欧洲医疗标准(EN medical standards)

序号	编号	中文名称	英文名称
1	CR 13217-1998	用于常规数据交换的医疗设备的术语体系 基本原理	Nomenclature system for medical devices for the purpose of regulatory data exchange - Rationale
2	CR 14060-2000	医疗设备示踪能力	Medical device traceability
3	CR 14230-2001	用于常规数据交换目的的全球医疗设备术语（ISO/TS 20225:2001）	Global medical device nomenclature for the purpose of regulatory data exchange (ISO/TS 20225:2001)
4	EN 1041-1998	厂商提供的医疗设备信息	Information supplied by the manufacturer with medical devices
5	EN 1174-1-1996	医疗器械的消毒 产品的微生物群数的估算 第1部分：要求	Sterilization of medical devices - Estimation of the population of micro-organisms on product - Part 1: Requirements
6	EN 1174-2-1996	医疗器械的消毒 产品的微生物总数的估算 第2部分：指南	Sterilization of medical devices - Estimation of the population of micro-organisms on product - Part 2: Guidance
7	EN 1174-3-1996	医疗器械的消毒 产品的微生物总数的估算 第3部分：微生物技术确认方法指南	Sterilization of medical devices - Estimation of the population of micro-organisms on product - Part 3: Guide to the methods for validation of microbiological techniques
8	EN 12218-1998+A1-2002	医疗设备用护栏系统	Rail systems for supporting medical equipment
9	EN 12286-1998+A1-2000	体外诊断医疗器械　生物起源样品中数量的测量　标准测量程序表达	In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Presentation of reference measurement procedures
10	EN 12287-1999	体外诊断医疗器械　生物起源样品中数量的测量　标准物质描述	In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Description of reference materials
11	EN 12322-1999+A1-2001	体外诊断医疗器械　微生物学用培养基　培养基的性能标准	In vitro diagnostic medical devices - Culture media for microbiology - Performance criteria for culture media
12	EN 12376-1999	体外诊断医疗器械　由制造商提供的有关生物学染色用体外诊断剂的信息	In vitro diagnostic medical devices - Information supplied by the manufacturer with in vitro diagnostic reagents for staining in biology
13	EN 12442-1-2000	医疗设备制造中使用的动物组织及其衍生物　第1部分：风险分析和管理	Animal tissues and their derivatives utilized in the manufacture of medical devices - Part 1: Analysis and management of risk
14	EN 12442-2-2000	医疗设备制造中使用的动物组织及其衍生物　第2部分：来源采集和处理的控制	Animal tissues and their derivatives utilized in the manufacture of medical devices - Part 2: Controls on sourcing, collection and handling
15	EN 12442-3-2000	医疗设备制造中使用的动物组织及其衍生物　第3部分：病毒和传染性试剂消除和/或钝化的验证	Animal tissues and their derivatives utilized in the manufacture of medical devices - Part 3: Validation of the elimination and/or inactivation of viruses and transmissible agents
16	EN 13532-2002	自检用体外诊断医疗设备的一般要求	General requirements for in vitro diagnostic medical devices for self-testing
17	EN 13612-2002+AC-2002	体外诊断医疗设备性能评估	Performance evaluation of in vitro diagnostic medical devices
18	EN 13718-1-2002	空气、水和困难场所救护车 第1部分：用于患者连续护理的医疗设备借口要求	Air, water and difficult terrain ambulances - Part 1: Medical device interface requirements for the continuity of patient care
19	EN 13726-3-2003	非活动医疗设备 原创口敷料试验方法 第3部分：防水性	Non-active medical devices - Test methods for primary wound dressings - Part 3: Waterproofness
20	EN 13726-4-2003	非活动医疗设备 原创口敷料试验方法 第4部分：合格性	Non-active medical devices - Test methods for primary wound dressings - Part 4: Conformability
21	EN 13726-6-2003	非活动医疗设备 原创口敷料试验方法 第6部分：气味控制	Non-active medical devices - Test methods for primary wound dressings - Part 6: Odour control
22	EN 13795-1-2002	作为医疗设备的患者、临床材料和器材用外科手术用帘、长袍和清洁气衣 第1部分：.制造者、加工者和产品的一	Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical stuff and equipment - Part 1: General requirements for manufacturers, processors and products
23	EN 13975-2003	体外诊断用医疗设备验收试验的取样方法　统计法	Sampling procedures used for acceptance testing of in vitro diagnostic medical devices - Statistical aspects
24	EN 14079-2003	非特效医疗设备　脱脂棉纱布、脱脂棉和粘胶纱布的性能要求和试验方法	Non-active medical devices - Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze
25	EN 14180-2003	医疗用消毒器 甲醛和低温蒸气消毒器 试验和要求	Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing
26	EN 1639-1996	牙科学 牙科用医疗设备 器械	Dentistry - Medical devices for dentistry - Instruments
27	EN 1640-1996	牙科学 牙科学用医疗装置 设备	Dentistry - Medical devices for dentistry - Equipment
28	EN 1641-1996	牙科学 牙科用医疗装置 材料	Dentistry - Medical devices for dentistry - Materials
29	EN 1642-1996	牙科学 牙科用医疗装置 牙科植入物	Dentistry - Medical devices for dentistry - Dental implants
30	EN 1707-1996	注射器、针头和其它医疗器械用有6%鲁尔的锥形接头 锁紧接头	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Lock fittings
31	EN 20594-1-1993+A1-1997+AC-1996	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 (ISO 594-1:1986)
32	EN 30993-3-1993	医疗器械的生物学评价 第3部分:遗传毒性、致癌性和生殖毒性试验	Biological evaluation of medical devices;-Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:1992)
33	EN 30993-6-1994	医疗器械的生物学评价 第6部分:植入后局部反应试验	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:1994)
34	EN 455-1-2000	一次性使用的医疗手套 第1部分：防洞要求和测试	Medical gloves for single use - Part 1: Requirements and testing for freedom from holes
35	EN 455-2-2000	一次性使用的医疗手套 第2部分：物理性能的要求和测试	Medical gloves for single use - Part 2: Requirements and testing for physical properties (including Technical Corrigendum 1:1996)
36	EN 455-3-1999	一次性使用的医疗手套 第3部分：生物评价的要求和测试	Medical gloves for single use - Part 3: Requirements and testing for biological evaluation
37	EN 45502-1-1997	活动可植入医疗器件 第1部分：制造商提供的安全、 标记和信息的一般要求	Active implantable medical devices - Part 1: General requirements for safety, marking and information to be provided by the manufacturer
38	EN 46003-1999	质量体系 医疗设备 EN ISO 9003应用的特殊要求	Quality systems - Medical devices - Particular requirements for the application of EN ISO 9003
39	EN 475-1995	医疗设备 电气报警信号	Medical devices - Electrically-generated alarm signals
40	EN 50103-1995	有源(包括有源可植入)医疗器械行业用ISO 9001/EN 46001和ISO 9002/EN 46002应用指南	Guidance on the application of ISO 9001 and EN 46001 and of ISO 9002 and EN 46002 for the active (including active implantable) medical device
41	EN 550-1994	医疗器械的消毒 用环氧乙烷消毒的确认和常规控制	Sterilization of medical devices - Validation and routine control of ethylene oxide sterilization
42	EN 55011-1998+A1-1999+A2-2002	工业、科学、医疗（ISM）射频设备　电磁骚扰特性　测量方法和限值	Industrial, scientific and medical (ISM) radio-frequency equipment - Radio disturbance characteristics - Limits and methods of measurement (CISPR 11:1997, modified)
43	EN 55011/prA3-1998	工业、科学、医疗（ISM）射频设备　电磁骚扰特性　测量方法和限值　修改prA3	Amendment 3 to CISPR 11
44	EN 55011/prAA-2002	工业、科学、医疗（ISM）射频设备　电磁骚扰特性　测量方法和限值　修改prAA	Industrial, scientific and medical (ISM) radio-frequency equipment - Radio disturbance characteristics - Limits and methods of measurement
45	EN 55011/prAB-2002	工业、科学、医疗（ISM）射频设备　电磁骚扰特性　测量方法和限值　修改prAB	Industrial, scientific and medical (ISM) radio-frequency equipment - Radio disturbance characteristics - Limits and methods of measurement

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46	EN 55011/prAC-2002	工业、科学、医疗（ISM）射频设备　电磁骚扰特性　测量方法和限值　修改prAC	Industrial, scientific and medical (ISM) radio-frequency equipment - Radio disturbance characteristics - Limits and methods of measurement
47	EN 552-1994+A1-1999+A2-2000	医疗器械的消毒 辐射消毒的确认和常规控制	Sterilization of medical devices - Validation and routine control of sterilization by irradiation
48	EN 554-1994	医疗器械的消毒 湿热消毒的确认和常规控制	Sterilization of medical devices - Validation and routine control of sterilization by moist heat
49	EN 556-1-2001	医疗器械的消毒 标明为“消过毒”的医疗器械的要求 第1部分：定期消毒的医疗器械的要求	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
50	EN 60598-2-25-1994	灯具　第2部分：特殊要求　第25节：医院和医疗保健中心临床用灯具	Luminaires - Part 2: Particular requirements - Section 25: Luminaires for use in clinical areas of hospitals and health care buildings (IEC 60598-2-25:1994 + Corrigendum 1994)
51	EN 60601-2-11-1997	医疗电气设备　第2-11部分：γ射束治疗设备安全专用要求	Medical electrical equipment - Part 2-11: Particular requirements for the safety of gamma beam therapy equipment (IEC 60601-2-11:1997)
52	EN 60601-2-16-1998	医疗电气设备　第2 - 16部分：血液透析、血液滤净、血液滤过设备安全的特殊要求	Medical electrical equipment - Part 2-16: Particular requirements for the safety of haemodialysis, haemodiafiltration and haemofiltration equipment (IEC 60601-2-16:1998)
53	EN 60601-2-17-1996+A1-1996	医疗电气设备　第2-17部分:遥控自动驱动式γ射线后装设备安全专用要求	Medical electrical equipment - Part 2: Particular requirements for the safety of remote-controlled automatically-driven gamma-ray after-loading equipment (IEC 60601-2-17:1989)
54	EN 60601-2-18-1996+A1-2000	医疗电气设备　第2 - 18部分：内窥镜设备安全专用要求	Medical electrical equipment - Part 2: Particular requirements for the safety of endoscopic equipment (IEC 60601-2-18:1996)
55	EN 60601-2-19-1996+A1-1996	医疗电气设备　第2 - 19部分：婴儿培养箱安全专用要求	Medical electrical equipment - Part 2: Particular requirements for the safety of baby incubators (IEC 60601-2-19:1990)
56	EN 60601-2-2-2000	医疗电气设备　第2 - 2部分： 高频手术设备安全专用要求	Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment (IEC 60601-2-2:1998)
57	EN 60601-2-20-1996	医疗电气设备　第2 - 20部分：运输培养箱安全专用要求	Medical electrical equipment - Part 2-20: Particular requirements for safety of transport incubators (IEC 60601-2-20:1990 + A1:1996)
58	EN 60601-2-21-1994+A1-1996	医疗电气设备　第2 - 21部分：婴儿辐射保暖箱安全专用要求	Medical electrical equipment - Part 2: Particular requirements for the safety of infant radiant warmers (IEC 60601-2-21:1994)
59	EN 60601-2-22-1996	医疗电气设备　第2 - 22部分：诊断和治疗用激光设备安全的特殊要求	Medical electrical equipment - Part 2-22: Particular requirements for the safety of diagnostic and therapeutic laser equipment (IEC 60601-2-22:1995)
60	EN 60601-2-23-2000	医疗电气设备　第2 - 23部分：经皮分压监测设备的安全专用要求	Medical electrical equipment - Part 2-23: Particular requirements for the safety, including essential performance, of transcutaneous partial pressure monitoring equipment (IEC 60601-2-23:1999)
61	EN 60601-2-24-1998	医疗电气设备　第2 - 24部分：输液泵和控制器的特殊安全要求	Medical electrical equipment - Part 2-24: Particular requirements for the safety of infusion pumps and controllers (IEC 60601-2-24:1998)
62	EN 60601-2-25-1995+A1-1999	医疗电气设备　第2 - 25部分：心电图机安全专用要求	Medical electrical equipment - Part 2: Particular requirements for the safety of electrocardiographs (IEC 60601-2-25:1993)
63	EN 60601-2-28-1993	医用电气设备　第2 - 28部分：医疗诊断用X射线源组件和X射线管组件规范	Medical electrical equipment; part 2-28: particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis (IEC 60601-2-28:1993)
64	EN 60601-2-29-1999	医疗电气设备　第2 - 29部分：放射疗法模拟器安全的特殊要求	Medical electrical equipment - Part 2-29: Particular requirements for the safety of radiotherapy simulators (IEC 60601-2-29:1999)
65	EN 60601-2-3-1993+A1-1998	医疗电气设备　第2 - 3部分：短波治疗设备安全专用要求	Medical electrical equipment; part 2: particular requirements for the safety of short-wave therapy equipment (IEC 60601-2-3:1991)
66	EN 60601-2-30-2000	医疗电器设备　第2-30部分：自动循环间接血压监视设备和特殊安全要求	Medical electrical equipment - Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment (IEC 60601-2-30:1999)
67	EN 60601-2-31-1995+A1-1998	医疗电器设备　第2 - 31部分：具有内部能源的体外心脏起搏器安全专用要求	Medical electrical equipment - Part 2: Particular requirements for the safety of external cardiac pacemakers with internal power source (IEC 60601-2-
68	EN 60601-2-33-2002	医疗电气设备　第2 - 33：部分：医疗诊断用磁共振设备安全专用规范	Medical electrical equipment - Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis (IEC 60601-2-33:2002) / Note: Endorsement notice
69	EN 60601-2-34-2000	医疗电器设备　第2 - 34部分：直接血压监视设备安全特殊要求.	Medical electrical equipment - Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment (IEC 60601-2-34:2000)
70	EN 60601-2-36-1997	医疗电气设备　第2 - 36部分：体外碎石机的安全特殊要求	Medical electrical equipment - Part 2-36: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy (IEC 60601-2-
71	EN 60601-2-37-2001	医疗电气设备　第2 - 37部分：超声医疗诊断和监护设备安全的特殊要求	Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment (IEC 60601-2-37:2001)
72	EN 60601-2-38-1996+A1-2000	医疗电器设备　第2 - 38部分：医院电动床的安全特殊要求	Medical electrical equipment - Part 2: Particular requirements for the safety of electrically operated hospital beds (IEC 60601-2-38:1996)
73	EN 60601-2-39-1999	医疗电气设备　第2 - 39部分：腹膜透析设备安全专用要求	Medical electrical equipment - Part 2-39: Particular requirements for the safety of peritoneal dialysis equipment (IEC 60601-2-39:1999)
74	EN 60601-2-4-2003	医疗电气设备　第2-4部分：心脏除纤维颤动器安全性的特殊要求	Medical electrical equipment - Part 2-4: Particular requirements for the safety of cardiac defibrillators (IEC 60601-2-4:2002) / Note: Endorsement
75	EN 60601-2-40-1998	医疗电气设备　第2 - 40部分：电子机动描记器及诱发反映设备安全专用要求	Medical electrical equipment - Part 2-40: Particular requirements for the safety of electromygraphs and evoked response equipment (IEC 60601-2-
76	EN 60601-2-41-2000	医疗电气设备　第2 - 41部分：外科手术灯和诊断用灯光的安全专用要求	Medical electrical equipment - Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis (IEC 60601-2-
77	EN 60601-2-43-2000	医疗电气设备　第2 - 43部分：介入过程用X射线设备安全专用要求	Medical electrical equipment - Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures (IEC 60601-2-
78	EN 60601-2-5-2000	医疗电气设备　第2 - 5部分：超声治疗设备安全专用要求	Medical electrical equipment - Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment (IEC 60601-2-5:2000)
79	EN 60601-2-7-1998	医疗电气设备　第2 - 7部分：诊断X射线发生装置的高压发生器安全专用要求	Medical electrical equipment - Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators (IEC
80	EN 60601-2-8-1997+A1-1997	医疗电气设备　第2 - 8部分：在10 kV至1 MV治疗X射线发生装置安全专用要求	Medical electrical equipment - Part 2: Particular requirements for the safety of therapeutic X-ray equipment operating in the range 10 kV to 1 MV (IEC 60601-2-8:1987)
81	EN 60601-3-1-1996	医疗电气设备　第3 - 1部分：经皮氧分压和二氧化碳分压监护基本性能要求	Medical electrical equipment - Part 3-1: Essential performance requirement for transcutaneous oxygen and carbon dioxide partial pressure monitoring equipment (IEC 60601-3-1:1996)

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82	EN 61010-2-041-1996	测量、控制和实验室用电气设备的安全要求　第２－４１部分：医疗材料处理及实验室加工用蒸压器的的特殊要求	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-041: Particular requirements for autoclaves using steam for the treatment of medical materials, and for laboratory processes (IEC 61010-2-041:1996)
83	EN 61010-2-045-2000	测量、控制和实验室用电气设备的安全要求　第2－045部分：医疗、制药、兽医和试验室用洗涤器消毒的特殊要求	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-045: Particular requirements for washer disinfectors used in medical, pharmaceutical, veterinary and laboratory fields (IEC 61010-2-045:2000)
84	EN 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：生物体外诊断(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 (IEC 61010-2-101:2002, modified)
85	EN 61157-1994	对医疗超声波诊断设备声输出的要求	Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment (IEC 61157:1992)
86	EN 61220-1995	超声学声场　0.5MHz至15MHz频率范围内用水听器测量和表征医疗超声设备产生的超声场的指南	Ultrasonics - Fields - Guidance for the measurement and characterization of ultrasonic fields generated by medical ultrasonic equipment using hydrophones in the frequency range 0,5 MHz to 15 MHz (IEC 61220:1993)
87	EN 61262-1-1994	医疗电气设备　光电X-射线影像增强器特性　第1部分：入射野的测定	Medical electrical equipment - Characteristics of electro-optical X-ray image intensifiers - Part 1: Determination of the entrance field size (IEC
88	EN 61262-2-1994	医疗电气设备　光电X-射线影像增强器特性　第2部分：换算因子的测定	Medical electrical equipment - Characteristics of electro-optical X-ray image intensifiers - Part 2: Determination of the conversion factor (IEC
89	EN 61262-3-1994	医疗电气设备　光电X-射线影像增强器特性　第3部分：亮度分布及非均匀性测定	Medical electrical equipment - Characteristics of electro-optical X-ray image intensifiers - Part 3: Determination of the luminance distribution and luminance non-uniformity (IEC 61262-3:1994)
90	EN 61262-4-1994	医疗电气设备　光电X-射线影像增强器特性　第4部分：影像畸变的测定	Medical electrical equipment - Characteristics of electro-optical X-ray image intensifiers - Part 4: Determination of the image distortion (IEC
91	EN 61262-5-1994	医疗电气设备　光电X-射线影像增强器特性　第5部分：次量子系统的测定	Medical electrical equipment - Characteristics of electro-optical X-ray image intensifiers - Part 5: Determination of the detective quantum efficiency (IEC 61262-5:1994)
92	EN 61262-6-1994	医疗电气设备　光电X-射线影像增强器特性　第6部分：对比度及伪影系数的测定	Medical electrical equipment - Characteristics of electro-optical X-ray image intensifiers - Part 6: Determination of the contrast ratio and veiling glare index (IEC 61262-6:1994)
93	EN 61262-7-1995	医疗电气设备　光电X-射线影像增强器特性　第7部分：调制传递函数的测定	Medical electrical equipment - Characteristics of electro-optical X-ray image intensifiers - Part 7: Determination of the modulation transfer function (IEC 61262-7:1995)
94	EN 61303-1995	医疗电气设备　放射性核素准直器　描述性能的特殊方法	Medical electrical equipment - Radionuclide calibrators - Particular methods for describing performance (IEC 61303:1994)
95	EN 61558-2-15-2001	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 (IEC 61558-2-15:1999, modified)
96	EN 61676-2002	医疗电气设备　用于诊断放射线学中X射线管电压非发病测量的剂量测定仪	Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology (IEC 61676:2002) / Note: Endorsement notice
97	EN 724-1994	无源医疗器械用EN29001、EN46001、EN29002、EN46002标准的应用指南	Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for non-active medical devices
98	EN 737-1-1998	医疗气体管道系统 第1部分：压缩医疗气体和真空用终端设备	Medical gas pipeline systems - Part 1: Terminal units for compressed medical gases and vacuum
99	EN 737-2-1998+A1-1999+AC-2000	医疗气体管道系统 第2部分：麻醉气体净化处理系统 基本要求	Medical gas pipeline systems - Part 2: Anaesthetic gas scavenging disposal systems - Basic requirements
100	EN 737-3-1998+A1-1999+AC-2000	医疗气体管道系统 第3部分：压缩医疗气体和真空用管道	Medical gas pipeline systems - Part 3: Pipelines for compressed medical gases and vacuum
101	EN 737-4-1998	医疗气体管道系统 第4部分：麻醉气体净化系统的终端设备	Medical gas pipeline systems - Part 4: Terminal units for anaesthetic gas scavenging systems
102	EN 738-4-1998+A1-2002	医用气体用压力调节器 第4部分：医疗设备用低压压力调节器	Pressure regulators for use with medical gases - Part 4: Low-pressure regulators intended for incorporation into medical equipment
103	EN 739-1998+A1-2002	医疗气体设备用低压软管组件	Low-pressure hose assemblies for use with medical gases
104	EN 793-1997	医疗供应设备安全的特殊要求	Particular requirements for safety of medical supply units
105	EN 868-1-1997	经消毒的医疗器械用包装材料和系统 第1部分：一般要求和试验方法	Packaging materials and systems for medical devices which are to be sterilized - Part 1: General requirements and test methods
106	EN 868-10-2000	经消毒的医疗器械用包装材料和系统 第10部分：生产热密封袋、卷轴和盖的聚烯烃粘性涂层非编织材料 要求和	Packaging materials and systems for medical devices which are to be sterilized - Part 10: Adhesive coated nonwoven materials of polyolefines for use in the manufacture of heat sealable pouches, reels and lids - Requirements and test methods
107	EN 868-2-1999	经消毒的医疗器械用包装材料和系统 第2部分：消毒包裹物要求和试验方法	Packaging materials and systems for medical devices which are to be sterilized - Part 2: Sterilization wrap - Requirements and test methods
108	EN 868-3-1999	经消毒的医疗器械用包装材料和系统 第3部分：生产纸袋（EN 868-4规定）和生产盒和卷筒用纸（EN 868-5规定	Packaging materials and systems for medical devices which are to be sterilized - Part 3: Paper for use in the manufacture of paper bags (specified in EN 868-4) and in the manufacture of pouches and reels (specified in EN 868-5) - Requirements and test methods
109	EN 868-4-1999	经消毒的医疗器械用包装材料和系统 第4部分：纸袋 要求和试验方法	Packaging materials and systems for medical devices which are to be sterilized - Part 4: Paper bags - Requirements and test methods
110	EN 868-5-1999+AC-2001	经消毒的医疗器械用包装材料和系统 第5部分：纸、塑料薄膜结构的热和可自密封袋及卷轴 要求和试验方法	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
111	EN 868-6-1999	经消毒的医疗器械用包装材料和系统 第6部分：生产经氧化乙烯或辐照消毒的医用包所用的纸 要求和试验方法	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
112	EN 868-7-1999	经消毒的医疗器械用包装材料和系统 第7部分：生产经氧化乙烯或辐射消毒的医用热密封包所用的粘性涂覆纸	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 methods
113	EN 868-8-1999	经消毒的医疗器械用包装材料和系统 第8部分：符合EN 285的蒸汽消毒器用可重复使用的消毒容器 要求和试验	Packaging materials and systems for medical devices which are to be sterilized - Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 - Requirements and test methods

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114	EN 868-9-2000	经消毒的医疗器械用包装材料和系统 第9部分：生产热密封袋、卷轴和盖的聚烯烃非涂层非编织材料 要求和试	Packaging materials and systems for medical devices which are to be sterilized - Part 9: Uncoated nonwoven materials of polyolefines for use in the manufacture of heat sealable pouches, reels and lids - Requirements
115	EN 928-1995	玻璃试管诊断系统 关于玻璃试管诊断医疗设备的EN 29001、EN 46001、EN 29002、EN 46002的应用指南	In vitro diagnostic systems - Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for in vitro diagnostic medical
116	EN 980-2003	医疗器械标签用图形符号	Graphical symbols for use in the labelling of medical devices
117	EN 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 (ISO 10079-1:1999)
118	EN 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 (ISO 10079-2:1999)
119	EN 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 (ISO 10079-3:1999)
120	EN ISO 10993-1-2003	医疗器械的生物学评价　第1部分：评价与试验	Biological evaluation of medical devices - Part 1: Evaluation and testing (ISO 10993-1:2003)
121	EN ISO 10993-10-2002	医疗器械的生物学评价　第10部分：刺激与致敏试验	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity (ISO 10993-10:2002)
122	EN ISO 10993-11-1995	医疗器械的生物学评价　第11部分：全身毒性试验	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:1993)
123	EN ISO 10993-12-1996	医疗器械的生物学评价　第12部分：样品制备和参照物	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:1996)
124	EN ISO 10993-13-1998	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 polymeric medical devices (ISO 10993-13:1998)
125	EN 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与合格鉴定	Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics (ISO 10993-14:2001)
126	EN 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 (ISO 10993-15:2000)
127	EN ISO 10993-16-1997	医疗器械的生物学评价　第16部分：降解产物与可容出物的毒物动力学研究设计	Biological evaluation of medical devices - Part 16: Toxickinetic study design for degradation products and leachables (ISO 10993-16:1997)
128	EN ISO 10993-17-2002	医疗器械的生物学评价　第17部分：可滤物质允许权限的评定	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances (ISO 10993-17:2002)
129	EN ISO 10993-2-1998	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 requirements (ISO 10993-2:1992)
130	EN ISO 10993-4-2002	医疗器械的生物学评价 第4部分:与血液相互作用的试验选择	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2002)
131	EN ISO 10993-5-1999	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 cytotoxicity (ISO 10993-5:1999)
132	EN ISO 10993-7-1995	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 (ISO 10993-7:1995)
133	EN ISO 10993-8-2000	医疗器械的生物学评价　第8部分：生物学试验参照样品的选择和定性	Biological evaluation of medical devices - Part 8: Selection and qualification of reference materials for biological tests (ISO 10993-8:2000)
134	EN ISO 10993-9-1999	医疗器械的生物学评价　第9部分：潜在降解产物的定性与定量总则	Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products (ISO
135	EN ISO 11737-2-2000	医疗器械灭菌　微生物学方法　第2部分：确认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 validation of a sterilization process (ISO 11737-
136	EN ISO 13485-2003	医疗器械 质量管理体系　　管理用途的要求	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
137	EN ISO 14155-1-2003	人用医疗器械的临床调查 第1部分：一般要求	Clinical investigation of medical devices for human subjects - Part 1: General requirements (ISO 14155-1:2003)
138	EN ISO 14155-2-2003	人体临床检查用医疗装置　第2部分：临床检查计划	Clinical investigation of medical devices for human subjects - Part 2: Clinical investigation plans (ISO 14155-2:2003)
139	EN 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 sterilants (ISO 14160:1998)
140	EN ISO 14161-2000	医疗保健产品灭菌　生物指示物　选择、使用和检验结果解释指南	Sterilization of health care products - Biological indicators - Guidance for the selection, use and interpretation of results (ISO 14161:2000)
141	EN ISO 14937-2000	医疗保健产品灭菌　消毒剂的特性及医疗装置消毒的开发、确认和程序控制的一般要求	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 (ISO
142	EN ISO 14971-2000+A1-2003	医疗器械　对医疗器械风险管理的应用	Medical devices - Application of risk management to medical devices (ISO 14971:2000)
143	EN ISO 15225-2000	命名　用于管理资料交流的医疗器械命名系统规范	Nomenclature - Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange (ISO 15225:2000)
144	EN ISO 15225/prA1-2002	命名　用于管理资料交流的医疗器械命名系统规范　修改1	Nomenclature - Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange; Amendment 1 (ISO 15225:2000/DAM 1:2002)
145	EN ISO 17511-2003	体外诊断医疗装置　生物样品的定量测量　已知校正器及控制材料值的计量跟踪性	In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials (ISO 17511:2003)
146	EN ISO 18153-2003	体外诊断医疗装置　生物样品的定量测量　用已知校准器和控制材料确定酶中催化剂浓度值的计量可跟踪性	In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values for catalytic concentration of enzymes assigned to calibrators and control materials
147	EN ISO 7405-1997	牙科学　用于牙科的医疗器械生物相容性临床前评价　牙科材料的试验方法	Dentistry - Preclinical evaluation of biocompatibility of medical devices used in dentistry - Test methods for dental materials (ISO 7405:1997)
148	EN ISO 9626-1995+A1-2002	供制造医疗器械用的不锈刚针管	Stainless steel needle tubing for the manufacture of medical devices (ISO 9626:1991)
149	ENV 1064-1993	医疗信息学 标准通讯协议 计算机辅助心电图学	Medical informatics - Standard communication protocol - Computer-assisted electrocardiography
150	ENV 1068-1993	医疗信息学 保健信息交换 代码方案注册	Medical informatics - Healthcare information interchange - Registration of coding schemes
151	ENV 12017-1997	医疗信息学　医疗信息学词汇(MIVoc)	Medical Informatics - Medical Informatics Vocabulary (MIVoc)
152	ENV 12052-1997	医疗信息学　医疗成像传送（MEDICOM）	Medical informatics - Medical Imaging Communication (MEDICOM)
153	ENV 12264-1997	医疗信息学　概念系统完备结构　警告表述模型	Medical informatics - Categorical structures of systems of concepts - Model for representation of sematics

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154	ENV 12388-1996	医疗信息学　保健中数字签字服务算法	Medical informatics - Algorithm for Digital Signature Services in Health
155	ENV 12435-1999	医疗信息学　健康学中测量结果的表述	Medical Informatics - Expression of the results of measurements in health sciences
156	ENV 12443-1999	医疗信息学　保健信息框架(HIF)	Medical informatics - Healthcare Information Framework (HIF)
157	ENV 12611-1997	医学信息学　概念体系的范畴结构　医疗器械	Medical informatics - Categorial structure of systems of concepts - Medical devices
158	ENV 12623-1997	医学信息学　在医疗图象传送中的媒介质交换（MI-MEDICOM）	Medical Informatics - Media Interchange in Medical Imaging Communications (MI-MEDICOM)
159	ENV 12967-1-1998	医疗信息学 保健信息系统结构（HISA） 第1部分：保健中间层	Medical informatics - Healthcare Information System Architecture (HISA) - Part 1: Healthcare middleware layer
160	ENV 13004-1999	用于管理数据交换的医疗设备命名系统 关于临时系统的建议和未来系统的原则	Nomenclature system for medical devices for the purposes of regulatory data exchange - Recommendations for an interim system and rules for a future system
161	ENV 13607-2000	健康信息学 医疗处方信息交换信息	Health informatics - Messages for the exchange of information on medicine prescription
162	ENV 13735-2000	健康信息学 与患者相关的医疗器械的互操作性	Health informatics - Interoperability of patient connected medical devices
163	ENV 13939-2001	健康信息 医疗数据交换 HIS/RIS-PACK和HIS/RIS 程式接口	Health informatics - Medical Data Interchange: HIS/RIS-PACS and HIS/RIS - Modality Interface
164	ENV 737-6-2003	医疗气体管道系统 第6部分：压缩医疗气体和真空用终端部件用探针的尺寸	Medical gas pipeline systems - Part 6: Dimensions and allocation of probes for terminal units for compressed medical gases and vacuum
165	HD 364 S2-1983	医疗X光设备用高压电缆插头和插座连接	High-voltage cable plug and socket connections for medical X-ray
166	HD 513 S1-1989	医疗诊断用最大旋转阳极X射线管对称辐射场的测定	Determination of the maximum symmetrical radiation field from a rotating anode X-ray tube for medical diagnosis
167	IEEE 1073-1996	医疗设备通讯的总论和框架	(Medical device communications - Overview and framework)
168	IEEE 1073.3.1a-2000	医疗通信装置.传送轮廓.连接模式.修改件1:改正和分类	(Medical device communications - Transport profile - Connection mode; Amendment 1: Corrections and clarifications)
169	IEEE 1073.3.2-2000	医疗装置通信.传输层.连接IrDA基电缆	(Medical device communications - Transport profile - IrDA based cable connected)
170	IEEE 1073.4.1-2000	医疗装置通信.物理层接口.电缆连结	(Medical device communications - Physical layer interface - Cable
171	prEN 13159-1999	带氧气的医疗设备的兼容性	Compatibility of medical equipment with oxygen
172	prEN 13824-2002	医疗器械的消毒 无菌加工的验证和常规控制 要求和指南	Sterilization of medical devices - Validation and routine control of aseptic processes - Requirements and guidance
173	prEN 14254-2001	体外诊断医疗设备 除血液外从人体采集的样品一次性贮存容器	In vitro diagnostic medical devices - Single-use receptacles for the collection of specimens, other than blood, from humans
174	prEN 14476-2002	化学防腐剂和消毒剂 人类医疗用化学防腐剂和消毒剂的杀病毒定量悬浮试验 试验方法和要求（2相/1段）	Chemical disinfectants and antiseptics - Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine - Test method and requirements (phase 2/step 1)
175	prEN 389-1990	非活性医疗器械的标签	Labelling of non-active medical devices
176	prEN 45502-2-1-2003	活动可植入的医疗器件 第2-1部分：对治疗心动过缓的活动可植入医疗器件(心脏起搏器)的特殊要求.	Active implantable medical devices - Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrythmia (cardiac pacemakers)
177	prEN 45502-2-2-1998	活动可科植入医疗器件 第2-2部分：用于治疗心动过速的活性可植入医疗器件的特殊要求（包括植入除纤颤器）	Active implantable medical devices - Part 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrythmia (includes implantable defibrillators)
178	prEN 50339-2000	医疗设备　X射线胶片	Medical devices - X-ray film
179	prEN 55011-2003	工业、科学、医疗（ISM）射频设备　电磁骚扰特性　测量方法和限值	CISPR 11, Ed. 4.0: Industrial, scientific and medical (ISM) radio-frequency equipment - Electromagnetic disturbance characteristics - Limits and methods of measurement
180	prEN 556-2-2003	医疗器械的消毒 标明为“消过毒”的医疗器械的要求 第2部分：消毒处理的医疗器械的要求	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 2: Requirements for aseptically processed medical devices
181	prEN 60601-1-8-2003	医院电气设备　第1部分：安全通用要求　第8节：并列标准　报警系统　要求　试验和指南　医疗电子和电气	Medical electrical equipment - Part 1-8: General requirements for safety; Collateral standard: Alarm systems; General requirements, tests and guidance for alarm systems in medical electrical equipment and medical
182	prEN 61010-2-041-1996	测量、控制和实验室用电气设备的安全要求　第2 - 41部分：医疗材料处理及实验室加工用蒸压器的的特殊要求	Draft IEC 1010-2-041: Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-041: Particular requirements for autoclaves using steam for the treatment of medical materials, and for laboratory processes
183	prEN 61681-1-2000	超声学　场安全　第1部分：医疗诊断超声波场分类表	IEC 61681-1: Ultrasonics - Field safety - Part 1: Classification scheme for medical diagnostic ultrasonic fields
184	prEN 61814-1997	人体接触电极器具　没有医疗监督条件下使用的安全要求	IEC 61814: Appliances with human body contact electrodes - Safety requirements for use without medical supervision
185	prEN 61948-1-1998	核医疗仪　特性和试验条件　第1部分：辐射计数系统	IEC 61948-1: Nuclear medicine instrumentation - Characteristics and test conditions - Part 1: Radiation counting systems
186	prEN 61948-2-1998	核医疗仪　特性和试验条件　第2部分：闪光照相机和旋转X线体层照相机	IEC 61948-2: Nuclear medicine instrumentation - Characteristics and test conditions - Part 2: Scintillation cameras and rotational tomographs
187	prEN 61973-2000	超声学　场特性　测定医疗诊断超声场安全分类曝光参数的试验方法	IEC 61973: Ultrasonics - Field characterisation - Test methods for the determination of exposure parameters for the safety classification of medical diagnostic ultrasonic fields
188	prEN ISO 10993-3-2003	医疗器械的生物学评价　第3部分：遗传毒性、致癌性和生殖毒性试验	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO/FDIS 10993-3:2003) / Note: Intended as replacement for EN 30993-3 (1993-12).
189	prEN ISO 17664-2003	医疗装置的消毒　由制造商提供的可消毒装置回收利用信息	Sterilization of medical devices - Information to be provided by the manufacturer for the reprocessing of resterilizable devices (ISO/FDIS 17664:2003)
190	prENV 12265-1995	医疗信息学　电子保健记录体系结构	Medical informatics - Electronic healthcare record architecture
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