Active Implantable Medical Devices Harmonized Standards

Note: This list of Active Implantable Medical Devices Harmonized Standards is from the Web Site: http://www.newapproach.org

European Standards Bodies	Standard reference	Titles	Ratification date	Publication OJ
CEN	EN 540	Clinical investigation of medical devices for humans	1993	C 181 of 1999-06-26
CEN	EN 550	Sterilization of medical devices - Validation and routine control of ethylene oxide sterilisation	1994	C 181 of 1999-06-26
CEN	EN 552	Sterilization of medical devices - Validation and routine control of sterilisation by irradiation	1994	C 181 of 1999-06-26
CEN	EN 554	Sterilization of medical devices - Validation and routine control of sterilisation by moist heat	1994	C 181 of 1999-06-26
CEN	EN 556	Sterilization of medical devices - requirements for medical devices to be labelled "Sterile"	1994	C 181 of 1999-06-26
CEN	EN 868-1	Packaging materials and systems for medical devices which are to be sterilized - Part 1 : general requirements and test methods	1997	C 181 of 1999-06-26
CEN	EN 980 A1	Graphical symbols for use in the labelling of medical devices	1996 1999	C 293 of 2000-10-14
CEN	EN 1041	Information supplied by the manufacturer with medical devices	1998	C 181 of 1999-06-26
CEN	EN 1174-1	Sterilization of medical devices - Estimation of the population of micro-organisms on product – Part 1 : requirements	1996	C 181 of 1999-06-26
CEN	EN 1174-2	Sterilization of medical devices - Estimation of the population of micro-organisms on product – Part 2 : guidance	1996	C 181 of 1999-06-26
CEN	EN 1174-3	Sterilization of medical devices - Estimation of the population of micro-organisms on product – Part 3 : guide to the methods for validation of microbiological techniques	1996	C 181 of 1999-06-26
CEN	EN 1441	Medical devices – risk analysis	1997	C 181 of 1999-06-26
CEN	EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing (ISO 10993-1:1997)	1997	C 181 of 1999-06-26
CEN	EN ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO	1999	C 288 of 1999-10-09

		10993-5:1999)		
CEN	EN ISO 10993-9	Biological evaluation of medical devices – Part 9: Framework for identification and quantification of potential degradation products (ISO 10993-9:1999)	1999	C 227 of 1999-08-10
CEN	EN ISO 10993-10	Biological evaluation of medical devices - Part 10 : tests for irritation and sensitization (ISO 10993-10:1995)	1995	C 181 of 1999-06-26
CEN	EN ISO 10993-12	Biological evaluation of medical devices - Part 12 : sample preparation and reference materials (ISO 10993-12:1996)	1996	C 181 of 1999-06-26
CEN	EN ISO 10993-13	Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices (ISO 10993-13:1998)	1998	C 227 of 1999-08-10
CEN	EN ISO 10993-16	Biological evaluation of medical devices – Part 16: toxicokinetic study design for degradation products and leachables (ISO 10993-16:1997)	1997	C 181 of 1999-06-26
CEN	EN 30993-3	Biological evaluation of medical devices - Part 3 : tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:1992)	1993	C 181 of 1999-06-26
CEN	EN 30993-4	Biological evaluation of medical devices - Part 4 : selection of tests for interactions with blood (ISO 10993-4:1992)	1993	C 181 of 1999-06-26
CEN	EN 30993-5	Biological evaluation of medical devices - Part 5 : tests for cytotoxicity - in vitro methods (ISO 10993-5:1992)	1993	C 181 of 1999-06-26
CEN	EN 30993-6	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:1994)	1994	C 181 of 1999-06-26
CEN	EN 30993-7	Biological evaluation of medical devices - Part 7: ethylene oxide sterilisation residuals (ISO 10993-7:1995)	1995	C 293 of 2000-10-14
CEN	EN 30993-11	Biological evaluation of medical devices - Part 11: tests for systemic toxicity (ISO 10993-11:1993)	1995	C 181 of 1999-06-26
CEN	EN 45502-1	Active implantable medical devices – Part 1: General requirements for safety, marking and information to be provided by the manufacturer	1997	C 268 of 1998-08-27
CEN/ CENELEC	EN 46001	Quality systems - Medical devices - Particular requirements for the application of EN ISO 9001	1995	C 181 of 1999-06-26
CEN/ CENELEC	EN 46002	Quality systems - Medical devices - Particular requirements for the application of EN ISO 9002	1995	C 181 of 1999-06-26
CEN/ CENELEC	EN 46003	Quality systems - Medical devices - Particular requirements for the application of EN ISO 9003	1999	C 293 of 2000-10-14

CENELEC	EN 50103	Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for the active (including active implantable) medical device industry	1994	C 181 of 1999-06-26
CENELEC	EN 60601-1	Medical electrical equipment. Part 1: General requirements for safety - IEC 601-1:1988	1990	C 181 of 1999-06-26
CENELEC	Amendment A1 to EN 60601-1	Medical electrical equipment. Part 1: General requirements for safety - IEC 601-1:1988/A1:1991	1992	C 181 of 1999-06-26
CENELEC	Amendment A2 to EN 60601-1	Medical electrical equipment. Part 1: General requirements for safety - IEC 601-1:1988/A2:1995 + corrigendum Jun. 1995	1995	C 181 of 1999-06-26
CENELEC	Amendment A13 to EN 60601-1	Medical electrical equipment. Part 1: General requirements for safety	1995	C 181 of 1999-06-26