波－リアルタイムパルスエコースキャナー－円筒形，細胞組織模倣材料内の円筒型人工嚢胞をもつファントム並びにボイド検出率(VDR)の3D分布の評価方法及び定期試験	TC 87											
IEC 62563-1 Ed. 1.0:2009	Medical electrical equipment – Medical image display systems – Part 1: Evaluation methods	医用電気機器－医用画像表示システム－第1部：評価方法	TC 62B	EN 62563-1:2010	2010-03-05	Medical electrical equipment – Medical image display systems – Part 1: Evaluation methods	CLC/TC 62					IEC 62563-1:	Radiology	○
IEC/TR 62649 Ed. 1.0:2010	Requirements for measurement standards for high intensity therapeutic ultrasound (HITU) devices	高輝度超音波診療(HITU)装置の測定基準に対する要求事項	TC 87											
IEC/TR 62653 Ed. 1.0:2012	Guideline for safe operation of medical equipment used for haemodialysis treatments	血液透析治療に使用される医用機器の安全操作の指針	TC 62D											
IEC 80001-1 Ed. 1.0:2010	Application of risk management for IT-networks incorporating medical devices – Part 1: Roles, responsibilities and activities	医療機器を含むITネットワークへのリスクマネジメントの適用－第1部：役割，責任及び活動	TC 62A	EN 80001-1:2011	2011-03-18	Application of risk management for IT-networks incorporating medical devices – Part 1: Roles, responsibilities and activities	CLC/TC 62							
IEC/TR 80001-2-1 Ed. 1.0:2012	Application of risk management for IT-networks incorporating medical devices – Part 2-1: Step by step risk management of medical IT-networks – Pratical applications and examples	医療機器を含むITネットワークへのリスクマネジメントの適用－第2-1部：医療ITネットワークのステップバイステップ・リスクマネジメント－実務への適用及び事例	TC 62A											
IEC/TR 80001-2-2 Ed. 1.0:2012	Application of risk management for IT-networks incorporating medical devices – Part 2-2: Guidance for the disclosure and communication of medical device security needs, risks and controls	医療機器を含むITネットワークへのリスクマネジメントの適用－第2-2部：医療機器のセキュリティーニーズ，リスク及び管理策の情報開示及びコミュニケーションの指針	TC 62A											
IEC/TR 80001-2-3 Ed. 1.0:2012	Application of risk management for IT-networks incorporating medical devices – Part 2-3: Guidance for wireless networks	医療機器を含むITネットワークへのリスクマネジメントの適用－第2-3部：無線ネットワークの手引	TC 62A											
IEC/TR 80002-1 Ed. 1.0:2009	Medical device software – Part 1: Guidance on the application of ISO 14971 to medical device software	医療機器ソフトウェア－第1部：医療機器ソフトウェアへのISO 14971の適用の手引	TC 62A											
IEC 80601-2-30 Ed. 1.0:2009 IEC 80601-2-30 Ed. 1.0 Cor.1:2010	Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers	医用電気機器－第2-30部：自動無侵襲血圧計の基礎安全及び基本性能の特定要求事項	TC 62D	EN 80601-2-30:2010	2010-09-10	Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers	CLC/TC 62					AAMI ANSI IEC 80601-2-30:2009 (IEC 80601-2-30:2009	Card	●[4]
IEC 80601-2-35 Ed. 2.0:2009 IEC 80601-2-35 Ed. 2.0 Cor.1:2012	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	医用電気機器－第2-35部：毛布，詰め物及びマットレスを使用する医療用加熱に意図された加熱装置の基礎安全及び基本性能の特定要求事項	TC 62D	EN 80601-2-35:2009 EN 80601-2-35:2009/A11:2011	2009-12-11 2011-10-14	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	CLC/TC 62	EN 80601-2-35:2009 (IEC 80601-2-35:2009)	●[1][*]			IEC 80601-2-35 Edition 2.0 2009-10 IEC 80601-2-35 (Second edition – 2009)/Cor 1	GPS/GH	○
IEC 80601-2-58 Ed. 1.0:2008	Medical electrical equipment – Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for	医用電気機器－第2-58部：眼科手術用レンズ除去装置及び硝子体茎切除術装置の基本的安全性及び必須性能の特定要求事項	TC 62D	EN 80601-2-58:2009 EN 80601-2-58:2009/A11:2011	2009-02-06 2011-10-14	Medical electrical equipment – Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic	CLC/TC 62	EN 80601-2-58:2009 (IEC 80601-2-58:2008)	○[1]					

医療関係IEC規格　（平成24年9月3日現在）

規格番号	規格名称	規格名称（仮邦訳）
IEC 80601-2-59 Ed. 1.0:2008 IEC 80601-2-59 Ed. 1.0 Cor.1:2009	Medical electrical equipment – Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening	医用電気機器－第2-59部：人の発熱温度スクリーニングのためのスクリーニングサーモグラフの基本的安全性及び必須性能の特定要求事項
IEC 80601-2-60 Ed. 1.0:2012	Medical electrical equipment -- Part 2-60: Particular requirements for basic safety and essential performance of dental equipment	医用電気機器－第2-60部：歯科用機器の基本的安全性及び必須性能の特定要求事項
IEEE C63:19:2007	American National Standard Methods of Measurement of Compatibility between Wireless Communication Devices and Hearing	
IEEE N42.13-2004	Calibration and Usage of "Dose Calibrator" Ionization Chambers for the Assay of Radionuclides	
備 考	1) 2012年に発行された規格等については、規格番号を赤文字で示す。	

European Norm（CENELEC）　調査日：2012-09-25

TC	Reference	Date	Title	
TC 62D	EN 80601-2-59:2009	2009-12-23	Medical electrical equipment – Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening	CLC/TC 62
TC 62D				
TC 62A	HD 395.1 S2:1988/A1:1993	1993-01-26	Safety of medical electrical equipment – Part 1: General requirements	CLC/TC 62

2012-08-30発行のOJ（2012-09-01時点で有効なもの）

EU Harmonised Standards　○：最新版　●：旧版等

ISO /IEC standard	MDD	AIMD	IVD
EN 80601-2-59:2009 (IEC 80601-2-59:2008)	○[1]		

[1] AIMD及びMDDの修正指令(2007/47/EC)の要求事項を必ずしも満たしていない。
[2] .AIMD及びMDDの修正指令(2007/47/EC)の要求事項を満たすための修正が必要。
[*] 2012年に発行された改正版ではない、または2012年に発行された追補・修正を含んでいない。

（2012-09-12時点のDB）

FDA Recognized Consensus Standards

（経過措置終了日）	○：最新版	●：旧版等
IEC 80601-2-59 Edition 1.0 2008-10 IEC 80601-2-59 (First edition – 2008)/Cor 1	GPS/GH	○
ANSI IEEE C63:19:2007 (Revision of ANSI C63-19-2006)	Dental/ENT	○
IEEE N42.13-2004	Radiology	○

[1] 規格の一部箇条が認知されていない。
[2] 追加情報提供等の注記を条件に認知。
[3] 安全性についてのみ認知された規格。（有効性の検証については、FDAは規格に拘束されない。）
[4] 他の規格との併用を前提として認知。
[5] CDRHガイダンスによる追加等があれば、規格の要求事項を置き換える。
[6] 安全性の立証には不十分と認識。
[7] CFRの要求事項を満たしていない。
[*] 2012年に発行された改正版ではない、または2012年に発行された追補・修正を含んでいない。

IV

(Notices)

NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

EUROPEAN COMMISSION

Commission communication in the framework of the implementation of the Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices

(Text with EEA relevance)

(Publication of titles and references of harmonised standards under the directive)

(2013/C 22/01)

ESO (1)	Reference and title of the harmonised standard (and reference document)	First publication OJ	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
(1)	(2)	(3)	(4)	(5)
CEN	EN 556-1:2001 Sterilization of medical devices - Requirements for medical devices to be designated 'STERILE' - Part 1: Requirements for terminally sterilized medical devices	31.7.2002	EN 556:1994 + A1:1998 Note 2.1	Date expired (30.4.2002)
	EN 556-1:2001/AC:2006	15.11.2006		
CEN	EN 556-2:2003 Sterilization of medical devices - Requirements for medical devices to be designated 'STERILE' - Part 2: Requirements for aseptically processed medical devices	9.8.2007		
CEN	EN 1041:2008 Information supplied by the manufacturer of medical devices	19.2.2009	EN 1041:1998 Note 2.1	Date expired (31.8.2011)
CEN	EN ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)	2.12.2009	EN ISO 10993-1:2009 Note 2.1	Date expired (21.3.2010)
	EN ISO 10993-1:2009/AC:2010	18.1.2011		
CEN	EN ISO 10993-4:2009 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2002, including Amd 1:2006)	2.12.2009	EN ISO 10993-4:2002 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)	2.12.2009	EN ISO 10993-5:1999 Note 2.1	Date expired (31.12.2009)

(1)	(2)	(3)	(4)	(5)
CEN	EN ISO 10993-6:2009 Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:2007)	2.12.2009	EN ISO 10993-6:2007 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008)	7.7.2010		
	EN ISO 10993-7:2008/AC:2009	7.7.2010		
CEN	EN ISO 10993-9:2009 Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products (ISO 10993-9:2009)	2.12.2009	EN ISO 10993-9:2009 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 10993-11:2009 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2006)	2.12.2009	EN ISO 10993-11:2006 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 10993-12:2012 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2012)	This is the first publication	EN ISO 10993-12:2009 Note 2.1	31.1.2013
CEN	EN ISO 10993-13:2010 Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices (ISO 10993-13:2010)	18.1.2011	EN ISO 10993-13:2009 Note 2.1	Date expired (31.12.2010)
CEN	EN ISO 10993-16:2010 Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables (ISO 10993-16:2010)	7.7.2010	EN ISO 10993-16:2009 Note 2.1	Date expired (31.8.2010)
CEN	EN ISO 10993-17:2009 Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances (ISO 10993-17:2002)	2.12.2009	EN ISO 10993-17:2002 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 10993-18:2009 Biological evaluation of medical devices - Part 18: Chemical characterization of materials (ISO 10993-18:2005)	2.12.2009	EN ISO 10993-18:2005 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 11135-1:2007 Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11135-1:2007)	9.8.2007	EN 550:1994 Note 2.1	Date expired (31.5.2010)
CEN	EN ISO 11137-1:2006 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006)	7.9.2006	EN 552:1994 Note 2.1	Date expired (30.4.2009)

(1)	(2)	(3)	(4)	(5)
CEN	EN ISO 11137-2:2012 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2012)	30.8.2012	EN ISO 11137-2:2007 Note 2.1	Date expired (30.9.2012)
CEN	EN ISO 11138-2:2009 Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2006)	2.12.2009	EN ISO 11138-2:2006 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 11138-3:2009 Sterilization of health care products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes (ISO 11138-3:2006)	2.12.2009	EN ISO 11138-3:2006 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 11140-1:2009 Sterilization of health care products - Chemical indicators - Part 1: General requirements (ISO 11140-1:2005)	2.12.2009	EN ISO 11140-1:2005 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 11607-1:2009 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006)	2.12.2009	EN ISO 11607-1:2006 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 11737-1:2006 Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2006)	7.9.2006	EN 1174-2:1996 EN 1174-1:1996 EN 1174-3:1996 Note 2.1	Date expired (31.10.2006)
	EN ISO 11737-1:2006/AC:2009	2.12.2009		
CEN	EN ISO 11737-2:2009 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2009)	7.7.2010		
CEN	EN ISO 13408-1:2011 Aseptic processing of health care products - Part 1: General requirements (ISO 13408-1:2008)	19.8.2011	EN 13824:2004 Note 2.1	Date expired (31.12.2011)
CEN	EN ISO 13408-2:2011 Aseptic processing of health care products - Part 2: Filtration (ISO 13408-2:2003)	19.8.2011	EN 13824:2004 Note 2.1	Date expired (31.12.2011)
CEN	EN ISO 13408-3:2011 Aseptic processing of health care products - Part 3: Lyophilization (ISO 13408-3:2006)	19.8.2011	EN 13824:2004 Note 2.1	Date expired (31.12.2011)
CEN	EN ISO 13408-4:2011 Aseptic processing of health care products - Part 4: Clean-in-place technologies (ISO 13408-4:2005)	19.8.2011	EN 13824:2004 Note 2.1	Date expired (31.12.2011)
CEN	EN ISO 13408-5:2011 Aseptic processing of health care products - Part 5: Sterilization in place (ISO 13408-5:2006)	19.8.2011	EN 13824:2004 Note 2.1	Date expired (31.12.2011)
CEN	EN ISO 13408-6:2011 Aseptic processing of health care products - Part 6: Isolator systems (ISO 13408-6:2005)	19.8.2011	EN 13824:2004 Note 2.1	Date expired (31.12.2011)

(1)	(2)	(3)	(4)	(5)
CEN	EN ISO 13485:2012 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)	30.8.2012	EN ISO 13485:2003 Note 2.1	Date expired (30.8.2012)
	EN ISO 13485:2012/AC:2012	30.8.2012		
CEN	EN ISO 14155:2011 Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2011)	27.4.2012	EN ISO 14155:2011 Note 2.1	Date expired (30.4.2012)
CEN	EN ISO 14937:2009 Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices (ISO 14937:2009)	7.7.2010	EN ISO 14937:2000 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 14971:2012 Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)	30.8.2012	EN ISO 14971:2009 Note 2.1	Date expired (30.8.2012)
CEN	EN ISO 17665-1:2006 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665-1:2006)	15.11.2006	EN 554:1994 Note 2.1	Date expired (31.8.2009)
CEN	EN 45502-1:1997 Active implantable medical devices - Part 1: General requirements for safety, marking and information to be provided by the manufacturer	27.8.1998		
CEN	EN 45502-2-1:2004 Active implantable medical devices - Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers)	24.6.2005		
CEN	EN 45502-2-3:2010 Active implantable medical devices - Part 2-3: Particular requirements for cochlear and auditory brainstem implant systems	7.7.2010		
Cenelec	EN 45502-1:1997 Active implantable medical devices - Part 1: General requirements for safety, marking and information to be provided by the manufacturer (*)	27.8.1998		
Cenelec	EN 45502-2-1:2003 Active implantable medical devices - Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers) (*)	8.7.2004		
Cenelec	EN 45502-2-2:2008 Active implantable medical devices - Part 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators) (*)	27.11.2008		
	EN 45502-2-2:2008/AC:2009	18.1.2011		

(1)	(2)	(3)	(4)	(5)
Cenelec	EN 45502-2-3:2010 Active implantable medical devices - Part 2-3: Particular requirements for cochlear and auditory brainstem implant systems (*)	18.1.2011		
Cenelec	EN 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1:2005 (*)	27.11.2008	EN 60601-1:1990 + A1:1993 + A2:1995 + A13:1996 Note 2.1	Date expired (1.6.2012)
	EN 60601-1:2006/AC:2010	18.1.2011		
Cenelec	EN 60601-1-6:2010 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability IEC 60601-1-6:2010 (*)	18.1.2011		
Cenelec	EN 62304:2006 Medical device software - Software life-cycle processes IEC 62304:2006 (*)	27.11.2008		
	EN 62304:2006/AC:2008	18.1.2011		

([1]) ESO: European Standards Organisation:
— CEN: Avenue Marnix 17, 1000 Bruxelles/Brussel, BELGIQUE/BELGIË, Tel. +32 25500811; fax +32 25500819 (http://www.cen.eu)
— Cenelec: Avenue Marnix 17, 1000 Bruxelles/Brussel, BELGIQUE/BELGIË, Tel. +32 25196871; fax +32 25196919 (http://www.cenelec.eu)
— ETSI: 650 route des Lucioles, 06921 Sophia Antipolis, FRANCE, Tel. +33 492944200; fax +33 493654716 (http://www.etsi.eu)
(*) This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

Note 1: Generally the date of cessation of presumption of conformity will be the date of withdrawal ('dow'), set by the European Standardisation Organisation, but attention of users of these standards is drawn to the fact that in certain exceptional cases this can be otherwise.

Note 2.1: The new (or amended) standard has the same scope as the superseded standard. On the date stated, the superseded standard ceases to give presumption of conformity with the essential requirements of the directive.

Note 2.2: The new standard has a broader scope than the superseded standard. On the date stated the superseded standard ceases to give presumption of conformity with the essential requirements of the directive.

Note 2.3: The new standard has a narrower scope than the superseded standard. On the date stated the (partially) superseded standard ceases to give presumption of conformity with the essential requirements of the directive for those products that fall within the scope of the new standard. Presumption of conformity with the essential requirements of the directive for products that still fall within the scope of the (partially) superseded standard, but that do not fall within the scope of the new standard, is unaffected.

Note 3: In case of amendments, the referenced standard is EN CCCCC:YYYY, its previous amendments, if any, and the new, quoted amendment. The superseded standard therefore consists of EN CCCCC:YYYY and its previous amendments, if any, but without the new quoted amendment. On the date stated, the superseded standard ceases to give presumption of conformity with the essential requirements of the directive.

NOTE:

— Any information concerning the availability of the standards can be obtained either from the European Standardisation Organisations or from the national standardisation bodies of which the list is annexed to the Directive 98/34/EC of the European Parliament and Council amended by the Directive 98/48/EC.

— Harmonised standards are adopted by the European Standardisation Organisations in English (CEN and Cenelec also publish in French and German). Subsequently, the titles of the harmonised standards are translated into all other required official languages of the European Union by the National Standards Bodies. The European Commission is not responsible for the correctness of the titles which have been presented for publication in the Official Journal.

— Publication of the references in the *Official Journal of the European Union* does not imply that the standards are available in all the Community languages.

— This list replaces all the previous lists published in the *Official Journal of the European Union*. The Commission ensures the updating of this list.

— More information about harmonised standards on the Internet at

http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/index_en.htm

Commission communication in the framework of the implementation of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

(Text with EEA relevance)

(Publication of titles and references of harmonised standards under the directive)

(2013/C 22/02)

ESO (1)	Reference and title of the harmonised standard (and reference document)	First publication OJ	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
(1)	(2)	(3)	(4)	(5)
CEN	EN 285:2006+A2:2009 Sterilization - Steam sterilizers - Large sterilizers	2.12.2009	EN 285:2006+A1:2008 Note 2.1	Date expired (21.3.2010)
CEN	EN 455-1:2000 Medical gloves for single use - Part 1: Requirements and testing for freedom from holes	30.9.2005	EN 455-1:1993 Note 2.1	Date expired (30.4.2001)
CEN	EN 455-3:2006 Medical gloves for single use - Part 3: Requirements and testing for biological evaluation	9.8.2007	EN 455-3:1999 Note 2.1	Date expired (30.6.2007)
CEN	EN 455-4:2009 Medical gloves for single use - Part 4: Requirements and testing for shelf life determination	7.7.2010		
CEN	EN 556-1:2001 Sterilization of medical devices - Requirements for medical devices to be designated 'STERILE' - Part 1: Requirements for terminally sterilized medical devices	31.7.2002	EN 556:1994 + A1:1998 Note 2.1	Date expired (30.4.2002)
	EN 556-1:2001/AC:2006	15.11.2006		
CEN	EN 556-2:2003 Sterilization of medical devices - Requirements for medical devices to be designated 'STERILE' - Part 2: Requirements for aseptically processed medical devices	9.8.2007		
CEN	EN 794-3:1998+A2:2009 Lung ventilators - Part 3: Particular requirements for emergency and transport ventilators	7.7.2010	EN 794-3:1998 Note 2.1	Date expired (21.3.2010)
CEN	EN 1041:2008 Information supplied by the manufacturer of medical devices	19.2.2009	EN 1041:1998 Note 2.1	Date expired (31.8.2011)
CEN	EN 1060-3:1997+A2:2009 Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems	7.7.2010	EN 1060-3:1997 Note 2.1	Date expired (31.5.2010)
CEN	EN 1060-4:2004 Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers	30.9.2005		
CEN	EN 1282-2:2005+A1:2009 Tracheostomy tubes - Part 2: Paediatric tubes (ISO 5366-3:2001, modified)	7.7.2010	EN 1282-2:2005 Note 2.1	Date expired (21.3.2010)
CEN	EN 1422:1997+A1:2009 Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods	2.12.2009	EN 1422:1997 Note 2.1	Date expired (21.3.2010)

(1)	(2)	(3)	(4)	(5)
CEN	EN 1618:1997 Catheters other than intravascular catheters - Test methods for common properties	9.5.1998		
CEN	EN 1639:2009 Dentistry - Medical devices for dentistry - Instruments	7.7.2010	EN 1639:2004 Note 2.1	Date expired (30.4.2010)
CEN	EN 1640:2009 Dentistry - Medical devices for dentistry - Equipment	7.7.2010	EN 1640:2004 Note 2.1	Date expired (30.4.2010)
CEN	EN 1641:2009 Dentistry - Medical devices for dentistry - Materials	7.7.2010	EN 1641:2004 Note 2.1	Date expired (30.4.2010)
CEN	EN 1642:2011 Dentistry - Medical devices for dentistry - Dental implants	27.4.2012	EN 1642:2009 Note 2.1	Date expired (30.4.2012)
CEN	EN 1707:1996 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Lock fittings	17.5.1997		
CEN	EN 1782:1998+A1:2009 Tracheal tubes and connectors	7.7.2010	EN 1782:1998 Note 2.1	Date expired (21.3.2010)
CEN	EN 1789:2007+A1:2010 Medical vehicles and their equipment - Road ambulances	18.1.2011		
CEN	EN 1820:2005+A1:2009 Anaesthetic reservoir bags (ISO 5362:2000, modified)	7.7.2010	EN 1820:2005 Note 2.1	Date expired (21.3.2010)
CEN	EN 1865-3:2012 Patient handling equipment used in road ambulances - Part 3: Heavy duty stretcher	30.8.2012	EN 1865:1999 Note 2.1	Date expired (31.12.2012)
CEN	EN 1865-4:2012 Patient handling equipment used in road ambulances - Part 4: Foldable patient transfer chair	30.8.2012	EN 1865:1999 Note 2.1	Date expired (31.10.2012)
CEN	EN 1865-5:2012 Patient handling equipment used in road ambulances - Part 5: Stretcher support	30.8.2012	EN 1865:1999 Note 2.1	Date expired (31.12.2012)
CEN	EN 1985:1998 Walking aids - General requirements and test methods	10.8.1999		

This standard still needs to be amended to take into account the requirements introduced by Directive 2007/47/EC. The amended standard will be published by CEN as soon as possible. Manufacturers are advised to check whether all relevant Essential Requirements of the amended directive are appropriately covered.

CEN	EN ISO 3826-2:2008 Plastics collapsible containers for human blood and blood components - Part 2: Graphical symbols for use on labels and instruction leaflets (ISO 3826-2:2008)	19.2.2009		
CEN	EN ISO 3826-3:2007 Plastics collapsible containers for human blood and blood components - Part 3: Blood bag systems with integrated features (ISO 3826-3:2006)	27.2.2008		
CEN	EN ISO 4074:2002 Natural latex rubber condoms - Requirements and test methods (ISO 4074:2002)	31.7.2002	EN 600:1996 Note 2.1	Date expired (31.8.2005)

(1)	(2)	(3)	(4)	(5)
	EN ISO 4074:2002/AC:2008	2.12.2009		
CEN	EN ISO 4135:2001 Anaesthetic and respiratory equipment - Vocabulary (ISO 4135:2001)	31.7.2002	EN ISO 4135:1996 Note 2.1	Date expired (28.2.2002)
CEN	EN ISO 5356-1:2004 Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets (ISO 5356-1:2004)	30.9.2005	EN 1281-1:1997 Note 2.1	Date expired (30.11.2004)
CEN	EN ISO 5356-2:2007 Anaesthetic and respiratory equipment - Conical connectors - Part 2: Screw-threaded weight-bearing connectors (ISO 5356-2:2006)	9.11.2007	EN 1281-2:1995 Note 2.1	Date expired (29.2.2008)
CEN	EN ISO 5359:2008 Low-pressure hose assemblies for use with medical gases (ISO 5359:2008)	23.7.2008	EN 739:1998 Note 2.1	Date expired (30.6.2010)
	EN ISO 5359:2008/A1:2011	30.8.2012	Note 3	Date expired (30.6.2012)
CEN	EN ISO 5360:2009 Anaesthetic vaporizers - Agent-specific filling systems (ISO 5360:2006)	2.12.2009	EN ISO 5360:2007 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 5366-1:2009 Anaesthetic and respiratory equipment - Tracheostomy tubes - Part 1: Tubes and connectors for use in adults (ISO 5366-1:2000)	2.12.2009	EN ISO 5366-1:2004 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 5840:2009 Cardiovascular implants - Cardiac valve prostheses (ISO 5840:2005)	2.12.2009	EN ISO 5840:2005 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 7197:2009 Neurosurgical implants - Sterile, single-use hydrocephalus shunts and components (ISO 7197:2006, including Cor 1:2007)	2.12.2009	EN ISO 7197:2006 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 7376:2009 Anaesthetic and respiratory equipment - Laryngoscopes for tracheal intubation (ISO 7376:2009)	2.12.2009	EN ISO 7376:2009 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 7396-1:2007 Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum (ISO 7396-1:2007)	9.8.2007	EN 737-3:1998 Note 2.1	Date expired (30.4.2009)
	EN ISO 7396-1:2007/A1:2010	7.7.2010	Note 3	Date expired (31.7.2010)
	EN ISO 7396-1:2007/A2:2010	7.7.2010	Note 3	Date expired (31.8.2010)
CEN	EN ISO 7396-2:2007 Medical gas pipeline systems - Part 2: Anaesthetic gas scavenging disposal systems (ISO 7396-2:2007)	9.8.2007	EN 737-2:1998 Note 2.1	Date expired (30.4.2009)
CEN	EN ISO 7886-3:2009 Sterile hypodermic syringes for single use - Part 3: Auto-disable syringes for fixed-dose immunization (ISO 7886-3:2005)	7.7.2010	EN ISO 7886-3:2005 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 7886-4:2009 Sterile hypodermic syringes for single use - Part 4: Syringes with re-use prevention feature (ISO 7886-4:2006)	7.7.2010	EN ISO 7886-4:2006 Note 2.1	Date expired (21.3.2010)

(1)	(2)	(3)	(4)	(5)
CEN	EN ISO 8185:2009 Respiratory tract humidifiers for medical use - Particular requirements for respiratory humidification systems (ISO 8185:2007)	2.12.2009	EN ISO 8185:2007 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 8359:2009 Oxygen concentrators for medical use - Safety requirements (ISO 8359:1996)	2.12.2009	EN ISO 8359:1996 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 8835-2:2009 Inhalational anaesthesia systems - Part 2: Anaesthetic breathing systems (ISO 8835-2:2007)	2.12.2009	EN ISO 8835-2:2007 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 8835-3:2009 Inhalational anaesthesia systems - Part 3: Transfer and receiving systems of active anaesthetic gas scavenging systems (ISO 8835-3:2007)	2.12.2009	EN ISO 8835-3:2007 Note 2.1	Date expired (21.3.2010)
	EN ISO 8835-3:2009/A1:2010	13.5.2011	Note 3	Date expired (30.4.2011)
CEN	EN ISO 8835-4:2009 Inhalational anaesthesia systems - Part 4: Anaesthetic vapour delivery devices (ISO 8835-4:2004)	2.12.2009	EN ISO 8835-4:2004 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 8835-5:2009 Inhalational anaesthesia systems - Part 5: Anaesthetic ventilators (ISO 8835-5:2004)	2.12.2009	EN ISO 8835-5:2004 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 9170-1:2008 Terminal units for medical gas pipeline systems - Part 1: Terminal units for use with compressed medical gases and vacuum (ISO 9170-1:2008)	19.2.2009	EN 737-1:1998 Note 2.1	Date expired (31.7.2010)
CEN	EN ISO 9170-2:2008 Terminal units for medical gas pipeline systems - Part 2: Terminal units for anaesthetic gas scavenging systems (ISO 9170-2:2008)	19.2.2009	EN 737-4:1998 Note 2.1	Date expired (31.7.2010)
CEN	EN ISO 9360-1:2009 Anaesthetic and respiratory equipment - Heat and moisture exchangers (HMEs) for humidifying respired gases in humans - Part 1: HMEs for use with minimum tidal volumes of 250 ml (ISO 9360-1:2000)	2.12.2009	EN ISO 9360-1:2000 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 9360-2:2009 Anaesthetic and respiratory equipment - Heat and moisture exchangers (HMEs) for humidifying respired gases in humans - Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml (ISO 9360-2:2001)	2.12.2009	EN ISO 9360-2:2002 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 9713:2009 Neurosurgical implants - Self-closing intracranial aneurysm clips (ISO 9713:2002)	2.12.2009	EN ISO 9713:2004 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 10079-1:2009 Medical suction equipment - Part 1: Electrically powered suction equipment - Safety requirements (ISO 10079-1:1999)	2.12.2009	EN ISO 10079-1:1999 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 10079-2:2009 Medical suction equipment - Part 2: Manually powered suction equipment (ISO 10079-2:1999)	2.12.2009	EN ISO 10079-2:1999 Note 2.1	Date expired (21.3.2010)

(1)	(2)	(3)	(4)	(5)
CEN	EN ISO 10079-3:2009 Medical suction equipment - Part 3: Suction equipment powered from a vacuum or pressure source (ISO 10079-3:1999)	2.12.2009	EN ISO 10079-3:1999 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 10328:2006 Prosthetics - Structural testing of lower-limb prostheses - Requirements and test methods (ISO 10328:2006)	9.8.2007		

This standard still needs to be amended to take into account the requirements introduced by Directive 2007/47/EC. The amended standard will be published by CEN as soon as possible. Manufacturers are advised to check whether all relevant Essential Requirements of the amended directive are appropriately covered.

CEN	EN ISO 10524-1:2006 Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow-metering devices (ISO 10524-1:2006)	2.6.2006	EN 738-1:1997 Note 2.1	Date expired (31.10.2008)
CEN	EN ISO 10524-2:2006 Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators (ISO 10524-2:2005)	7.6.2009	EN 738-2:1998 Note 2.1	Date expired (31.10.2008)
CEN	EN ISO 10524-3:2006 Pressure regulators for use with medical gases - Part 3: Pressure regulators integrated with cylinder valves (ISO 10524-3:2005)	7.9.2006	EN 738-3:1998 Note 2.1	Date expired (31.10.2008)
CEN	EN ISO 10524-4:2008 Pressure regulators for use with medical gases - Part 4: Low-pressure regulators (ISO 10524-4:2008)	23.7.2008	EN 738-4:1998 Note 2.1	Date expired (30.6.2010)
CEN	EN ISO 10535:2006 Hoists for the transfer of disabled persons - Requirements and test methods (ISO 10535:2006)	9.8.2007	EN ISO 10535:1998 Note 2.1	Date expired (30.6.2007)

This standard still needs to be amended to take into account the requirements introduced by Directive 2007/47/EC. The amended standard will be published by CEN as soon as possible. Manufacturers are advised to check whether all relevant Essential Requirements of the amended directive are appropriately covered.

CEN	EN ISO 10555-1:2009 Sterile, single-use intravascular catheters - Part 1: General requirements (ISO 10555-1:1995, including Amd 1:1999 and Amd 2:2004)	2.12.2009	EN ISO 10555-1:1996 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 10651-2:2009 Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 2: Home care ventilators for ventilator-dependent patients (ISO 10651-2:2004)	2.12.2009	EN ISO 10651-2:2004 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 10651-4:2009 Lung ventilators - Part 4: Particular requirements for operator-powered resuscitators (ISO 10651-4:2002)	2.12.2009	EN ISO 10651-4:2002 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 10651-6:2009 Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 6: Home-care ventilatory support devices (ISO 10651-6:2004)	2.12.2009	EN ISO 10651-6:2004 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)	2.12.2009	EN ISO 10993-1:2009 Note 2.1	Date expired (21.3.2010)