

## LIST OF INTERNATIONAL STANDARDS FOR MEDICAL DEVICES

NO	STANDARD	DESCRIPTION
1.	ISO 13485: 2003	Medical Devices: Quality Management System: Requirements For Regulatory Purposes
2.	EN540	Clinical Investigation of Medical Devices For Human
3.	EN285	Sterilization – Steam Sterilizer – Large Sterilizers
4.	ISO 14971:2000	Medical Devices : Application of risk management to medical devices
5.	EN550	Sterilization of Medical Device –Validation and routine control of ethylene oxide sterilization appliances for household and similar purposes, electric tools and similar electric apparatus
6.	EN552	Sterilization of Medical Device- Validation and routine control of sterilization by irradiation
7.	EN554	Sterilization of Medical Device by Moist Heat
8.	EN556	Sterilization of Medical Device – Requirement for terminally-sterilized devices to be labeled Sterile polyurethane thermal insulation and outer casing of polyethylene.
9.	EN556-1: 2001	Sterilization of Medical Device – Part1: Requirements for terminally sterilized medical devices
10.	EN793	Particular Requirements for Safety of Medical Supply Units
11.	EN867-2	Non Biological System for use in Sterilizers Part 2: Process Indicator (Class A)
12.	EN867-3	Non Biological System for use in Sterilizers Part 2: Process Indicator for Class B for use in the Bowie and Dick Test
13.	EN868-1	Packaging Materials and Systems for Medical Devices which are to be sterilized – Part 1: General Requirements and Test Method
14.	EN980A1	Graphical Symbols for use in the labeling of medical devices
15.	EN1401	Information supplied by the manufacturer with medical devices
16.	EN1174-1	Sterilization of Medical Device – Estimation of the population of Micro Organisms on Product – Part 1: Color Coding
17.	EN1174-2	Sterilization of Medical Device – Estimation of the population of Micro Organisms on Product – Part 2: Guidance
18.	EN1174-3	Sterilization of Medical Device – Estimation of the population of Micro Organisms on Product – Part 3: Guide to the methods for validation of microbiological techniques
19.	EN1422	Sterilizers for Medical Purposes – Ethylene Oxide Sterilizers – Requirements and methods
20.	EN1639	Dentistry – Medical Devices for Dentistry - Instruments
21.	EN1641	Dentistry – Medical Devices for Dentistry - Material
22.	EN1642	Dentistry – Medical Devices for Dentistry – Dental Implants

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23.	EN1782	Tracheal Tubes and Connectors
24.	EN1789:1999/A1: 2003	Medical Vehicles and their equipment – Road Ambulances
25.	EN1865	Specifications for stretchers and other patient handling equipment used in road ambulances
26.	EN ISO 8395	Oxygen Connectors for Medical Use – Safety Requirement
27.	EN ISO 10079-1	Medical Suction Equipment – Part 1: Electrically Powered Suction Equipment Safety Requirement
28.	EN ISO 10079-2	Medical Suction Equipment – Part 2: Manually powered suction equipment (ISO 10079-2:1999)
29.	EN ISO 10079-3	Medical Suction Equipment – Part 3: Suction Equipment powered from a vacuum or pressure source ( ISO 10079-3:1999)
30.	EN ISO 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and Testing (ISO 10993-1:1997)
31.	EN ISO 10993-4: 2002	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood (ISO 10993-4:2002)
32.	EN ISO 10993-5	Biological evaluation of medical devices – Part 5: Test for in vitro cytotoxicity (ISO 10993-7:1995)
33.	EN ISO 10993-7	Biological evaluation of medical devices – Part 7: Sterilization residuals (ISO 10993-7:1995)
34.	EN ISO 10993-8	Biological evaluation of medical devices – Part 8: Selection and qualification of reference for materials for biological tests (ISO 10993-8:2000)
35.	EN ISO 10993-9	Biological evaluation of medical devices – Part 9: Framework for identification and qualification of potential degradation products (ISO 10993-9:1999)
36.	EN ISO 10993-10: 2002	Biological evaluation of medical devices – Part 10: Tests for irritation and sensitization (ISO 10993-10:2002)
37.	EN ISO 10993-12	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials (ISO 10993-1:1996)
38.	EN ISO 10993-13	Biological evaluation of medical devices – Part 13: Identification and quantification of degradation products from polymeric medical devices (ISO 10993-12:1998)
39.	EN ISO 10993-14	Biological evaluation of medical devices – Part 14: Identification and quantification of degradation products from ceramics (ISO 10993-14:2001)
40.	EN ISO 10993-15	Biological evaluation of medical devices – Part 15: Identification and quantification of degradation products from metal and alloys (ISO 10993-15:2000)
41.	EN ISO 10993-16	Biological evaluation of medical devices – Part 16: Toxicokinetic study design for degradation products and leacheables (ISO 10993-16:1997)
42.	EN ISO 10993-17: 2002	Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leach able substances (ISO 10993-117:2002)
43.	EN 12010	Non active surgical implants – Joint replacement implants – Particular requirements

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44.	ISO 12572 ; Pt 10	Guide for evaluation of medical devices for biological hazards : Part 10 : Methods of biological testing and evaluation of dentals materials
45.	ISO 7405	Dentistry – Preclinical evaluation of biocompatibility of medical devices used in dentistry –test method for dental materials
46.	ISO 9626	Stainless steel needle tubing for manufacturer of medical devices
47.	ISO 12572 ; Pt 11	Guide for evaluation of medical devices for biological hazards ; Part 11 : Methods of test for eye irritation
48.	ISO 10993-2	Biological evaluation of medical devices : part 2 : Animal welfare requirements
49.	ISO 10993-3	Biological evaluation of medical devices: part 3: Test for genotoxicity, carcinogenicity and reproductive toxicity
50.	ISO 10993-5	Biological evaluation of medical devices. Part 5: Tests for in vitro cytotoxicity
51.	ASTM 13.01	Annual book of ASTM standards: Section 13: Medical Devices and Services: Volume 13.01: Medical Devices: Emergency medical services
52.	ISO 10993 Pt 11	Biological evaluation of medical devices; Part 11: Test for systematic toxicity
53.	BS EN 46001	Specification for application of EN ISO 9001 to the manufacturer of medical devices
54.	BS EN 46002	Specification for application of EN ISO 9002 to the manufacturer of medical devices
55.	ISO 11135	Medical devices- Validation and routine control of ethylene oxide sterilization
56.	DS EN 46001	Quality System- Medical devices- Particular requirements for the application of EN 29001
57.	DS EN 46002	Quality system- Medical devices- Particular requirements for the application of EN 29002
58.	AAMI/OPEO	Guideline for industrial ethylene oxide sterilization of medical devices: Process design validation routine sterilization
59.	ISO 10993-6	Biological evaluation of medical devices: Part 6 : Test for local effect after implantation
60.	ISO 10993-3	Biological evaluation of medical devices: Part 3 : test for genotoxicity, carcinogenicity and reproductive toxicity.
61.	BS EN 724	Guidance on the application of EN 29001 and EN 46001 and EN 29002 and EN 46002 for non-active medical devices
62.	BS EN 30993-6: ISO 10993-6	Biological evaluation of medical devices: Part 6: Test for local effects after implantation
63.	BS EN 475	Medical devices- Electrically-generated alarm signals
64.	ISO 11737-1	Sterilization of medical devices- Microbiological methods: part 1: Estimation of population of microorganisms on products
65.	ANSI/AAMI OPEO- 12	Guideline for industrial ethylene oxide sterilization of medical devices: process design, validation, routine sterilization
66.	DIN EN 30993-6	Biological evaluation of medical devices- Test for local effects after implantation ( ISO 10993-6: 1994)

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67	DIN EN ISO 9626	Stainless steel needle tubing for manufacturer of medical devices
68	BS 5736:Part 1	Evaluation of medical devices for biological hazards: part 1; Guide for the selection of biological methods
69	BS 5736:Part 2	Evaluation of medical devices for biological hazards: part 2; Method of testing by tissue implantation
70	BS 5736: Part 4	Evaluation of medical device for biological hazards: part 4: Method of test for intracutaneous reactivity of extract from medical devices.
71	BS 5736: Part 5	Evaluation of medical device for biological hazards: part 5: Method of test for systematic toxicity; assessment of pyrogenicity in rabbits of extracts from medical devices
72	BS 5736: Part 6	Evaluation of medical device for biological hazards: part 6: Method of test for sensitization: assessment of the potential of medical devices to produce delayed contact dermatitis
73	BS 5736: Part 7	Evaluation of medical device for biological hazards: part 7: Method of test for skin irritation of extracts from medical devices
74	BS 5736: Part 8	Evaluation of medical device for biological hazards: part 8: Method of test for skin irritation of solid medical devices
75	BS 5736: Part 9	Evaluation of medical device for biological hazards: part 9: Method of test for eye irritation
76	BS 5736: Part 10	Evaluation of medical device for biological hazards: part 10: Method of test for toxicity to cells in culture of extract from medical devices.
77	BS 5736: Part 11	Evaluation of medical device for biological hazards: part 11: Method of test for hemolysis
78	ISO 14155	Clinical investigation of medical devices
79	AS/NZS 3551	Technical management programs for medical devices
80	BS 7547	Stainless steel needle tubing for the manufacturer of medical devices
81	BS EN 928	Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for in vitro diagnostic medical devices
82	DS/EN 475	Medical devices- electrically-generated alarm signals
83	DIN EN 46002	Quality systems Medical devices particular requirements for the application of EN ISO 9002
84	DIN EN 46001	Quality systems Medical devices particular requirements for the application of EN ISO 9001
85	DIN EN 1640	Medical Devices for dentistry equipment
86	ANSI/AAMI ST35	Safe handling and biological decontamination of medical devices in healthcare facilities and in non clinical settings
87	AS/NZS 2696	Medical Devices-Polymer Urethral catheters for general medical use
88	DIN EN 475	Medical Devices- Electrically generated alarm signals to part of the body
89	BS ISO/IEC 14709-1	Information technology- Configuration of Customer Premises Cabling (CPC) for application Part 1: ISDN basic access

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90	DIN EN 46001	Quality system- Medical devices- Particular requirements for the application of EN 29001
91	BS EN ISO 7405	Dentistry- Preclinical evaluation of biocompatibility of medical devices used in dentistry- Test Methods for dentals materials
94	BS EN 1441	Medical Devices- Risk Analysis
95	BS EN 45502-1	Active Implantable medical devices Part 1: General requirements for safety marking and information to be provide by the manufacturer.
96	BS EN 868-1	Packaging materials and systems for medical devices which are to be sterilized- Part 1: General requirements and test methods
97	ISO 11607	Packaging for terminally sterilized medical devices
98	DIN EN 868-1	Packaging materials and systems for medicals devices which are to be sterilized-Part 1: General requirements and test methods.
99	ISO 14160	Sterilization of single use medical devices incorporating materials of animals origin- Validation by liquid sterilants
100	ISO 15225:2000	Nomenclature-Specification for a nomenclature system for medical devices for purposes of regulatory data exchange
101	IEC 60601-1-1-1:2000	Medical Device Equipment: Part 1 General Requirement For safety- Collateral standard: safety requirements for medical electrical systems