

**APPROVED MALAYSIAN STANDARDS**

<b>NO.</b>	<b>MS NO. REFERENCE DOC.</b>	<b>STANDARD/TECHNICAL REGULATION</b>	<b>DATE ISC APPROVED</b>	<b>SCOPE</b>
			<b>DATE REGISTERED</b>	
			<b>DATE STARTED</b>	
1.	MS ISO 15225:2000  ISO 15225:2000 and its Amendment 1:2004, Nomenclature - Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange	Nomenclature - Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange	30/11/2004  30/11/2005	Medical Devices
2.	04R005R0  MS ISO 10993-1:2003  ISO 10993-1:2003, Biological evaluation of medical devices - Part 1: Evaluation and testing	Biological evaluation of medical devices - Part 1: Evaluation and testing	30/11/2004  30/11/2005	Medical Devices
3.	04R006R0  MS ISO 10993-3:2003  ISO 10993-3:2003, Biological evaluation of medical devices ? Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	Biological evaluation of medical devices ? Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	30/11/2004  30/11/2005	Medical Devices
4.	04R007R0  MS ISO 10993-13:1998  ISO 10993-13:1998, Biological evaluation of medical devices ? Part 13: Identification and quantification of degradation products from polymeric medical devices	Biological evaluation of medical devices ? Part 13: Identification and quantification of degradation products from polymeric medical devices	30/11/2004  30/11/2005	Medical Devices
5.	04R008R0  MS ISO 10993-14:2001	Biological evaluation of medical devices ? Part 14: Identification and quantification of degradation products from ceramics	30/11/2004	Medical Devices

	ISO 10993-14:2001,		30/11/2005	
6.	04R009R0  MS ISO 10993-15:2000  ISO 10993-15:2000, Biological evaluation of medical devices ? Part 15: Identification and quantification of degradation of products from metals and alloys	Biological evaluation of medical devices ? Part 15: Identification and quantification of degradation of products from metals and alloys	30/11/2004  30/11/2005	Medical Devices
7.	04R010R0  MS ISO 10993-16:1997  ISO 10993-16:1997, Biological evaluation of medical devices ? Part 16: Toxicokinetic study design for degradation products and leachables	Biological evaluation of medical devices ? Part 16: Toxicokinetic study design for degradation products and leachables	30/11/2004  30/11/2005	Medical Devices
8.	04R011R0  MS ISO 10993-17:2002  ISO 10993-17:2002, Biological evaluation of medical devices ? Part 17: Establishment of allowable limits for leachable substances	Biological evaluation of medical devices ? Part 17: Establishment of allowable limits for leachable substances	30/11/2004  30/11/2005	Medical Devices
9.	04R012R0  MS IEC 60601-1-1:2005  IEC 60601-1-1:2000, Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems	Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems	30/11/2004  30/11/2005	Medical Devices
10	MS ISO 13485:2006  ISO 13485:2003, Medical devices - Quality management systems - Requirements for regulatory purposes	Medical devices - Quality management systems - Requirements for regulatory purposes	30/11/2004  29/11/2005	Quality Management and corresponding general aspect for Medical Device

11	04R002R0 MS ISO 14971:2006 ISO 14971:2000, Medical devices - Application of risk management to medical devices; and its Amendment 1:2003	Medical devices - Application of risk management to medical devices	30/11/2004  29/11/2005	Quality Management and corresponding general aspect for Medical Device
12	04R003R0 MS 1961:2007 ISO/TR 14969:2004, Medical Devices - Quality management systems - Guidance on the application of ISO 13485:2003	Medical Devices - Quality management systems - Guidance on the application of MS ISO 13485:2003	30/11/2004  29/11/2005	Quality Management and corresponding general aspect for Medical Device
13	MS 1948:2006 : 2007 EN 1616 (1997), Sterile urethral catheters for single use, MS 1369:1995, Specification for sterile, single use urethral catheters of the relation and foley types	Sterile urethral catheters for single use	06/04/2006  30/12/2006	Disposable Single use Devices
14	06R027R0 MS 1949:2006 : 2007 EN 1617 (1997), Sterile drainage catheters and accessory devices for single use, MS 1369:1995, Specification for sterile, single use urethral catheters of the relation and foley types.	Sterile drainage catheters and accessory devices for single use	06/04/2006  30/12/2006	Disposable Single use Devices
15	06R028R0 MS 1950:2006 : 2007 EN 1618 (1997), Catheters other than intravascular catheters - Test methods for common properties, MS 1369:1995, Specification for sterile, single use urethral catheters of the relation and foley types	Catheters other than intravascular catheters - Test methods for common properties	06/04/2006  30/12/2006	Disposable Single use Devices
16	MS ISO 5366: PART 1:2007	Anaesthetic and respiratory equipment - Tracheostomy tubes - Part 1: Tubes	06/04/2006	Disposable Single

	EN 1282-1 (1996), Anaesthetic and respiratory equipment - Tracheostomy tubes - Part 1: Tubes for use in adults, ISO 5366-1:2000, Anaesthetic and respiratory equipment Tracheostomy tubes Part 1: Tubes and connectors for use in adults	for use in adults (ISO 5366-1:2000, IDT)	30/12/2006	use Devices
17	MS ISO 5366: PART 3:2006 : 2007  EN 1282-2 (1997), Tracheostomy tubes - Part 2: Paediatric tubes, ISO 5366-3:2001, Anaesthetic and respiratory equipment ? Tracheostomy tubes ? Part 3: Paediatric tracheostomy tubes	Anaesthetic and respiratory equipment - Tracheostomy tubes - Part 3: Paediatric tubes (ISO 5366-3:2001, IDT)	06/04/2006  30/12/2006	Disposable Single use Devices
18	MS ISO 5316:2006  EN 1782 (1998), Tracheal tubes and connectors, ISO 5361:1999, Anaesthetic and respiratory equipment ? Tracheal tubes and connectors.	Anaesthetic and respiratory equipment - Tracheal tubes and connectors (ISO 5361:1999, IDT)	06/04/2006  30/12/2006	Disposable Single use Devices
19	MS ISO 5361: PART 4:2006  ISO 5361-4:1987, Tracheal tubes - Part 4: Cole type	Tracheal tubes - Part 4: Cole type (ISO 5361-4:1987, IDT)	06/04/2006  30/12/2006	Disposable Single use Devices
20	MS ISO 8669: PART 2:2006  ISO 8669-2:1996, Urine collection bags - Part 2: Requirements and test methods	Urine collection bags Part 2: Requirements and test methods (ISO 8669-2:1996, IDT)	06/04/2006  30/12/2006	Disposable Single use Devices
21	MS 1927: Part 1:2006  EN 868-1 (1997), Packaging materials and systems for medical devices which are to be sterilized - Part 1: General requirements and test methods	Packaging materials and systems for medical devices which are to be sterilized - Part 1: General requirements and test methods	06/04/2006  30/12/2006	Disposable Single use Devices
22	MS 1927: Part 2:2006  EN 868-2 (1999), Packaging materials and systems for medical devices which are to be sterilized Part 2: Sterilization	Packaging materials and systems for medical devices which are to be sterilized Part 2: Sterilization Requirements and test methods	06/04/2006  30/12/2006	Disposable Single use Devices

	wrap Requirements and test methods			
24	MS 1927: Part 3:2006  Refer to Annex	Packaging materials and systems for medical devices which are to be sterilized Part 3: Paper for use in the manufacture of paper bags and in the manufacture of pouches and reels Requirements and test methods	06/04/2006  30/12/2006	Disposable Single use Devices
25	MS 1927: Part 4:2006  EN 868-4 (1999), Packaging materials and systems for medical devices which are to be sterilized Part 4: Paper bags Requirements and test methods	Packaging materials and systems for medical devices which are to be sterilized Part 4: Paper bags Requirements and test methods	06/04/2006  30/12/2006	Disposable Single use Devices
26	MS 1927: Part 5:2006  EN 868-5 (1999), Packaging materials and systems for medical devices which are to be sterilized - Part 5: Heat and self-sealable pouches and reels of paper and plastic film construction Requirements and test methods	Packaging materials and systems for medical devices which are to be sterilized - Part 5: Heat and self-sealable pouches and reels of paper and plastic film construction Requirements and test methods	06/04/2006  30/12/2006	Disposable Single use Devices
27	MS 1927: Part 6:2006  EN 868-6 (1999), Packaging materials and systems for medical devices which are to be sterilized Part 6: Paper for the manufacture of packs for medical use for sterilization by ethylene oxide or irradiation Requirements and test methods	Packaging materials and systems for medical devices which are to be sterilized Part 6: Paper for the manufacture of packs for medical use for sterilization by ethylene oxide or irradiation Requirements and test methods	06/04/2006  30/12/2006	Disposable Single use Devices
28	MS 1927: Part 7:2006  Refer to Annex	Packaging materials and systems for medical devices which are to be sterilized Part 7: Adhesive coated paper for the manufacture of heat sealable packs for medical use for sterilization by ethylene oxide or irradiation Requirements and test	06/04/2006  30/12/2006	Disposable Single use Devices

		methods		
29	MS 1927: Part 8:2006  EN 868-8 (1999), Packaging materials and systems for medical devices which are to be sterilized Part 8: Re-usable sterilization containers for steam sterilizers Requirements and test methods	Packaging materials and systems for medical devices which are to be sterilized Part 8: Re-usable sterilization containers for steam sterilizers Requirements and test methods	06/04/2006  30/12/2006	Disposable Single use Devices
30	MS ISO 10651-2:2006  ISO 10651-2:2004, Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 2: Home care ventilators for ventilator-dependent patients	Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 2: Home care ventilators for ventilator-dependent patients	17/11/2005  17/11/2006	Anaesthetic/ respiratory  And electromechanical devices
31	MS ISO 10651-3:2006  ISO 10651-3:1997, Lung ventilators for medical use - Part 3: Particular requirements for emergency and transport ventilators	Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 3: Particular requirements for emergency and transport ventilators	17/11/2005  17/11/2006	Anaesthetic/ respiratory  And electromechanical devices
32	MS ISO 10651-4:2006  ISO 10651-4:2002, Lung ventilators for medical use - Part 4: Particular requirements for operator-powered resuscitators	Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 4: Particular requirements for operator-powered resuscitators	17/11/2005  17/11/2006	Anaesthetic/ respiratory  And electromechanical devices

33	MS ISO 10651-6:2006  ISO 10651-6:2004, Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 6: Home-care ventilatory support devices	Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 6: Home-care ventilatory support devices	17/11/2005  17/11/2006	Anaesthetic/ respiratory  And electromechanical devices
34	MS IEC 60601-2-13:2006  IEC 60601-2-13:2003, Medical electrical equipment - Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems	Medical electrical equipment - Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems	17/11/2005  17/11/2006	Anaesthetic/ respiratory  And electromechanical devices
35	MS ISO 9919:2006  ISO 9919:2005, Medical electrical equipment Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use	Medical electrical equipment ? Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use	17/11/2005  17/11/2006	Anaesthetic/ respiratory  And electromechanical devices
36	MS IEC 60601-1:2006  IEC 60601-1:1988 and its Amendment	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	17/11/2005	Anaesthetic/

	1:1991, Amendment 2:1995 and Amendment 2 Corrigendum 1:1995, Medical electrical equipment - Part 1: General requirements for safety		17/11/2006	respiratory And electromechanical devices
37	MS ISO 11197:2006  ISO 11197:2004, Medical supply units	Medical supply units	17/11/2005  17/11/2006	Anaesthetic/ respiratory  And electromechanical devices
38	MS ISO 4135:2006  ISO 4135:2001, Anaesthetic and respiratory equipment Vocabulary	Anaesthetic and respiratory equipment Vocabulary	17/11/2005  17/11/2006	Anaesthetic/ respiratory  And electromechanical devices
39	MS ISO 15001:2006  ISO 15001:2003, Anaesthetic and respiratory equipment - Compatibility with oxygen	Anaesthetic and respiratory equipment - Compatibility with oxygen	17/11/2005  17/11/2006	Anaesthetic/ respiratory  And electromechanical devices

40	MS IEC 61010-1:2006  Refer Annex	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements	30/11/2005  03/11/2006	Anaesthetic/  respiratory  And electromechanical  devices
41	MS IEC 60601: PART 1-2:2006 : 2007  IEC 60601-1-2:2001 and its Amendment 1:2004, Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests	06/04/2006  01/09/2006	Anaesthetic/  respiratory  And electromechanical  devices
42	MS IEC 60601: PART 1-8:2006  IEC 60601-1-8:2005 and Amd 1:2006, Medical electrical equipment - Part 1-8: General requirements for safety - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	Medical electrical equipment - Part 1-8: General requirements for safety - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	06/04/2006  06/04/2006  01/09/2006	Anaesthetic/  respiratory  And electromechanical  devices
43	MS IEC 60601: PART 2-2:2007  IEC 60601-2-2:1998, Medical electrical	Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment	06/04/2006	Anaesthetic/

	equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment		01/09/2006	respiratory And electromechanical devices
44	MS IEC 60601: PART 2-3:2007  IEC 60601-2-3:1991 and its Amendment 1:1998, Medical electrical equipment - Part 2: Particular requirements for the safety of short-wave therapy equipment	Medical electrical equipment - Part 2-3: Particular requirements for the safety of short-wave therapy equipment	06/04/2006  01/09/2006	Anaesthetic/ respiratory  And electromechanical devices
45	MS IEC 60601: PART 2-4:2007  IEC 60601-2-4:2005, Medical electrical equipment - Part 2-4: Particular requirements for the safety of cardiac defibrillators	Medical electrical equipment - Part 2-4: Particular requirements for the safety of cardiac defibrillators	06/04/2006  01/09/2006	Anaesthetic/ respiratory  And electromechanical devices
46	MS IEC 60601: PART 2-5:2007  IEC 60601-2-5:2005, Medical electrical equipment - Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment	Medical electrical equipment - Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment	16/06/2006  01/09/2006	Anaesthetic/ respiratory  And

				electromechanical devices
47	MS IEC 60601: PART 2-6:2007  IEC 60601-2-6:1984, Medical electrical equipment Part 2-6: Particular requirements for safety of microwave therapy equipment	Medical electrical equipment Part 2-6: Particular requirements for the safety of microwave therapy equipment	16/06/2006  01/09/2006	Anaesthetic/ respiratory  And electromechanical devices
48	MS IEC 60601: PART 2-10:2007  IEC 60601-2-10:1987, Medical electrical equipment Part 2-10: Particular requirements for the safety of nerve and muscle stimulators	Medical electrical equipment Part 2-10: Particular requirements for the safety of nerve and muscle stimulators	16/06/2006  01/09/2006	Anaesthetic/ respiratory  And electromechanical devices
47	MS IEC 60601: PART 2-12:2007  IEC 60601-2-12:2001, Medical electrical equipment ? Part 2-12: Particular requirements for the safety of lung ventilators ? Critical care ventilators	Medical electrical equipment Part 2-12: Particular requirements for the safety of lung ventilators ? Critical care ventilators	16/06/2006  01/09/2006	Anaesthetic/ respiratory  And electromechanical devices

48	MS IEC 60601: PART 2-16:2007  IEC 60601-2-16:1998, Medical electrical equipment Part 2-16: Particular requirements for the safety of haemodialysis, haemodiafiltration and haemofiltration equipment	Medical electrical equipment ? Part 2-16: Particular requirements for the safety of haemodialysis, haemodiafiltration and haemofiltration equipment	16/06/2006  01/09/2006	Anaesthetic/  respiratory  And electromechanical  devices
49	MS IEC 60601: PART 2-18:2007  IEC 60601-2-18:1996 and its Amendment 1:2000, Medical electrical equipment - Part 2-18: Particular requirements for the safety of endoscopic equipment	Medical electrical equipment - Part 2-18: Particular requirements for the safety of endoscopic equipment	16/06/2006  01/09/2006	Anaesthetic/  respiratory  And electromechanical  devices
50	MS IEC 60601: PART 2-19:2007  IEC 60601-2-19:1990 and its Amendment 1:1996, Medical electrical equipment Part 2-19: Particular requirements for safety of baby incubators.	Medical electrical equipment ? Part 2-19: Particular requirements for safety of baby incubators.	16/06/2006  01/09/2006	Anaesthetic/  respiratory  And electromechanical  devices

51	MS IEC 60601: PART 2-20:2007  IEC 60601-2-20:1990, Medical electrical equipment Part 2-20: Particular requirements for safety of transport incubators	Medical electrical equipment Part 2-20: Particular requirements for safety of transport incubators	16/06/2006  01/09/2006	Anaesthetic/ respiratory  And electromechanical devices
52	MS IEC 60601: PART 2-21:2007  IEC 60601-2-21:1994 and its Amendment 1:1996, Medical electrical equipment ? Part 2-21: Particular requirements for safety of infant radiant warmers	Medical electrical equipment ? Part 2-21: Particular requirements for the safety of infant radiant warmers	16/06/2006  01/09/2006	Anaesthetic/ respiratory  And electromechanical devices
53	MS IEC 60601: PART 2-23:2007  IEC 60601-2-23:1999, Medical electrical equipment - Part 2-23: Particular requirements for the safety, including essential performance, of transcutaneous partial pressure monitoring equipment	Medical electrical equipment - Part 2-23: Particular requirements for the safety, including essential performance, of transcutaneous partial pressure monitoring equipment	16/06/2006  01/09/2006	Anaesthetic/ respiratory  And electromechanical devices
54	MS IEC 60601: PART 2-24:2007  IEC 60601-2-24:1998, Medical electrical equipment - Part 2-24: Particular requirements for the safety of infusion pumps and controllers	Medical electrical equipment - Part 2-24: Particular requirements for the safety of infusion pumps and controllers	16/06/2006  01/09/2006	Anaesthetic/ respiratory  And

				electromechanical devices
55	MS IEC 60601: PART 2-25:2007  IEC 60601-2-25:1993, Medical electrical equipment - Part 2-25: Particular requirements for the safety of electrocardiographs	Medical electrical equipment Part 2-25: Particular requirements for the safety of electrocardiographs	16/06/2006  01/09/2006	Anaesthetic/  respiratory  And electromechanical  devices
56	MS IEC 60601: PART 2-26:2007  IEC 60601-2-26:2003, Medical electrical equipment - Part 2-26: Particular requirements for the safety of electroencephalographs	Medical electrical equipment - Part 2-26: Particular requirements for the safety of electroencephalographs	16/06/2006  01/09/2006	Anaesthetic/  respiratory  And electromechanical  devices
57	MS IEC 60601: PART 2-27:2007  IEC 60601-2-27:2005, Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment	Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment	16/06/2006  01/10/2006	Anaesthetic/  respiratory  And electromechanical  devices

58	MS IEC 60601: PART 2-30:2007  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	Medical electrical equipment - Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment	16/06/2006  01/10/2006	Anaesthetic/  respiratory  And electromechanical  devices
59	MS IEC 60601: PART 2-31:2007  IEC 60601-2-31:1994, Medical electrical equipment Part 2-31: Particular requirements for the safety of external cardiac pacemakers with internal power source	Medical electrical equipment Part 2-31: Particular requirements for the safety of external cardiac pacemakers with internal power source	16/06/2006  01/10/2006	Anaesthetic/  respiratory  And electromechanical  devices
60	MS IEC 60601: PART 2-34:2007  IEC 60601-2-34:2005, Medical electrical equipment - Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment	Medical electrical equipment - Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment	16/06/2006  01/10/2006	Anaesthetic/  respiratory  And electromechanical  devices
61	MS IEC 60601: PART 2-35:2007	Medical electrical equipment - Part 2-35: Particular requirements for the	16/06/2006	Anaesthetic/

	IEC 60601-2-35:1996, Medical electrical equipment - Part 2-35: Particular requirements for the safety of blankets, pads and mattresses, intended for heating in medical use	safety of blankets, pads and mattresses, intended for heating in medical use	01/10/2006	respiratory And electromechanical devices
62	MS IEC 60601: PART 2-36:2007  IEC 60601-2-36:1997, Medical electrical equipment Part 2-36: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy	Medical electrical equipment Part 2-36: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy	16/06/2006  01/10/2006	Anaesthetic/ respiratory  And electromechanical devices
63	MS IEC 60601: PART 2-38:2007  IEC 60601-2-38:1996 and its Amendment 1:1999, Medical electrical equipment - Part 2-38: Particular requirements for the safety of electrically operated hospital beds	Medical electrical equipment - Part 2-38: Particular requirements for the safety of electrically operated hospital beds	16/06/2006  01/10/2006	Anaesthetic/ respiratory  And electromechanical devices
64	MS IEC 60601: PART 2-39:2007  IEC 60601-2-39:2003, Medical electrical equipment - Part 2-39: Particular requirements for the safety of peritoneal dialysis equipment	Medical electrical equipment - Part 2-39: Particular requirements for the safety of peritoneal dialysis equipment	16/06/2006  01/10/2006	Anaesthetic/ respiratory  And

				electromechanical devices
65	MS IEC 60601: PART 2-40:2007  IEC 60601-2-40:1998, Medical electrical equipment - Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment	Medical electrical equipment - Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment	16/06/2006  01/10/2006	Anaesthetic/ respiratory  And electromechanical devices
66	MS IEC 60601: PART 2-41:2007  IEC 60601-2-41:2000, 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 the safety of surgical luminaires and luminaires for diagnosis	16/06/2006  01/10/2006	Anaesthetic/ respiratory  And electromechanical devices
67	MS IEC 60601: PART 2-46:2007  IEC 60601-2-46:1998, Medical electrical equipment - Part 2-46: Particular requirements for the safety of operating tables	Medical electrical equipment - Part 2-46: Particular requirements for the safety of operating tables	16/06/2006  01/10/2006	Anaesthetic/ respiratory  And electromechanical devices

68	06R074R0 MS IEC 60601: PART 2-47:2007  IEC 60601-2-47:2001, Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems	Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems	16/06/2006  01/10/2006	Anaesthetic/ respiratory  And electromechanical  devices
69	MS IEC 60601-2-49 : 2007  IEC 60601-2-49:2006, Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment	Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment	16/06/2006  16/06/2006  01/10/2006	Anaesthetic/ respiratory  And electromechanical  devices
70	MS IEC 60601-2-50 : 2007  IEC 60601-2-50:2005, Medical electrical equipment - Part 2-50: Particular requirements for the safety of infant phototherapy equipment	Medical electrical equipment - Part 2-50: Particular requirements for the safety of infant phototherapy equipment	16/06/2006  16/06/2006  01/10/2006	Anaesthetic/ respiratory  And electromechanical  devices
71	MS IEC 60601-2-51 : 2007	Medical electrical equipment - Part 2-51: Particular requirements for safety,	16/06/2006	Anaesthetic/

	IEC 60601-2-51:2005, Medical electrical equipment - Part 2-51: Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs	including essential performance, of recording and analysing single channel and multichannel electrocardiographs	16/06/2006 01/10/2006	respiratory And electromechanical devices
72	MS IEC 60601-3-1 : 2007  IEC 60601-3-1:1996, Medical electrical equipment Part 3-1: Essential performance requirements for transcutaneous oxygen and carbon dioxide partial pressure monitoring equipment	Medical electrical equipment - Part 3-1: Essential performance requirements for transcutaneous oxygen and carbon dioxide partial pressure monitoring equipment	16/06/2006 16/06/2006 01/10/2006	Anaesthetic/ respiratory And electromechanical devices
73	06R043R0  MS IEC 60601: PART 2-8:2007  IEC 60601-2-8, Medical electrical equipment -Part 2-8: Particular requirements for the safety of therapeutic X-ray equipment operating in range 10 kV to 1 MV, The Atomic Energy Licensing Act 1984 (Act 304) and Regulations	Medical electrical Equipment - Part 2-8: Particular requirements for the safety of therapeutic X-ray equipment operating in range 10kV to 1MV (IEC 60601-2-8, IDT)	06/04/2006  01/08/2006	Diagnostic and Therapeutic Radiation
74	MS IEC 60601-2-43:2006  IEC 60601-2-43, Medical electrical equipment - Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures, The Atomic Energy Licensing Act (Act 304) and Regulations		06/04/2006  01/08/2006	Diagnostic and Therapeutic Radiation
	MS IEC 60601-1-3:2006		06/04/2006	Diagnostic and

75	IEC 60601-1-3, Medical electrical equipment - Part 1-3: General requirements for safety - Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment, The Atomic Energy Licensing Act (Act 304) and Regulations		01/08/2006	Therapeutic Radiation
76	MS IEC 60601-2-32:2006 IEC 60601-2-32, Medical electrical equipment - Part 2: Particular requirements for the safety of associated equipment of X-ray equipment, The Atomic Energy Licensing Act (Act 304) and Regulations	Medical electrical equipment - Part 2: Particular requirements for the safety of associated equipment of X-ray equipment	06/04/2006 01/08/2006	Diagnostic and Therapeutic Radiation
77	MS IEC 60601-2-44:2006 IEC 60601-2-44, Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography (with Amendment), The Atomic Energy Licensing Act (Act 304) and Regulations	-	06/04/2006 01/08/2006	Diagnostic and Therapeutic Radiation
78	MS IEC 60601-2-45:2006 IEC 60601-2-45, Medical electrical equipment - Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices, The Atomic Energy Licensing Act (Act 304) and Regulations	Medical electrical equipment - Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices	06/04/2006 01/08/2006	Diagnostic and Therapeutic Radiation
79	MS IEC 60601: PART 2-1:2006 IEC 60601-2-1:1998+A1:2000, Medical Electrical Equipment - Part 2-1: Particular Requirements for the Safety of Electron Accelerators in the Range 1 MeV to 50 MeV, Atomic Energy Licensing Act 1984 (Act 304) and Regulations	Medical Electrical Equipment - Part 2-1: Particular Requirements for the Safety of Electron Accelerators in the Range 1 MeV to 50 MeV	16/06/2006 01/08/2006	Diagnostic and Therapeutic Radiation 13/06/2006
80	MS IEC 60601:PART 2-9:2006	Medical Electrical Equipment - Part 2: Particular Requirements for the Safety	16/06/2006	Diagnostic and Therapeutic

	IEC 601-2-9:1996, Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Patient Contact Dosemeters Used in Radiotherapy with Electrically Connected Radiation Detector, Atomic Energy Licensing Act (Act 304) & Regulations	of Patient Contact Dosemeters Used in Radiotherapy with Electrically Connected Radiation Detector	01/08/2006	Radiation
81	MS IEC 60601 PART 2-11:2006  IEC 60601-2-11:1997+A1:2004, Medical Electrical Equipment Part 2-11: Particular Requirements for the Safety of Gamma Beam Therapy Equipment, Atomic Energy Licensing Act (Act 304) and Regulations	Evaluation and Routine Testing in Medical Imaging Departments ? Part 3-3: Acceptance Tests ? Imaging Performance of X-Ray Equipment for Digital Subtraction Angiography (DSA)	16/06/2006  01/08/2006	Diagnostic and Therapeutic Radiation
82	MS IEC 60601: PART 2-17:2006  IEC 60601-2-17:2005, Medical Electrical Equipment Part 2-17: Particular Requirements for the Safety of Automatically-Controlled Brachytherapy Afterloading Equipment, Atomic Energy Licensing Act (Act 304) and Regulations		16/06/2006  01/08/2006	Diagnostic and Therapeutic Radiation
83	MS IEC 60601: PART 2-29:2007  IEC 60601-2-29:1999, Medical Electrical Equipment Part 2-29: Particular Requirements for the Safety of Radiotherapy Simulators, Atomic Energy Licensing Act (Act 304) and Regulations	Evaluation and Routine Testing in Medical Imaging Departments ? Part 2-7: Constancy Tests ? Equipment for Intra-Oral Dental Radiotherapy Excluding Dental Panoramic Equipment	16/06/2006  01/08/2006	Diagnostic and Therapeutic Radiation
84	MS IEC 61217:2007  IEC 61217:1996+A1:2000, Radiotherapy Equipment ? Coordinates, Movements and Scales, Atomic Energy Licensing Act (Act 304) and Regulations	Radiotherapy Equipment ? Coordinates, Movements and Scales	16/06/2006  01/08/2006	Diagnostic and Therapeutic Radiation  21/07/2006
85	MS IEC 61223: PART 2-10:2007  IEC 61223-2-10:1999, Evaluation and Routine Testing in Medical Imaging	Evaluation and Routine Testing in Medical Imaging Departments ? Part 3-1: Acceptance Tests ? Imaging Performance of X-Ray Equipment for	16/06/2006	Diagnostic and Therapeutic

	Departments ? Part 2-10: Constancy Tests ? X-Ray Equipment for Mammography, Atomic Energy Licensing Act (Act 304) and Regulations	Radiographic and Radioscopic Systems	01/08/2006	Radiation
86	MS IEC 61223: PART 3-3:2007  IEC 1223-3-3:1996, Evaluation and Routine Testing in Medical Imaging Departments Part 3-3: Acceptance Tests ? Imaging Performance of X-Ray Equipment for Digital Subtraction Angiography (DSA), Atomic Energy Licensing Act (Act 304) and Regulations	Evaluation and Routine Testing in Medical Imaging Departments Part 3-2: Acceptance Tests Imaging Performance of Mammographic X-Ray Equipment	16/06/2006  01/08/2006	Diagnostic and Therapeutic Radiation
87	MS IEC 61223: PART 3-4:2007  IEC 61223-3-4:2000, Evaluation and Routine Testing in Medical Imaging Departments ? Part 3-4: Acceptance Tests ? Imaging Performance of Dental X-Ray Equipment, Atomic Energy Licensing Act (Act 304) and Regulations	Evaluation and Routine Testing in Medical Imaging Departments ? Part 3-4: Acceptance Tests ? Imaging Performance of Dental X-Ray Equipment	16/06/2006  01/08/2006	Diagnostic and Therapeutic Radiation
88	MS IEC 61223: PART 3-5:2007  IEC 61223-3-5:2004, Evaluation and Routine Testing in Medical Imaging Departments ? Part 3-5: Acceptance Tests ? Imaging Performance of Computed Tomography X-Ray Equipment, Atomic Energy Licensing Act (Act 304) and Regulations	Evaluation and Routine Testing in Medical Imaging Departments ? Part 3-5: Acceptance Tests ? Imaging Performance of Computed Tomography X-Ray Equipment	16/06/2006  01/08/2006	Diagnostic and Therapeutic Radiation
89	MS IEC 61674:2007  IEC 61674:1997+A1:2002, Medical Electrical Equipment Dosimeters with Ionization Chambers and/or Semi-Conductor Detectors as Used in X-Ray Diagnostic Imaging, Atomic Energy Licensing Act (Act 304) and Regulations	Medical Electrical Equipment ? Dosimeters with Ionization Chambers and/or Semi-Conductor Detectors as Used in X-Ray Diagnostic Imaging	16/06/2006  01/08/2006	Diagnostic and Therapeutic Radiation
90	MS IEC 61223: PART 2-4:2007  IEC 1223-2-4:1994, Evaluation and Routine Testing in Medical Imaging Departments ? Part 2-4: Constancy Tests	Evaluation and Routine Testing in Medical Imaging Departments ? Part 2-4: Constancy Tests ? Hard Copy Cameras	14/07/2006  31/12/2006	Diagnostic and Therapeutic Radiation

	? Hard Copy Cameras, Atomic Energy Licensing Act (Act 304) and Regulations			
91	06R061R0 MS IEC 61223: PART 2-5:2007  IEC 1223-2-5:1994, Evaluation and Routine Testing in Medical Imaging Departments ? Part 2-5: Constancy Tests ? Image Display Devices, Atomic Energy Licensing Act (Act 304) and Regulations	Evaluation and Routine Testing in Medical Imaging Departments ? Part 2-5: Constancy Tests ? Image Display Devices	14/07/2006  31/12/2006	Diagnostic and Therapeutic Radiation
92	MS IEC 61223: PART 2-6:2007  IEC 1223-2-6:1994, Evaluation and Routine Testing in Medical Imaging Departments ? Part 2-6: Constancy Tests ? X-Ray Equipment for Computed Tomography, Atomic Energy Licensing act (Act 304) and Regulations	Evaluation and Routine Testing in Medical Imaging Departments ? Part 2-6: Constancy Tests ? X-Ray Equipment for Computed Tomography	14/07/2006  31/12/2006	Diagnostic and Therapeutic Radiation
93	MS IEC 61223: PART 2-7:2007  IEC 61223-2-7:1999, Evaluation and Routine Testing in Medical Imaging Departments Part 2-7: Constancy Tests Equipment for Intra-Oral Dental Radiotherapy Excluding Dental Panoramic Equipment, Atomic Energy Licensing Act (Act 304) and Regulations	Evaluation and Routine Testing in Medical Imaging Departments – Part 2-7: Constancy Tests – Equipment for Intra-Oral Dental Radiotherapy Excluding Dental Panoramic Equipment	14/07/2006  31/12/2006	Diagnostic and Therapeutic Radiation
94	MS IEC 61223: PART 2-9:2007  IEC 61223-2-9:1999, Evaluation and Routine Testing in Medical Imaging Departments ? Part 2-9: Constancy Tests ? Equipment for Indirect Radioscopy and Indirect Radiography, Atomic Energy Licensing Act (Act 304) and Regulations	Evaluation and Routine Testing in Medical Imaging Departments – Part 2-9: Constancy Tests – Equipment for Indirect Radioscopy and Indirect Radiography	14/07/2006  31/12/2006	Diagnostic and Therapeutic Radiation
95	MS IEC 61223: PART 2-11:2007  IEC 61223-2-11:1999, Evaluation and Routine Testing in Medical Imaging Departments ? Part 2-11: Constancy Tests ? Equipment for General Direct Radiography, Atomic Energy Licensing	Evaluation and Routine Testing in Medical Imaging Departments ? Part 2-11: Constancy Tests ? Equipment for General Direct Radiography	14/07/2006  31/12/2006	Diagnostic and Therapeutic Radiation

	Act (Act 304) and Regulations			
96	MS IEC 61223: PART 3-1:2007  IEC 61223-3-1:1999, Evaluation and Routine Testing in Medical Imaging Departments ? Part 3-1: Acceptance Tests ? Imaging Performance of X-Ray Equipment for Radiographic and Radioscopic Systems, Atomic Energy Licensing Act (Act 304) and Regulations		14/07/2006  31/12/2006	Diagnostic and Therapeutic Radiation
97	MS IEC 61223: PART 3-2:2006  IEC 61223-3-2:1996, Evaluation and Routine Testing in Medical Imaging Departments ? Part 3-2: Acceptance Tests ? Imaging Performance of Mammographic X-Ray Equipment, Atomic Energy Licensing Act (Act 304) and Regulations	Evaluation and Routine Testing in Medical Imaging Departments – Part 3-2: Acceptance Tests – Imaging Performance of Mammographic X-Ray Equipment	14/07/2006  31/12/2006	Diagnostic and Therapeutic Radiation
98	MS IEC 60601: PART 2-7:2007  IEC 60601-2-7, Medical Electrical Equipment - Part 2-7: Particular Requirements for the Safety of High-Voltage Generators of Diagnostic X-ray Generators, Atomic Energy Licensing Act (Act 304) and Regulations	Medical Electrical Equipment - Part 2-7: Particular Requirements for the Safety of High-Voltage Generators of Diagnostic X-ray Generators	14/07/2006  31/12/2006	Diagnostic and Therapeutic Radiation
99	MS IEC 60336 : 2007  IEC 60336:2005, Medical Electrical Equipment - X-ray Tube Assemblies for Medical Diagnosis - Characteristics of Focal Spots	Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Characteristics of focal spots	07/12/2006  26/01/2007  01/04/2007	Diagnostic and Therapeutic Radiation
100	MS IEC 60522 : 2007  IEC 60522:2003, Determination of the Permanent Filtration of X-ray Tube	Determination of the permanent filtration of x-ray tube assemblies	07/12/2006  26/01/2007  01/04/2007	Diagnostic and Therapeutic Radiation

	Assemblies			
101	MS IEC 60526 : 2007  IEC 60526:1978, High-voltage Cable Plug and Socket Connections for Medical X-ray Equipment	High-voltage cable plug and socket connections for medical x-ray equipment	07/12/2006  26/01/2007  01/04/2007	Diagnostic and Therapeutic Radiation
102	MS IEC 60613 : 2007  IEC 60613:1989, Electrical, Thermal and Loading Characteristics of Rotating Anode X-ray Tubes for Medical Diagnosis	Electrical, thermal and loading characteristics of rotating anode x-ray tubes for medical diagnosis	07/12/2006  09/01/2007  01/04/2007	Diagnostic and Therapeutic Radiation
103	MS IEC 60806 : 2007  IEC 60806:1984, Determination of the Maximum Symmetrical Radiation Field from a Rotating Anode X-ray Tube for Medical Diagnosis	Determination of the maximum symmetrical radiation field from a rotating anode x-ray tube for medical diagnosis	07/12/2006  07/12/2006  01/04/2007	Diagnostic and Therapeutic Radiation
104	MS IEC 61676 : 2007  IEC 61676:2002, Medical Electrical Equipment - Dosimetric Instruments Used for Non-invasive Measurement of X-ray Tube Voltage in Diagnostic Radiology	Medical electrical equipment - dosimetric instruments used for non-invasive measurement of x-ray tube voltage in diagnostic radiology	07/12/2006  07/12/2006  01/04/2007	Diagnostic and Therapeutic Radiation
105	MS IEC 61223-1 : 2007  IEC 61223-1:1993, Evaluation and Routine Testing in Medical Imaging Departments - Part 1: General Aspects	Evaluation and routine testing in medical imaging departments - Part 1: General aspects	07/12/2006  07/12/2006  01/04/2007	Diagnostic and Therapeutic Radiation
106	MS IEC 61223-2-1 : 2007  IEC 61223-2-1 1993, Evaluation and Routine Testing in Medical Imaging Departments - Part 2-1: Constancy Tests - Film Processors	Evaluation and routine testing in medical imaging departments - Part 2-1: Constancy tests - Film processors	07/12/2006  07/12/2006  01/04/2007	Diagnostic and Therapeutic Radiation