

美国医疗标准(ANSI medical standards)

序号	编号	中文名称	英文名称
1	ANSI INCITS284-1997	信息技术.识别卡.医疗保健识别卡	Information Technology - Identification Cards - Health Care Identification Cards
2	ANSI IT2.41-1997	摄影.医疗放射照相不用屏蔽/胶片系统的感光测定.第1部分:感光曲线形状、速度和平均梯度的测定ANSI/ISO 9236	Photography - Sensitometry of Screen/Film Systems for Medical Radiography - Part 1: Determination of Sensitometric Curve Shape, Speed and Average Gradient ANSI/ISO
3	ANSI N42.17B-1989	健康医疗仪器的性能规范.职业性的空气中放射性物质的监控仪器	Performance Specifications for Health Physics Instrumentation - Occupational Airborne Radioactivity Monitoring Instrumentation
4	ANSI N42.17C-1989	健康医疗仪器的性能规范.极端环境下使用的便携式仪器	Radiation Instrumentation - Performance Specifications for Health Physics Instrumentation - Portable Instrumentation for Use in Extreme Environmental Conditions
5	ANSI N43.3-2008	一般辐射安全.用于非医疗的X射线和密封γ射线源辐射安全能量小于10Mev(兆电子伏特)的装置	General Radiation Safety - Installations Using Non-Medical X-Ray and Sealed Gamma-Ray Sources, Energies Up to 10 MeV
6	ANSI P1073.1.1.1/D08-2003	健康信息学用标准草案.床旁检测用医疗装置通信.术语	Draft Standard for Health informatics - Point-of-care medical devicecommunication - Nomenclature
7	ANSI P1073.1.2.1/D06-2003	健康信息学用标准草案.床旁检测用医疗装置通信.域信息模型	Draft Health Informatics - Point-of-care medicaldevice communications - Domain information model
8	ANSI P1073.1.3.10/D3.0-1999	医疗装置通信用标准草案.专用虚拟医疗装置的医疗装置数据语言(MDDL).心输出量	Draft Standard forMedical Device Communications -Medical Device Data Language (MDDL)Virtual Medical Device, Specialized -Cardiac Output
9	ANSI P1073.1.3.11/D3.0-1999	医疗装置通信用标准草案.专用虚拟医疗装置的医疗装置数据语言(MDDL).二氧化碳测定计	Draft Standard forMedical Device Communications -Medical Device Data Language (MDDL)Virtual Medical Device, Specialized -Capnometer
10	ANSI P1073.1.3.5/D04-2000	医疗装置通信用标准草案.专用虚拟医疗装置的医疗装置数据语言(MDDL).去纤颤器装置	Standard forMedical Device Communications -Medical Device Data Language (MDDL)Virtual Medical Device, Specialized -Defibrillator Device
11	ANSI P1073.1.3.6/D6.0-1999	医疗装置通信用标准草案.专用虚拟医疗装置的医疗装置数据语言(MDDL).心电图	Draft Standard forMedical Device Communications -Medical Device Data Language (MDDL)Virtual Medical Device, Specialized -ECG
12	ANSI P1073.1.3.7/D4.0-1999	医疗装置通信用标准草案.专用虚拟医疗装置的医疗装置数据语言(MDDL).血压	Draft Standard forMedical Device Communications -Medical Device Data Language (MDDL)Virtual Medical Device, Specialized -Blood Pressure
13	ANSI P1073.1.3.8/D4.0-1999	医疗装置通信用标准草案.专用虚拟医疗装置的医疗装置数据语言(MDDL).温度	Draft Standard forMedical Device Communications -Medical Device Data Language (MDDL)Virtual Medical Device, Specialized -Temperature
14	ANSI P1073.1.3.9/D3.0-1999	医疗装置通信用标准草案.专用虚拟医疗装置的医疗装置数据语言(MDDL).导气气流	Draft Standard forMedical Device Communications -Medical Device Data Language (MDDL)Virtual Medical Device, Specialized -Airway Flow
15	ANSI P1073.2.1.1/D08-2003	健康信息学用标准草案.床旁检测用医疗装置通信.应用轮廓.基础标准	Draft Standard for Health informatics - Point-of-care medical devicecommunication - Application profiles - Base standard
16	ANSI P1073.3.3/D08-2003	健康信息学用标准草案.床旁检测用医疗装置通信.传输轮廓.基于IrDA.红外无线	Draft Standard for Health informatics - Point-of-care medical devicecommunication - Transport profile - IrDa based - Infrared wireless
17	ANSI PH2.50-1983	摄影.医疗和牙科用直接曝光射线摄影胶片/照相版图片的ISO感光速度和平均梯度的测定	Photography - Direct-Exposure Medical and Dental Radiographic Film/Process Combinations - Determination of ISO Speed and Average Gradient
18	ANSI/AAMI BE78-2002	医疗设施生物评估.第10部分:刺激作用和致敏作用试验	Biological evaluation of medical devices, Part 10: Tests for irritation and delayed type hypersensitivity
19	ANSI/AAMI BE78-2002/A1-2006	医疗装置的生物学评估.第10部分:刺激和延迟型超敏性试验.修改件1	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity - Amendment 1
20	ANSI/AAMI BE83-2006	医疗器械的生物评价.第18部分:材料的化学特性	Biological evaluation of medical devices - Part 18: Chemical characterization of materials
21	ANSI/AAMI DF80-2003	医疗电气设备.第2部分:心脏除颤器安全性的特殊要求(包括体外心脏电击去颤器)	Medical electrical equipment - Part 2: Particular requirements for the safety of cardiac defibrillators [including automated external defibrillators]
22	ANSI/AAMI EC13-2002	医疗电气设备.第2-27部分:心电图仪用监控设备的基本安全和性能的特殊要求	Medical electrical equipment - Part 2-27: Particular requirements for basic safety and essential performance of electrocardiographic monitoring equipment
23	ANSI/AAMI EC38-2007	医疗电气设备.第2-47部分:非固定式心电图仪系统的安全(包括基本性能)的特殊要求	Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, or ambulatory electrocardiographic systems
24	ANSI/AAMI EQ56-1999	医疗设备管理项目的推荐实施规范	Recommended practices for a medical equipment management program
25	ANSI/AAMI ES60601-1-2005	医疗电器设备.第一部分:基本安全和实用性的一般要求	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
26	ANSI/AAMI ES60601-1/Amendment 1-2009	医疗电气设备.第1部分:基本安全性和必要性能一般要求	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance
27	ANSI/AAMI ES60601-1/Amendment 2-2010	医疗电气设备.第1部分:基本安全性和必要性能一般要求.修改件2	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance/Amendment 2
28	ANSI/AAMI HE74-2001	医疗装置人性因素设计过程	Human factors design process for medical devices
29	ANSI/AAMI HE75-2009	人因工程学.医疗设备设计	Human factors engineering - Design of medical devices
30	ANSI/AAMI ID26-2004	医疗电气设备.第2部分:输液泵和控制器安全的特殊要求	Medical electrical equipment, Part 2: Particular requirements for the safety of infusion pumps and controllers
31	ANSI/AAMI PB70-2003	医疗保健设施中使用的防护服和防护布的防液性能和分类	Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities
32	ANSI/AAMI PC69-2007	活性可植入医疗装置.电磁兼容性(EMC).可植入心脏起搏器和可植入心律转复除颤器用EMC试验协议	Active Implantable Medical Devices - Electromagnetic Compatibility - EMC Test Protocols for Implantable Cardiac Pacemakers and Implantable Cardioverter Defibrillators
33	ANSI/AAMI ST 63-2002	保健品灭菌.医疗器械工业灭菌过程的设计、批准和常规控制要求.干热	Sterilization of Health Care Products - Requirements for the development,validation,and routine control of an industrial sterilization process for medical devices - Dry heat
34	ANSI/AAMI ST25-1987	医疗产品的工业湿热灭菌用指南	Guideline for Industrial Moist Heat Sterilization of Medical Products
35	ANSI/AAMI ST27-1988	医疗设备的工业环氧乙烷灭菌用指南.工艺流程设计、验证、例行灭菌和合同灭菌	Guideline for Industrial Ethylene Oxide Sterilization of Medical Devices. Process Design, Validation, Routine Sterilization, and Contract Sterilization
36	ANSI/AAMI ST29-1988	医疗设备中残留环氧乙烷的测定用推荐实施规程	Recommended Practice for Determining Residual Ethylene Oxide in Medical Devices
37	ANSI/AAMI ST30-1989	医疗设备中残留氯乙醇和乙二醇的测定	Determining Residual Ethylene Chlorohydrin and Ethylene Glycol in Medical Devices
38	ANSI/AAMI ST58-2005	医疗保健设施中化学药剂杀菌和高水平消毒	Chemical sterilization and high-level disinfection in health care facilities
39	ANSI/AAMI ST67-2003	医疗装置的消毒.贴有“已消毒”标签的产品要求	Sterilization of medical devices - Requirements for products labeled "sterile"
40	ANSI/AAMI ST77-2006	可再利用的医疗设备杀菌用密封装置	Containment devices for reusable medical device sterilization
41	ANSI/AAMI ST79-2006	医疗设备中蒸汽消毒和灭菌保证用综合指南	Comprehensive guide to steam sterilization and sterility assurance in health care facilities
42	ANSI/AAMI ST81-2004	医疗器件的消毒.由生产商提供的可反复消毒的医疗器件的处理信息	Sterilization of medical devices -- Information to be provided by the manufacturer for the processing of resterilizable medical devices
43	ANSI/AAMI/IEC 60601-2-19-2009	医疗电气设备.第2-19部分:婴儿保育器基本安全和重要性能的特殊要求	Medical electrical equipment - Part 2-19: Particular requirements for basic safety and essential performance of baby incubators
44	ANSI/AAMI/IEC 60601-2-20-2009	医疗电气设备.第2-20部分:运输保育箱基本安全和重要性能的特殊要求	Medical electrical equipment - Part 2-20: Particular requirements for basic safety and essential performance of transport incubators
45	ANSI/AAMI/IEC 60601-2-21-2009	医疗电气设备.第2-21部分:婴儿辐射温热装置基本安全和重要性能的特殊要求	Medical electrical equipment - Part 2-21: Particular requirements for basic safety and essential performance of infant radiant warmers
46	ANSI/AAMI/IEC 62304,Ed.1-2006	医疗器械用软件.软件寿命循环过程	Medical device software - Software life-cycle processes
47	ANSI/AAMI/IEC 80601-2-30-2009	医疗电气设备.第2-30部分:自动无创性血压计的基本安全和性能的专用要求	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
48	ANSI/AAMI/IEC 80601-2-30-2009/C1-2009	医疗电气设备.第2-30部分:自动无创性血压计的基本安全和性能的详细要求	Medical electrical equipment - Part 2-30: Particular requirements for basic safety and essential performance of automated type non-invasive sphygmomanometers
49	ANSI/AAMI/IEC 80601-2-58-2008	医疗电气设备.第2-58部分:眼外科用晶体移除装置和玻璃体切除装置基本安全及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 device for ophthalmic

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50	ANSI/AAMI/ISO 10993-1-2009	医疗器械的生物学评价.第1部分:风险管理系统内的评价与测试	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system
51	ANSI/AAMI/ISO 10993-11-2006	医疗器械的生物评定.第11部分:系统毒性试验(收集在ANSI/AAMI/ISO 10993-1993汇编集中)	Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity (included in ANSI/AAMI/ISO 10993-1993: A collection)
52	ANSI/AAMI/ISO 10993-12-2007	医疗器械的生物学评价.第12部分:样品制备和标样	Biological Evaluation of Medical Devices - Part 12: Sample Preparation and Reference Materials
53	ANSI/AAMI/ISO 10993-13-1999	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定性与定量	Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymers
54	ANSI/AAMI/ISO 10993-14-2001	医疗器械的生物评定.第14部分:来自陶瓷的降解产品的识别和量化	Biological Evaluation of Medical Devices - Part 14: Identification and Quantification of Degradation Products from Ceramics
55	ANSI/AAMI/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量	Biological Evaluation of Medical Devices - Part 15: Identification and Quantification of Degradation Products from Metals and Alloys
56	ANSI/AAMI/ISO 10993-16-1997	医疗器械的生物评定.第16部分:降解产品和可沥滤物质毒性动态研究设计	Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables
57	ANSI/AAMI/ISO 10993-17-2002	医疗器械的生物评估.第17部分:可沥出物质允许极限值的确定	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances
58	ANSI/AAMI/ISO 10993-2-2006	医疗器械的生物评定.第2部分:动物福利要求	Biological evaluation of medical devices - Part 2: Animal welfare requirements
59	ANSI/AAMI/ISO 10993-3-2003	医疗器械的生物评定.第3部分:基因毒性、致癌作用和生殖毒性的测试	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
60	ANSI/AAMI/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 tests for interactions with blood
61	ANSI/AAMI/ISO 10993-4AMD 1-2006	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(修改件1)	Biological evaluation of medical devices - Part 4: Selection of test for interactions with blood (Amendment 1)
62	ANSI/AAMI/ISO 10993-5-2009	医疗器械生物学评价.第5部分:体外细胞毒性试验	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
63	ANSI/AAMI/ISO 10993-6-2007	医疗装置的生物学评估.第6部分:植入后局部效应的试验	Biological Evaluation of Medical Devices - Part 6: Tests for Local Effects after Implantation
64	ANSI/AAMI/ISO 10993-7-2008	医疗装置用生物学评估.第7部分:环氧乙烷灭菌残留物	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
65	ANSI/AAMI/ISO 11135-1-2007	卫生保健产品灭菌.环氧乙烷.第1部分:医疗设备灭菌过程开发、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
66	ANSI/AAMI/ISO 11137-1-2006	保健产品的灭菌.辐射.第1部分:医疗装置消毒的开发、确认和程序控制的要求	Sterilization of health care products - Radiation - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
67	ANSI/AAMI/ISO 11138-1-2006	医疗保健产品灭菌.生物指示器.第1部分:一般要求	Sterilization of health care products - Biological indicators - Part 1: General requirements
68	ANSI/AAMI/ISO 11138-2-2006	医疗保健产品灭菌.生物指示器.第2部分:环氧乙烷灭菌处用生物指示器	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes
69	ANSI/AAMI/ISO 11138-3-2006	医疗保健产品灭菌.生物指示器.第3部分:湿热灭菌处用生物指示剂	Sterilization of health care products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes
70	ANSI/AAMI/ISO 11138-4-2006	医疗保健产品灭菌.生物指示器.第4部分:干热灭菌处用生物指示器	Sterilization of health care products - Biological indicators - Part 4: Biological indicators for dry heat sterilization processes
71	ANSI/AAMI/ISO 11138-5-2006	医疗保健产品灭菌.生物指示器.第5部分:甲醛溶液灭菌处用生物指示器	Sterilization of health care products - Biological indicators - Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes
72	ANSI/AAMI/ISO 11607-1-2006	最后灭菌的医疗器械的包装.第1部分:原材料、消毒阻挡系统和包装的要求	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging
73	ANSI/AAMI/ISO 11607-2-2006	最后灭菌的医疗器械的包装.第2部分:组成、密封和装配过程的确认和要求	Packaging for terminally sterilized medical devices - Part 2: Validation and requirements for forming, sealing and assembly processes
74	ANSI/AAMI/ISO 11737-1-2006	医疗器械消毒.微生物法.第1部分:产品微生物群落数测定	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
75	ANSI/AAMI/ISO 11737-2-2009	医疗器械灭菌.微生物学方法.第2部分:定义、确认及维持灭菌过程中进行的无菌试验	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
76	ANSI/AAMI/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
77	ANSI/AAMI/ISO 13485-2003	医疗设备.质量管理体系.管理用系统要求	Medical devices - Quality management systems - Requirements for regulatory purposes
78	ANSI/AAMI/ISO 14155-1-2003	医疗器械的临床调查	Clinical investigation of medical devices for human subjects - Part 1: General requirements
79	ANSI/AAMI/ISO 14155-2-2003	受治疗人员用医疗器械的临床调查.第二部分:临床调查计划	Clinical investigation of medical devices for human subjects - Part 2: Clinical investigation plans
80	ANSI/AAMI/ISO 14160-1998	对包括动物源材料在内的一次性使用医疗器具的灭菌.使用液体化学灭菌剂的确认和常规控制	Sterilization of single-use medical devices incorporating materials of animal origin - Validation and routine control of sterilization by liquid chemical sterilants
81	ANSI/AAMI/ISO 14708-3-2008	外科植入物.可植入式医疗器械.第3部分:可植入神经刺激器	Implants for surgery - Active implantable medical devices - Part 3: Implantable neurostimulators
82	ANSI/AAMI/ISO 14708-4-2008	外科植入物.有源植入式医疗设备.第4部分:植入式输液泵	Implants for surgery - Active implantable medical devices - Part 4: Implantable infusion pumps
83	ANSI/AAMI/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
84	ANSI/AAMI/ISO 14937-2000	医疗保健产品灭菌.医用设备用消毒剂的特性及消毒方法的开发、确认和常规控制的一般要求	Sterilization of Health Care Products - General Requirements for Characteristics of a Sterilizing Agent and the Development, Validation and Routine Control of a Sterilization
85	ANSI/AAMI/ISO 14971-2007	医疗器械.风险管理.医疗器械风险管理的应用	Medical devices - Risk management - Application of risk management to medical devices
86	ANSI/AAMI/ISO 15223-1-2007	医疗设备.用于医疗设备标签、加标签和提供信息的符号.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
87	ANSI/AAMI/ISO 15223-1/A1-2008	医疗器械.用于医疗器械标签、标记和提供信息的符号	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied
88	ANSI/AAMI/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
89	ANSI/AAMI/ISO 15225-2010	命名法.医疗设备命名数据结构	Nomenclature - Medical device nomenclature data structure
90	ANSI/AAMI/ISO 17665-1-2005	医疗保健产品.湿热.医疗装置消毒的开发、确认和程序控制的要求	Sterilization of health care products - Moist heat - Requirements for development, validation and routine control of a sterilization process for medical devices
91	ANSI/AAMI/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
92	ANSI/AAMI/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
93	ANSI/AAMI/ISO 22442-3-2007	医疗设备用动物组织及其衍生物.第3部分:病毒和遗传性海绵状脑病(TSE)试剂的消灭和/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
94	ANSI/ASHRAE 170a-2009	医疗卫生设施的通风	Ventilation of Health Care Facilities
95	ANSI/ASTM E1744-2005	电子健康记录中紧急医疗的观测规范	Practice for View of Emergency Medical Care in the Electronic Health Record
96	ANSI/ASTM E1762-1997	医疗保健信息电子鉴定规范	Guide for Electronic Authentication of Health Care Information
97	ANSI/ASTM E1959-2006	医疗保健机构医药处方服务提议要求的标准指南	Guide for Requests for Proposals Regarding Medical Transcription Services for Healthcare Institutions
98	ANSI/ASTM E2017-1999	医疗信息修改件指南	Guide for Amendments to Health Information

美国医疗标准(ANSI medical standards)

序号	编号	中文名称	英文名称
99	ANSI/ASTM E2084-2000	用数字签名证明医疗保健信息规范	Specification for Authentication of Healthcare Information using Digital Signatures
100	ANSI/ASTM E2085-2001	医疗保健信息安全框架指南	Guide on Security Framework for Healthcare Information
101	ANSI/ASTM E2086-2000	因特网和内部网医疗保健安全保密指南	Guide for Internet and Intranet Healthcare Security
102	ANSI/ASTM E2117-2006	医疗记录质量保证计划的鉴定和确立用分类指南	Classifications Guide for Identification and Establishment of a Quality Assurance Program for Medical Transcription
103	ANSI/ASTM E2502-2006	医疗转录工作站的标准指南	Standard Guide for Medical Transcription Workstations
104	ANSI/ASTM E2538-2007	电子医疗记录环境和网络体系机构内定义和执行药物疗法信息服务的实施规程	Practice for Defining and Implementing Pharmacotherapy Information Services Within the Electronic Health Record Environment and Networked Architectures
105	ANSI/ASTM E2682-2009	医疗转录部门和事务用灾难恢复方案开发的指南	Guide for Developing a Disaster Recovery Plan for Medical Transcription Departments and Businesses
106	ANSI/ASTM F2290-2003	医疗气体用ISO 5359低压软管组件的采用	Adoption of ISO 5359 Low-pressure Hose Assemblies for Use with Medical Gases
107	ANSI/ASTM F2402-2004	与医疗气体管道系统终端装置相连的流量测量装置,采用ISO 15002作为美国国家标准(有所偏差)	Flow-metering Devices for Connection to Terminal Units of Medical Gas Pipeline Systems, Adoption of ISO 15002 as an American National Standard (with Deviations)
108	ANSI/ASTM/ISO 21647-2006	医疗电气设备,呼吸气体监测器的基本安全性能的特殊要求	Medical Electrical Equipment - Particular requirements for the basic safety and essential performance of respiratory gas monitors
109	ANSI/ASTM/ISO 9919-2009	医疗电气设备,医用脉冲血氧仪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 Pulse Oximeter Equipment for Medical Use
110	ANSI/AWS D10.13/D 10.13M-2001	医疗气体系统用铜管和管道钎焊的推荐规程	Recommended Practices for the Brazing of Copper Pipe and Tubing for Medical Gas Systems
111	ANSI/CAP SNOMED-1-2003	医疗保健术语结构	Healthcare Terminology Structure
112	ANSI/HL 7CDAR 1.0-2000	HL7版3标准:医疗数据结构,发表1.0	The HL7 Version 3 Standard: Clinical Data Architecture, Release 1.0
113	ANSI/HL7 V3 RBAC, R 2-2010	HL7版本3标准:基于任务的访问控制医疗审批目录,版本2	HL7 Version 3 Standard: Role-based Access Control Healthcare Permission Catalog, Release 2
114	ANSI/HL7 V3 RCMR, R 1-2006	HL7第3版标准:医疗记录/信息管理,版本1	HL7 Version 3 Standard: Medical Records/Information Management, Release 1
115	ANSI/HL7 V3 SPDIR, R 1-2010	HL7版本3标准:医疗保健,社区服务部和供应商名录,发行1	HL7 Version 3 Standard: Healthcare, Community Services and Provider Directory, Release 1
116	ANSI/IEEE 1073.1.1.1-2004	健康信息学标准:床旁检测用医疗装置通信,术语	Standard for Health Informatics – Point-of-Care Medical Device Communication – Nomenclature
117	ANSI/IEEE 1073.1.2.1-2004	健康信息学标准:床旁检测用医疗装置通信,域信息模式	Standard for Health Informatics – Point-of-Care Medical Device Communication – Domain Information Model
118	ANSI/IEEE 1073.2.1.1-2004	健康信息学标准:床旁检测用医疗装置通信,应用轮廓,基础标准	Standard for Health Informatics – Point-of-Care Medical Device Communication – Application Profiles – Base Standard
119	ANSI/IEEE 1073.3.2-2000	医疗装置通信,传输轮廓,以IrDA为基的连接电缆	Medical Device Communications - Transport Profile - IrDA Based - Cable Connected
120	ANSI/IEEE 1073.3.3-2004	健康信息学标准:床旁检测用医疗装置通信,传输轮廓,基于IrDA的红外无线	Standard for Health Informatics – Point-of-Care Medical Device Communication – Transport Profile – IrDA Based – Infrared Wireless
121	ANSI/IEEE 11073-00101-2008	健康信息指南:医疗服务点的医疗器械通信,技术报告使用指南	Guide for Health Informatics - Point-of-Care Medical Device Communication - Technical Report - Guidelines for the Use
122	ANSI/IEEE 602-2007	医疗保健设施用电子系统的推荐实施规程	Recommended Practice for Electric Systems in Health Care Facilities
123	ANSI/IEEE C63.011-2000	测量工业、科技、医疗射频设备的抗无线电干扰特性的限值和方法	Limits and Methods of Measurement of Radio Disturbance Characteristics of Industrial, Scientific and Medical (ISM) Radio-Frequency Equipment
124	ANSI/NAPM IT2.41-1997	摄影,医疗放射照相术用屏蔽/胶片系统的感光测定,第1部分:感光曲线形状、速度和平均梯度的测定	Photography - Sensitometry of Screen/Film Systems for Medical Radiography - Part 1: Determination of Sensitometric Curve Shape, Speed and Average Gradient
125	ANSI/NCPDP MSV 3.0-2007	批次标准版本3.0用医疗补助代理执行指南	Medicaid Subrogation Implementation Guide for Batch Standard Version 3.0
126	ANSI/NFPA 1582-2007	消防队的全职医疗计划标准	Standard on Comprehensive Occupational Medical Program for Fire Departments
127	ANSI/NFPA 1710-2010	职业消防队灭火操作,急救医疗操作和特殊操作的组织和调度标准	Standard for the Organization and Deployment of Fire Suppression Operations, Emergency Medical Operations, and Special Operations to the Public by Career Fire
128	ANSI/NFPA 1720-2010	专业消防部门消防行动,紧急医疗事故处理和特别行动组织和部署标准	Standard for the Organization and Deployment of Fire Suppression Operations, Emergency Medical Operations and Special Operations to the Public by Volunteer Fire
129	ANSI/NFPA 1999-2008	急救医疗手术用防护服的的标准	Standard on Protective Clothing for Emergency Medical Operations
130	ANSI/NFPA 450-2009	应急医疗设施和系统用指南	Guide for Emergency Medical Services and Systems
131	ASTM ANSI/IEC60601.2.12-2001	医疗用电气设备,第2-12部分:对于肺通气器安全性的特殊要求,重症护理(被批准为美国国家标准,与ASTM国际标准)	Medical Electrical Equipment&8212;Part 2-12: Particular Requirements for the Safety of Lung Ventilators&8212;Critical Care Ventilators Approved as an American National
132	ASTM ANSI/ISO15002-2000	连接医疗气体管道系统终端装置的流量计量仪表	Flow-metering devices for connection to terminal units of medical gas pipeline systems
133	ASTM ANSI/ISO5359-2000E	偏离ASTM国际组织批准成为美国国家标准的与医疗气体一同使用的低压软管组件	Low-Pressure Hose Assemblies for Use with Medical Gases Approved as an American National Standard with Deviations by ASTM International
134	ASTM ANSI/ISO21647-2004	医疗电气设备,8212呼吸监测器的基本安全和基本性能的特殊要求	Medical Electrical Equipment&8212;Particular Requirements for the Basic Safety and Essential Performance of Respiratory Gas Monitors
135	ASTM E1902-2002	口授、录音和录制的医疗记录的机密性和安全性的管理标准规范	Standard Specification for Management of the Confidentiality and Security of Dictation, Transcription, and Transcribed Health Records
136	ASTM E1959-2005	视为医疗保健机构医药处方服务建议要求的标准指南	Standard Guide for Requests for Proposals Regarding Medical Transcription Services for Healthcare Institutions
137	ASTM E2117-2006	医疗记录质量保证计划的鉴定和确立用标准指南	Standard Guide for Identification and Establishment of a Quality Assurance Program for Medical Transcription
138	ASTM E2436-2005	医疗信息系统中人类特征数据表示法的标准规范	Standard Specification for the Representation of Human Characteristics Data in Healthcare Information Systems
139	ASTM E2502-2006	医疗摹本工作站的标准指南	Standard Guide for Medical Transcription Workstations
140	ASTM E2682-2009	医疗转移科和职业用灾难恢复方案开发的标准指南	Standard Guide for Developing a Disaster Recovery Plan for Medical Transcription Departments and Businesses
141	ASTM F1031-2000(2006)	急救医疗技师培训(基础)的标准操作规程	Standard Practice for Training the Emergency Medical Technician (Basic)
142	ASTM F1220-1995(2006)	应急医疗服务系统(EMSS)远程通信	Standard Guide for Emergency Medical Services System (EMSS) Telecommunications
143	ASTM F1224-1989(2004)e1	提供急救医疗服务系统评定用标准指南	Standard Guide for Providing System Evaluation for Emergency Medical Services
144	ASTM F1229-2001(2006)	急救医疗服务机上患者医疗护理人员的资格鉴定和训练计划的标准指南	Standard Guide for the Qualification and Training of EMS Air-Medical Patient Care Providers
145	ASTM F1251-1989(2003)	医疗和外科器械用聚合物生物材料的相关术语	Standard Terminology Relating to Polymeric Biomaterials in Medical and Surgical Devices
146	ASTM F1258-1995(2006)	应急医疗调度	Standard Practice for Emergency Medical Dispatch
147	ASTM F1287-1990(2007)	提供应急医疗护理的急救应答器性能范围	Standard Guide for Scope of Performance of First Responders Who Provide Emergency Medical Care

美国医疗标准(ANSI medical standards)

序号	编号	中文名称	英文名称
148	ASTM F1560-2000(2006)	医疗紧急调度管理标准实施规程	Standard Practice for Emergency Medical Dispatch Management
149	ASTM F1629-1995(2007)	建立外科手术的急救医疗服务和管理信息系统或二者同时建立的标准导则	Standard Guide for Establishing Operating Emergency Medical Services and Management Information Systems, or Both
150	ASTM F1652-1995(2007)	为住院前应急医疗机构提前提供所需主要数据的标准指南	Standard Guide for Providing Essential Data Needed in Advance for Prehospital Emergency Medical Services
151	ASTM F1705-1996(2007)	紧急医疗救护服务操作训练用标准指南	Standard Guide for Training Emergency Medical Services Ambulance Operations
152	ASTM F1800-2007	整体膝关节替代物的医疗胫骨盘部件的周期疲劳测试的标准试验方法	Standard Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements
153	ASTM F1929-1998(2004)	用染色渗透液检测多孔医疗包装汽封泄漏的标准试验方法	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
154	ASTM F1980-2007	医疗装置用无菌阻隔系统加速老化的标准指南	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
155	ASTM F2038-2000(2005)	医疗设施中用的硅弹性体、凝胶和泡沫的标准指南 第I部分:组成和未硫化材料	Standard Guide for Silicone Elastomers, Gels and Foams Used in Medical Applications Part I - Formulations and Uncured Materials
156	ASTM F2042-2000(2005)	医疗设施中用的硅弹性体、凝胶和泡沫的标准指南 第II部分:交联材料和制造	Standard Guide for Silicone Elastomers, Gels, and Foams Used in Medical Applications Part II - Crosslinking and Fabrication
157	ASTM F2052-2006e1	测量磁共振环境中医疗设备磁感应位移力的标准试验方法	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
158	ASTM F2063-2005	医疗器械和外科植入物用锻造镍钛形状记忆合金标准规范	Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants
159	ASTM F2076-2001(2006)	EMS病人报告关于接收医疗设备的通知的标准实施规程	Standard Practice for Communicating an EMS Patient Report to Receiving Medical Facilities
160	ASTM F2150-2007	组织工程医疗产品中使用的生物材料支架的表征和试验用标准指南	Standard Guide for Characterization and Testing of Biomaterial Scaffolds Used in Tissue-Engineered Medical Products
161	ASTM F2210-2002	组织工程医疗产品中使用的细胞、组织和器官处理的标准指南	Standard Guide for Processing Cells, Tissues, and Organs for Use in Tissue Engineered Medical Products
162	ASTM F2211-2004	组织工程医疗产品的标准分类	Standard Classification for Tissue Engineered Medical Products (TEMPs)
163	ASTM F2213-2006	磁共振环境中医疗设备中磁感应扭矩测量的标准试验方法	Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
164	ASTM F2318-2004	旋转机翼的基本生命保障、高级生命保障和专业医疗保障救护飞机的标准规格	Standard Specification for Rotary Wing Basic Life Support, Advanced Life Support, and Specialized Medical Support Air Ambulances
165	ASTM F2319-2004	固定机翼的基本生命保障、高级生命保障和专业医疗保障救护飞机的标准规格	Standard Specification for Fixed Wing Basic Life Support, Advanced Life Support, and Specialized Medical Support Air Ambulances
166	ASTM F2347-2003	生物医疗和组织工程医疗产品中使用的作为初始材料的透明质酸盐的表征和试验标准指南	Standard Guide for Characterization and Testing of Hyaluronan as Starting Materials Intended for Use in Biomedical and Tissue Engineered Medical Product Applications
167	ASTM F2382-2004e1	根据部分促凝血酶原激酶时间评估血管内医疗设备材料的标准试验方法	Standard Test Method for Assessment of Intravascular Medical Device Materials on Partial Thromboplastin Time (PTT)
168	ASTM F2383-2005	组织工程医疗产品中附加剂评定的标准指南	Standard Guide for Assessment of Adventitious Agents in Tissue Engineered Medical Products (TEMPs)
169	ASTM F2386-2004	组织工程医疗产品的保存的标准指南	Standard Guide for Preservation of Tissue Engineered Medical Products (TEMPs)
170	ASTM F2459-2005	从金属医疗部件提取残余物并由化学分离测重法确定数量的标准试验方法	Standard Test Method for Extracting Residue from Metallic Medical Components and Quantifying via Gravimetric Analysis
171	ASTM F2475-2005	医疗器件包装材料的生物可兼容性评价的标准指南	Standard Guide for Biocompatibility Evaluation of Medical Device Packaging Materials
172	ASTM F2633-2007	医疗设备和外科植入物用无缝镍钛形状记忆合金管标准规范	Standard Specification for Wrought Seamless Nickel-Titanium Shape Memory Alloy Tube for Medical Devices and Surgical Implants
173	ASTM F2761-2009	医疗器械和医疗系统 包含病人的设备用基础安全要求 中心综合临床环境 (ICE) 第1部分:一般要求和概念模型	Medical Devices and Medical Systems - Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) - Part 1: General
174	ASTM F561-2005a	医疗器件和相关组织及液体的修复和分析的标准实施规程	Standard Practice for Retrieval and Analysis of Medical Devices, and Associated Tissues and Fluids
175	ASTM F640-2007	医疗用辐射不透明度测定的标准试验方法	Standard Test Methods for Determining Radiopacity for Medical Use
176	ASTM F813-2007	直接接触细胞培养评估医疗器械材料的标准实施规程	Standard Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices
177	ASTM F882-1984(2002)	低温外科医疗器械的性能和安全	Standard Performance and Safety Specification for Cryosurgical Medical Instruments
178	ASTM G175-2003	医疗和应急设备用氧气调节器的引燃敏感性和耐故障性评价的标准试验方法	Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications
179	IEEE C 63.011-2000	测量工业、科技、医疗射频设备的抗无线电干扰特性的限值和方法	(Limits and methods of measurement of radio disturbance characteristics of Industrial, Scientific, and Medical (ISM) radio-frequency equipment)
180	IEEE C 63.18-1997	医疗设备防特定射频发射器电磁辐射干扰评估的现场特别试验方法推荐规程	(Recommended practice for an on-site, ad hoc test method for estimating radiated electromagnetic immunity of medical devices to specific radio-frequency transmitters)
181	UL 416-1993	制冷医疗设备	(Refrigerated medical equipment)
182	UL 544-1998	医疗和牙科设备	(Medical and dental equipment)
序号	编号	中文名称	英文名称



医课汇
公众号
专业医疗器械资讯平台
WECHAT OF
HLONGMED



hlongmed.com
医疗器械咨询服务
MEDICAL DEVICE
CONSULTING
SERVICES



医课培训平台
医疗器械任职培训
WEB TRAINING
CENTER



医械宝
医疗器械知识平台
KNOWLEDG
ECENTEROF
MEDICAL DEVICE



MDCPP.COM
医械云专业平台
KNOWLEDG
ECENTEROF MEDICAL
DEVICE