ISO医疗标准(ISO medical standards)

序号	编号	中文名称	英文名称
1	CISPR 11 AMD 2-2006	工业用,科研用以及医疗用(ISM)射频设备.电磁干扰特性.限值和测量方法.修改件2	Industrial, scientific and medical (ISM) radio-frequency equipment - Electromagnetic disturbance characteristics - Limits and methods of measurement; Amendment 2
2	CISPR 11-2003	工业,科研和医疗(ISM)用射频设备.电磁干扰特性.限值和测量方法.注:本文件及其单独的修正件均与合并版本同时	Industrial, scientific and medical (ISM) radio-frequency equipment - Electromagnetic disturbance characteristics - Limits and methods of measurement / Note: This document and its separate amendments continue to be valid together with the consolidated version * To be replaced by CISPR/B/418/CDV (2006-12), CISPR/B/434/CD (2007-07), CISPR/B/435/CDV (2007-07), CISPR/B/440/CDV (2007-08, t). * To be amended by CISPR/B/324/FDIS (2004-02), CISPR/B/394/FDIS (2006-03),
3	CISPR 28-1997	工业,科学和医疗设备(ISM).国际电信联盟(ITU)指定频段内的辐射电平指南	Industrial, scientific and medical equipment (ISM) - Guidelines for emission levels within the bands designated by the ITU
4	IEC 60336 Corrigendum 1-2006	医用电气设备.医疗诊断用X射线管组件.焦点特性.勘误1	Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Characteristics of focal spots; Corrigendum 1
5	IEC 60336-2005	医疗电气设备.医疗诊断用X射线管组件.焦点的特性	Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Characteristics of focal spots
6	IEC 60364-7-710-2002	建筑物的电气设施.第7-710部分:特殊设施或场所的要求.医疗场所	Electrical installations of buildings - Part 7-710: Requirements for special installations or locations; Medical locations
7	IEC 60601-1 Corrigendum 1-2006	医疗电气设备.第1部分:基本安全和实用性的一般要求.技术勘误1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance; Corrigendum 1
8	IEC 60601-1 Interpretation Sheet 1-	医疗电气设备.第1部分:基本安全和重要性能的一般要求	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
9	IEC 60601-1 Interpretation Sheet 2-	医疗电气设备.第1部分:基本安全和基本性能的通用要求.解释清单2	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Interpretation sheet 2
10	IEC 60601-1-11-2010	医疗电气设备.第1-11部分:基本安全和重要性能的一般要求.附属标准:家庭保健用医疗电气设备和医疗电气系统的	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
11	IEC 60601-1-4-1996	医疗电气设备.第1部分:安全的一般要求.第4节:对照标准:程序控制的电气医疗系统	Medical electrical equipment - Part 1: General requirements for safety - 4. Collateral standard: Programmable electrical medical systems
12	IEC 60601-1-4-2000	医疗用电气设备.第1-4部分:一般安全性要求.并行标准:可编程电气医疗系统	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems
13	IEC 60601-1-8-2006	医用电气设备.第1-8部分:基本安全和基本性能通用要求.汇编标准:医疗电气设备和医疗电气系统中警报系统的一	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
14	IEC 60601-1-9-2007	医疗电气设备.第1-9部分:基本安全和重要性能的一般要求.附属标准:环境意识设计的要求	Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design
15	IEC 60601-2-13 Edition 3.1-2009	医疗电气设备.第2-13部分:麻醉系统安全性的特殊要求	Medical electrical equipment - Part 2-13: Particular requirements for the safety of anaesthetic systems
16	IEC 60601-2-18-2009	医疗电气设备.第2-18部分:内窥镜设备基本安全和主要性能的特殊要求	Medical electrical equipment - Part 2-18: Particular requirements for basic safety and essential performance of endoscopic equipment
17	IEC 60601-2-22-2007	医疗电气设备.第2-22部分:外科、整容、治疗和诊断用激光设备基本安全和基本性能的特殊要求	Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
18	IEC 60601-2-28-2010	医用电气设备.第2-28部分:医疗诊断用X射线管组件的基本安全和基本性能用特殊要求	Medical electrical equipment - Part 2-28: Particular requirements for basic safety and essential performance of X-ray tube assemblies for medical
19	IEC 60601-2-29-2008	医疗电气设备.第2-29部分:放射疗法模拟器的基本安全和重要性能的特殊要求	Medical electrical equipment - Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators
20	IEC 60601-2-33-2010	医用电气设备.第2-33部分:医疗诊断用磁共振设备的基本安全和基本性能用特殊要求	Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis
21	IEC 60601-2-37-2007	医疗电气设备.第2-37部分:超声波医疗诊断和监测设备的基本安全和基本性能用特殊要求	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
22	IEC 60601-2-41-2009	医疗电气设备.第2-41部分:诊断用手术照明和灯具的基本安全和基本性能的特殊要求	Medical electrical equipment - Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for
23	IEC 60601-2-50-2009	医疗电气设备.第2-50部分:婴儿光线疗法设备的基本安全及重要性能用特殊要求	Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment
24	IEC 60601-2-52-2009	医疗电气设备.第2-52部分:医用病床的基本安全及基本性能的详细要求	Medical electrical equipment - Part 2-52: Particular requirements for basic safety and essential performance of medical beds
25	IEC 60601-2-8-1987	医疗电气设备.第2部分:治疗用X射线发生器安全的特殊要求	Medical electrical equipment. Part 2 : Particular requirements for the safety of therapeutic X-ray generators
26	IEC 60613-2010	医疗诊断用X射线管组件的电气和负载特性	Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis
27	IEC 60789 Corrigendum 1-2009	医疗电气设备.放射性核素成象装置的特性和试验条件.安格型伽马射线照相机.勘误表1	Medical electrical equipment - Characteristics and test conditions of radionuclide imaging devices - Anger type gamma cameras; Corrigendum
28	IEC 60806-1984	医疗诊断旋转阳极X射线管最大对称辐射场的测定	Determination of the maximum symmetrical radiation field from a rotating anode X-ray tube for medical diagnosis
29	IEC 61010-2-040-2005	测量、控制和实验室用电气设备的安全要求.第2-040部分:处理医疗材料用灭菌器和清洗消毒器的特殊要求	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials
30	IEC 61010-2-101-2002	测量、控制和实验室用电气设备的安全要求.第2-101部分:实验室诊断(IVD)医疗设备的特殊要求	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
31	IEC 61157 Corrigendum 1-2008	医疗诊断超声波设备的声输出报告用标准方法.技术勘误1	Standard means for the reporting of the acoustic output of medical diagnostic ultrasonic equipment; Corrigendum 1
32	IEC 61157-2007	医疗诊断超声波设备声输出的报告用标准方法	Standard means for the reporting of the acoustic output of medical diagnostic ultrasonic equipment
33	IEC 61223-3-5 Corrigendum 1-2006	医疗成像部门的评价和常规检验.第3-5部分:验收试验.计算机断层摄影X射线设备的成像性能.勘误1	Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance tests - Imaging performance of computed tomography X-ray equipment; Corrigendum 1
34	IEC 61326-2-6 Corrigendum 1-2007	测量、控制和实验室用电气设备.电磁兼容性(EMC)要求.第2-6部分:特殊要求.体外诊断(IVD)医疗设备.技术勘误1	Electrical equipment for measurement, control and laboratory use, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In-vitro diagnostic (IVD) medical equipment; Corrigendum 1

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35	IEC 61326-2-6-2005	测量、控制和实验室用电气设备.电磁兼容性要求.第2-6部分:特殊要求.实验室条件下诊断（IVD)医疗设备	Electrical equipment for measurement, control and laboratory use, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In-vitro diagnostic (IVD) medical equipment
36	IEC 61558-2-15-1999	电力变压器、电源装置及类似设备的安全 第2-15部分:医疗场所供电用隔离变压器的特殊要求	Safety of power transformers, power supply units and similar - Part 2-15: Particular requirements for isolating transformers for the supply of medical locations
37	IEC 61676 Edition 1.1-2009	医疗电气设备.在放射诊断中X射线管电压的无伤害性测量用剂量测定仪器	Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology
38	IEC 62127-1 Corrigendum 1-2008	超音波学.水听器.第1部分:频率小于40 MHz的医疗超声波场的测量和特性.技术勘误1	Ultrasonics - Hydrophones - Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz; Corrigendum 1
39	IEC 62220-1-2-2007	医疗电气设备.数字X射线成像装置的特性.第1-2部分:侦探量子效率的测定.X射线测定法用探测器	Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-2: Determination of the detective quantum efficiency - Detectors used in mammography
40	IEC 62220-1-3-2008	医疗电气设备.数字X射线成像装置的特性.第1-3部分:探测量子效率的测定.动态成像用探测器	Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-3: Determination of the detective quantum efficiency - Detectors used in dynamic imaging
41	IEC 62274-2005	医疗电气设备.放射疗法记录和检定系统的安全	Medical electrical equipment - Safety of radiotheraphy record and verify
42	IEC 62304-2006	医疗器械用软件.软件寿命过程	Medical device software - Software life cycle processes
43	IEC 62353-2007	医疗电气设备.医疗电气设备的循环试验和维修后试验	Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment
44	IEC 62359-2006	超声波.声场特性.测定与医疗诊断超声场相关的热和机械指数的试验方法	Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic
45	IEC 62366-2007	医疗设备.医疗设备可用性工程的应用	Medical devices - Application of usability engineering to medical devices
46	IEC 62464-1-2007	医疗成象磁共振设备.第1部分:测定实际成象质量参数	Magnetic resonance equipment for medical imaging - Part 1: Determination of essential image quality parameters
47	IEC 62494-1-2008	医疗电气设备.数字X射线成像系统的曝光指数.第1部分:通用X射线照相术的定义和要求	Medical electrical equipment - Exposure index of digital X-ray imaging systems - Part 1: Definition and requirements of general radiography
48	IEC 62563-1-2009	医疗电气设备.医学图像显示系统.第1部分:评价方法	Medical electrical equipment - Medical image display systems - Part 1: Evaluation methods
49	IEC 80601-2-30-2009	医疗电气设备.第2-30部分:自动非入侵式血压测量计的基本安全和基本性能用特殊要求	Medical electrical equipment - Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive
50	IEC 80601-2-35-2009	医疗电气设备.第2-35部分:应用于加热的毛毯,衬垫或床垫及医用加热装置基本安全性及基本性能的详细规范	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
51	IEC 80601-2-58-2008	医疗电气设备.第2-58部分:眼科手术用晶状体移除装置和玻璃体切除装置基本安全和重要性能的特殊要求	Medical electrical equipment - Part 2-58: Particular requirements for basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery
52	IEC 80601-2-59 Corrigendum 1-2009	医疗电气设备.第2-59部分:人类发热检查用检查温度记录仪的基本安全和基本性能用特殊要求	Medical electrical equipment - Part 2-59: Particular requirements for basic safety and essential performance of screening thermographs for human febrile temperature screening; Corrigendum 1
53	IEC 80601-2-59-2008	医疗电气设备.第2-59部分:人类发热检查用检查温度记录仪的基本安全和基本性能用特殊要求	Medical electrical equipment - Part 2-59: Particular requirements for basic safety and essential performance of screening thermographs for human febrile temperature screening
54	IEC/PAS 61910-1-2007	医疗用电气设备.辐照剂量文件.第1部分:射线照相和射线透视用设备	Medical electrical equipment - Radiation dose documentation - Part 1: Equipment for radiography and radioscopy
55	IEC/TR 60788-2004	医疗电气设备.定义的术语汇编	Medical electrical equipment - Glossary of defined terms
56	IEC/TR 60878-2003	医疗规程中电气设备的图形符号	Graphical symbols for electrical equipment in medical practice
57	IEC/TR 60930-2008	管理、医疗、护理人员安全使用医疗电气设备和医疗电气系统用指南	Guidelines for administrative, medical, and nursing staff concerned with the safe use of medical electrical equipment and medical electrical systems
58	IEC/TR 61258-2008	医疗电气设备教材的开发和使用指南	Guidelines for the development and use of medical electrical equipment educational materials
59	IEC/TR 61948-1-2001	核医疗设备 常规试验 第1部分：辐射计数系统	Nuclear medicine instrumentation - Routine tests - Part 1: Radiation counting systems
60	IEC/TR 61948-2-2001	核医疗设备 常规试验 第2部分：闪烁照相机与单光子发射计算机子X射线断层成像	Nuclear medicine instrumentation - Routine tests - Part 2: Scintillation cameras and single photon emission computed tomography imaging
61	IEC/TR 61948-3-2005	核医疗设备.常规试验.第3部分:正电子放射断层摄影	Nuclear medicine instrumentation - Routine tests - Part 3: Positron emission tomographs
62	IEC/TR 61948-4-2006	核医疗设备.常规试验.第4部分:放射性核素校准器	Nuclear medicine instrumentation - Routine tests - Part 4: Radionuclide calibrators
63	IEC/TR 62266-2002	医疗电气设备.放射疗法中DICOM的实现指南	Medical electrical equipment - Guidelines for implementation of DICOM in radiotherapy
64	IEC/TR 62354-2009	医疗电气设备的一般试验规程	General testing procedures for medical electrical equipment
65	IEC/TR 80002-1-2009	医疗设备软件.第1部分:用于医疗设备软件的ISO 14971 应用指南	Medical device software - Part 1: Guidance on the application of ISO 14971 to medical device software
66	ISO 10079-1-1999	医疗吸引设备 第1部分:电动吸引设备 安全要求	Medical suction equipment - Part 1: Electrically powered suction equipment - Safety requirements
67	ISO 10079-2-1999	医疗吸引设备 第2部分:手动吸引设备	Medical suction equipment - Part 2: Manually powered suction equipment
68	ISO 10079-3-1999	医疗吸引设备 第3部分:真空或用压力驱动吸引设备	Medical suction equipment - Part 3: Suction equipment powered from a vacuum or pressure source
69	ISO 10524-4-2008	医疗气体用压力调节器.第4部分:低压调节器	Pressure regulators for use with medical gases - Part 4: Low-pressure
70	ISO 10993-1 Technical Corrigendum 1-2010	医疗器械的生物评定.第1部分:风险管理过程内的试验和评定.技术勘误表1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process; Technical Corrigendum 1
71	ISO 10993-1-2009	医疗器械的生物学评价.第1部分:在风险管理过程内的评价与试验	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
72	ISO 10993-10 AMD 1-2006	医疗器械的生物评定.第10部分:刺激与持续型过敏症试验	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity; Amendment 1
73	ISO 10993-10-2002	医疗器械的生物评定.第10部分:刺激与持续型过敏症试验	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
74	ISO 10993-11-2006	医疗器械的生物学评价.第11部分:身体组织毒性试验	Biological evaluation of medical devices - Part 11: Tests for systemic
75	ISO 10993-12-2007	医疗器械的生物学评估.第12部分:样品制备和参考材料	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
76	ISO 10993-13-2010	医疗器械的生物学评价.第13部分:聚合物医疗器械降解产物的鉴定与定量	Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices
77	ISO 10993-14-2001	医疗器械的生物学评价 第14部分：陶瓷降解产物的识别和量化	Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics

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78	ISO 10993-15-2000	医疗器械的生物学评价 第15部分:金属与合金降解产物的识别与定性	Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys
79	ISO 10993-16-2010	医疗器械的生物学评估.第16部分:降解产物和可滤取物的毒物动力学研究设计	Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables
80	ISO 10993-17-2002	医疗器械的生物评定.第17部分:可浸出物质容许限值的确定	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances
81	ISO 10993-18-2005	医疗器械的生物学评价.第18部分:材料的化学特性	Biological evaluation of medical devices - Part 18: Chemical characterization of materials
82	ISO 10993-2-2006	医疗器械的生物学评价.第2部分:动物保护要求	Biological evaluation of medical devices - Part 2: Animal welfare
83	ISO 10993-3-2003	医疗器械的生物评定.第3部分:遗传毒性、致癌性和生殖毒性的试验	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
84	ISO 10993-4 AMD 1-2006	医疗器械的生物评定.第4部分:与血液相互作用的选择试验	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
85	ISO 10993-4-2002	医疗器械的生物评定.第4部分:与血液相互作用的试验的选择	Biological evaluation of medical devices - Part 4: Selection of test for interactions with blood
86	ISO 10993-5-2009	医疗器械的生物学评价.第5部分:体外细胞毒性试验	Biological evaluation of medical devices - Part 5: Tests for in vitro
87	ISO 10993-7 Technical Corrigendum 1-2009	医疗器械的生物学评价.第7部分:环氧乙烷灭菌残留物.勘误表1	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals; Technical Corrigendum 1
88	ISO 10993-7-2008	医疗器械的生物学评价 第7部分:环氧乙烷灭菌残留量	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
89	ISO 11073-90101-2008	健康信息学.床旁监护用医疗装置通信.第90101部分:分析仪器.床旁监护试验	Health informatics - Point-of-care medical device communication - Part 90101: Analytical instruments - Point-of-care test
90	ISO 11135-1-2007	卫生保健品灭菌.环氧乙烷.第1部分:医疗设备消毒过程的制定、确认和常规控制的要求	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
91	ISO 11137-1-2006	保健产品的灭菌.辐射.第1部分:医疗器件消毒过程的制定、确认、和常规控制的要求	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
92	ISO 11138-1-2006	医疗保健产品灭菌.生物指示物.第1部分:一般要求	Sterilization of health care products - Biological indicators - Part 1: General requirements
93	ISO 11138-2-2006	医疗保健产品灭菌.生物指示物.第2部分:环氧乙烷灭菌同生物指示剂	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes
94	ISO 11138-3-2006	医疗保健产品灭菌.生物指示物.第3部分:湿热灭菌用生物指示剂	Sterilization of health care products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes
95	ISO 11138-4-2006	医疗保健产品灭菌.生物指示器.第4部分:干热灭菌处理用生物指示器	Sterilization of health care products - Biological indicators - Part 4: Biological indicators for dry heat sterilization processes
96	ISO 11138-5-2006	医疗保健产品灭菌.生物指示器.第5部分:低温蒸汽和甲醛溶液灭菌处理用生物指示器	Sterilization of health care products - Biological indicators - Part 5: Biological indicators for low-temperature steam and formaldehyde
97	ISO 11737-1 Technical Corrigendum 1-2007	医疗设备灭菌.微生物法.第1部分:产品上微生物群落的测定.技术勘误1	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products; Technical Corrigendum 1
98	ISO 11737-1-2006	医疗器械灭菌.微生物学方法.第1部分:产品上微生物群落的测定	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
99	ISO 11737-2-2009	医疗器械灭菌.微生物学方法.第2部分:灭菌过程的定义、有效性和维护中进行的无菌试验	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
100	ISO 12894-2001	热环境的人类工效学 对暴露在极热或极冷环境的人的医疗监督	Ergonomics of the thermal environment - Medical supervision of individuals exposed to extreme hot or cold environments
101	ISO 13408-1-2008	医疗保健产品的无菌加工.第1部分:一般要求	Aseptic processing of health care products - Part 1: General requirements
102	ISO 13408-2-2003	医疗保健产品的无菌加工.第2部分:过滤	Aseptic processing of health care products - Part 2: Filtration
103	ISO 13485 Technical Corrigendum 1-2009	医疗器械.质量管理体系.管理用途的要求,技术勘误表1	Medical devices - Quality management systems - Requirements for regulatory purposes; Technical Corrigendum 1
104	ISO 13485-2003	医疗器械.质量管理系统.管理目标的要求	Medical devices - Quality management systems - Requirements for regulatory purposes
105	ISO 13606-1-2008	医疗信息学.电子健康记录信息.第1部分:参考模型	Health informatics - Electronic health record communication - Part 1: Reference model
106	ISO 13606-2-2008	医疗信息学.电子健康记录信息.第2部分:原型交换规范	Health informatics - Electronic health record communication - Part 2: Archetype interchange specification
107	ISO 13606-3-2009	医疗信息学.电子健康记录通信.第3部分:参考原型和术语清单	Health informatics - Electronic health record communication - Part 3: Reference archetypes and term lists
108	ISO 13606-5-2010	医疗信息学.电子健康记录通信.第5部分:接口规范	Health informatics - Electronic health record communication - Part 5: Interface specification
109	ISO 14155-1-2003	人用医疗设备的临床调查.第1部分:一般要求	Clinical investigation of medical devices for human subjects - Part 1: General requirements
110	ISO 14155-2-2003	医学受验者用医疗器械的临床调查.第2部分:临床调查设备	Clinical investigation of medical devices for human subjects - Part 2: Clinical investigation plants
111	ISO 14160-1998	使用液体化学灭菌剂对包括动物源材料在内的一次性使用医疗器具进行灭菌的确认和常规控制	Sterilization of single-use medical devices incorporating materials of animal origin - Validation and routine control of sterilization by liquid
112	ISO 14161-2009	医疗保健产品灭菌.生物指示物选择,使用及检验结果判断指南	Sterilization of health care products - Biological indicators - Guidance for the selection, use and interpretation of results
113	ISO 14708-1-2000	外科植入物.有源可植入医疗装置.第1部分:安全、标记及制造商提供信息的一般要求	Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
114	ISO 14708-2-2005	外科植入物.有源可植入医疗装置.第2部分:心脏起搏器	Implants for surgery - Active implantable medical devices - Part 2: Cardiac pacemakers
115	ISO 14708-4-2008	外科植入物.有源可植入医疗装置.第4部分:可植入输注管	Implants for surgery - Active implantable medical devices - Part 4: Implantable infusion pumps
116	ISO 14708-5-2010	外科植入物.有源可植入医疗装置.第5部分:循环支撑装置	Implants for surgery - Active implantable medical devices - Part 5: Circulatory support devices
117	ISO 14708-6-2010	外科植入物.有源可植入医疗装置.第6部分:用于治疗快速性心律失常(包括可植入去纤颤器)有源植入式医疗器件的	Implants for surgery - Active implantable medical devices - Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)
118	ISO 14937-2009	保健产品灭菌.医疗器械用消毒剂的特性和消毒方法的研发,验证及常规控制的一般要求	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
119	ISO 14971-2007	医疗装置.医疗装置风险管理的应用	Medical devices - Application of risk management to medical devices

ISO医疗标准(ISO medical standards)

序号	编号	中文名称	英文名称
120	ISO 15002-2008	医疗气体管道系统连接到终端装置用流量计测量装置	Flow-metering devices for connection to terminal units of medical gas pipeline systems
121	ISO 15193-2009	体外诊断医疗器械.生物起源样品中数量的测量.内容要求和参考测量法的说明	In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for content and presentation of reference measurement procedures
122	ISO 15194-2009	体外诊断医疗设备.生物原始试样数量测量.认证参考材料和证明文件的内容要求	In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for certified reference materials and the content of supporting documentation
123	ISO 15198-2004	临床实验室药物.体外诊断医疗设备.由制造商证实的用户质量控制程序	Clinical laboratory medicine - In vitro diagnostic medical devices - Validation of user quality control procedures by the manufacturer
124	ISO 15223 AMD 1-2002	医疗装置.与医疗装置标签、加标签和提供的信息一起使用的符号.修改件1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied; Amendment 1
125	ISO 15223 AMD 2-2004	医疗器械.用于医疗器械标签、作标记和提供信息的符号.修改件2	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied; Amendment 2
126	ISO 15223-1 AMD 1-2008	医疗器械.用于医疗器械标签、标记和提供信息的符号.第1部分:一般要求.修改件1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements;
127	ISO 15223-1-2007	医疗器械.用于医疗器械标签、作标记和提供信息的符号.第1部分:一般要求	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
128	ISO 15223-2-2010	医疗器械.用于医疗器械标签、作标记和提供信息的符号.第2部分:符号的制定、筛选和批准	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 2: Symbol development, selection and validation
129	ISO 15225-2010	医疗设备.质量管理.医疗设备命名法数据结构	Medical devices - Quality management - Medical device nomenclature data structure
130	ISO 16428-2005	外科植入物.可植入物质和医疗器械的静态和动态腐蚀试验用试验溶液和环境条件	Implants for surgery - Test solutions and environmental conditions for static and dynamic corrosion tests on implantable materials and medical
131	ISO 16429-2004	外科植入物.金属可植入材料和长期医疗器械的评估腐蚀性能用断路电位的测量	Implants for surgery - Measurements of open-circuit potential to assess corrosion behaviour of metallic implantable materials and medical devices over extended time periods
132	ISO 17090-1-2008	医疗信息学.公开密钥基础设施.第1部分:数字证书业务综述	Health informatics - Public key infrastructure - Part 1: Overview of digital certificate services
133	ISO 17090-3-2008	医疗信息学.公开密钥基础设施.第3部分:认证管理机构的政策管理	Health informatics - Public key infrastructure - Part 3: Policy management of certification authority
134	ISO 17511-2003	体外诊断医疗装置.生物试样的定量测量.校准仪和控制材料赋值的计量溯源性	In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials
135	ISO 17593-2007	临床实验室测试和体外医疗装置.口服抗凝血剂治疗自测用体外监测系统的要求	Clinical laboratory testing and in vitro medical devices - Requirements for in vitro monitoring systems for self-testing of oral anticoagulant therapy
136	ISO 17664-2004	医疗器械的消毒.生产商提供的可重复消毒医疗器械的处理信息	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices
137	ISO 17665-1-2006	保健产品的灭菌.湿热.第1部分:医疗机械消毒过程的制定、确认和常规控制的要求	Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
138	ISO 18104-2003	医疗信息.护理用参考术语模式的综合	Health informatics - Integration of a reference terminology model for
139	ISO 18113-1-2009	体外诊断医疗器械.制造商提供的信息(标签).第1部分:术语、定义和一般要求	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general
140	ISO 18113-2-2009	体外诊断医疗器械.制造商提供的信息(标签).第2部分:专业用途的体外诊断试剂	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for
141	ISO 18113-3-2009	体外诊断医疗器械.制造商提供的信息(标签).第3部分:专业用体外诊断仪器	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for
142	ISO 18113-4-2009	体外诊断医疗器械.制造商提供的信息(标签).第4部分:自测用体外诊断剂	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 4: In vitro diagnostic reagents for self-
143	ISO 18113-5-2009	体外诊断医疗器械.制造商提供的信息(标签).第5部分:自测用体外诊断仪器	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 5: In vitro diagnostic instruments for self-
144	ISO 18153-2003	体外诊断医疗装置.生物样品的定量测量.校准仪和控制材料所赋酶的催化浓度值的计量溯源性	In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values for catalytic concentration of enzymes assigned calibrators and control materials
145	ISO 18779-2005	储存氧气和氧气混合物的医疗设备.特殊要求	Medical devices for conserving oxygen and oxygen mixtures - Particular requirements
146	ISO 18812-2003	医疗信息学.医用分析仪与实验室信息系统的接口.使用说明文件	Health informatics - Clinical analyser interfaces to laboratory information systems - Use profiles
147	ISO 19001-2002	实验室诊断医疗设备.生物着色用实验室诊断试剂生产厂商提供的信息	In vitro diagnostic medical devices - Information supplied by the manufacturer with in vitro diagnostic reagents for staining in biology
148	ISO 19054-2005	医疗设备辅助用轨道系统	Rail systems for supporting medical equipment
149	ISO 21171-2006	医疗专用手套.可移动表面粉末的测定	Medical gloves - Determination of removable surface powder
150	ISO 21549-5-2008	医疗信息学.病人医疗卡数据.第5部分:识别数据	Health informatics - Patient healthcard data - Part 5: Identification data
151	ISO 21549-6-2008	医疗信息学.病人医疗卡数据.第6部分:管理数据	Health informatics - Patient healthcard data - Part 6: Administrative data
152	ISO 21647 Technical Corrigendum 1-2005	医疗电气设备.呼吸气监测器的基本安全和主要性能的特殊要求.技术勘误1	Medical electrical equipment - Particular requirements for the basic safety and essential performance of respiratory gas monitors; Technical
153	ISO 21647-2004	医疗电气设备.呼吸气监测器的基本安全和主要性能的特殊要求	Medical electrical equipment - Particular requirements for the basic safety and essential performance of respiratory gas monitors
154	ISO 21969-2009	与医疗气体系统一起使用的高压柔性连接	High-pressure flexible connections for use with medical gas systems
155	ISO 22442-1-2007	医疗设备用动物组织及其衍生物.第1部分:风险管理的应用	Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management
156	ISO 22442-2-2007	医疗设备用动物组织及其衍生物.第2部分:来源控制、采集和处理	Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling
157	ISO 22442-3-2007	医疗设备用动物组织及其衍生物.第3部分:病毒和传染性海绵状脑病(TSE)试剂的销毁和/或失效的确认	Medical devices utilizing animal tissues and their derivatives - Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents
158	ISO 22609-2004	传染试剂防护服.医疗面罩.防人造血渗透的试验方法(固定容积,水平喷射)	Clothing for protection against infectious agents - Medical face masks - Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)
159	ISO 25424-2009	医疗器械的消毒.低温蒸汽和甲醛.医疗器械消毒工序的制订,认证和日常控制要求	Sterilization of medical devices - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices
160	ISO 27186-2010	有源可植入医疗器械.可植入心节律管理装置用四极连接器系统.尺寸和试验要求	Space systems - Programme management - Quality assurance requirements

ISO医疗标准(ISO medical standards)

序号	编号	中文名称	英文名称
161	ISO 28620-2010	医疗设备.非电驱动的便携式输液设备	Medical devices - Non-electrically driven portable infusion devices
162	ISO 594-1-1986	注射器、针头及其他医疗器械为6%(鲁尔)的锥形接头 第1部分:一般要求	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment; Part 1 : General requirements
163	ISO 594-2-1998	注射器、针头及其他医疗器械为6%(鲁尔)的锥形接头 第2部分:锁紧接头	Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings
164	ISO 7396-1 AMD 1-2010	医用气体管道系统.第1部分:压缩的医用气体和真空用管道系统.修改件1:装配于操作者可调部件医疗补给装置和连	Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum - Amendment 1: Requirements for terminal units for vacuum fitted on medical supply units with operator-adjustable portions and connected to the pipeline through flexible hoses
165	ISO 7405-2008	牙科学.牙科医疗器械生物相容性评估	Dentistry - Evaluation of biocompatibility of medical devices used in
166	ISO 80601-2-56-2009	医疗电气设备.第2-56部分:人体体温测量用体温计的基本安全和主要性能的特殊要求	Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
167	ISO 8600-2-2002	光学和光学仪器.医疗内窥镜和内窥镜附件.第2部分:硬支气管内窥镜的特殊要求	Optics and optical instruments - Medical endoscopes and endoscopic accessories - Part 2: Particular requirements for rigid bronchoscopes
168	ISO 9626 AMD 1-2001	供制造医疗器械用的不锈钢针管 修改1	Stainless steel needle tubing for the manufacture of medical devices; Amendment 1
169	ISO 9626-1991	供制造医疗器械用的不锈钢针管	Stainless steel needle tubing for manufacture of medical devices
170	ISO/HL7 27931-2009	数据交换标准.HL7标准2.5版本.在医疗环境下电子数据交换的应用协议	Data Exchange Standards - Health Level Seven Version 2.5 - An application protocol for electronic data exchange in healthcare environments
171	ISO/IEC Guide 63-1999	医疗器械安全方面的开发并纳入国际标准指南	Guide to the development and inclusion of safety aspects in International Standards for medical devices
172	ISO/IEEE 11073-10101-2004	健康信息学.床旁检测医疗设备通信.第10101部分:术语	Health informatics - Point-of-care medical device communication - Part 10101: Nomenclature
173	ISO/IEEE 11073-10201-2004	健康信息学.床旁检测医疗设备通信.第10201部分:域信息模式	Health informatics - Point-of-care medical device communication - Part 10201: Domain information model
174	ISO/IEEE 11073-10471-2010	保健信息学.床边体外诊断(POC)医疗设备通信.第10471部分:设备规范.独立的现场动态指示器集线器	Health informatics - Point-of-care medical device communication - Part 10471: Device specialization - Independant living activity hub
175	ISO/IEEE 11073-20101-2004	健康信息学.床旁检测医疗设备通信.第20101部分:应用轮廓.基本标准	Health informatics - Point-of care medical device communications - Part 20101: Application profiles; Base standard
176	ISO/IEEE 11073-30200-2004	健康信息学.床旁检测医疗设备通信.第30200部分:传输轮廓.电缆连接	Health informatics - Point-of-care medical device communications - Part 30200: Transport profile; Cable connected
177	ISO/IEEE 11073-30300-2004	健康信息学.床旁检测医疗设备通信.第30300部分:传输轮廓.红外无线	Health informatics - Point-of-care medical device communications - Part 30300: Transport profile; Infrared wireless
178	ISO/TR 11633-1-2009	卫生信息学.医疗设备及医疗信息系统的远程维护用信息安全管理.第1部分:要求和风险分析	Health informatics - Information security management for remote maintenance of medical devices and medical information systems - Part 1: Requirements and risk analysis
179	ISO/TR 13154-2009	医疗电气设备.筛选温度计用鉴定发热人群用部署、实施和操作指南	Medical electrical equipment - Deployment, implementation and operational guidelines for indentifying febrile humans using a screening
180	ISO/TR 14969-2004	医疗装置.质量管理系统.ISO 13485-2003应用指南	Medical devices - Quality mangement systems - Guidance on the application of ISO 13485: 2003
181	ISO/TR 16056-1-2004	医疗信息学.远程医疗系统和网络的交替使用性.第1部分:介绍和定义	Health informatics - Interoperability of telehealth systems and networks - Part 1: Introduction and definitions
182	ISO/TR 16056-2-2004	医疗信息学.远程医疗系统和网络的交替使用性.第2部分:实时系统	Health informatics - Interoperability of telehealth systems and networks - Part 2: Real-time systems
183	ISO/TR 16142-2006	医疗器械.医疗器械安全和性能公认基本原则的配套标准选用指南	Medical devices - Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical
184	ISO/TR 21089-2004	医疗信息学.可信端到端信息流	Health informatics - Trusted end-to-end information flows
185	ISO/TR 21730-2007	医疗信息.保健设施中移动无线通信和计算技术应用.推荐关于医疗设备电磁兼容性应用(被动电磁兼容性干扰管理)	Health informatics - Use of mobile wireless communication and computing technology in healthcare facilities - Recommendations for electromagnetic compatibility (management of unintentional electromagnetic interference) with medical devices
186	ISO/TR 25257-2009	健康信息学.医疗产品国际代码系统的业务要求	Health informatics - Business requirements for an international coding system for medicinal products
187	ISO/TS 10993-19-2006	医疗设备的生物评定.第19部分:材料的物理化学、形态学和地形学特点	Biological evaluation of medical devices - Part 19: Physico-chemical, morphological and topographical characterization of materials
188	ISO/TS 10993-20-2006	医疗设备的生物评定.第20部分:医疗设备的免疫毒物学试验的原则和方法	Biological evaluation of medical devices - Part 20: Principles and methods for immunotoxicology testing of medical devices
189	ISO/TS 11073-92001-	健康信息学.医疗波形格式.第92001部分:编码规则	Health informatics - Medical waveform format - Part 92001: Encoding rules
190	ISO/TS 16058-2004	医疗信息学.远程学习系统的交替使用性	Health informatics - Interoperability of telelearning systems
191	ISO/TS 18308-2004	医疗信息学.电子病历体系结构要求	Health informatics - Requirements for an electronic health record
192	ISO/TS 19218-2005	医疗设备.不良反应的类型和起因的编码体系	Medical devices - Coding structure for adverse event type and cause
序号	编号	中文名称	英文名称