Standards Manager Web Standards List

AAMI-Association for the Advancement of Medical Instrumentation

Id	Number	Title	Year	Organization	Page
1	13485	Medical devices-Quality management systems-Requirements for regulatory purposes	2020	AAMI	
2	RD47	Reprocessing of hemodialyzers - FDA RECOGNIZED	2020	AAMI	
3	ST67	Sterilization of health care products-Requirements and guidance for selecting a sterility assurance level (SAL) for products labeled sterile - FDA RECOGNIZED	2019	AAMI	
4	ST72	Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing	2019	AAMI	
5	TIR38	Medical device safety assurance case report guidance	2019	AAMI	
6	TIR75	Sorbent-based regenerative hemodialysis systems	2019	AAMI	
7	TIR97	Principles for medical device security - Postmarket risk management for device manufacturers	2019	AAMI	
8	TIR102	U.S. FDA 21 CFR mapping to the applicable regulatory requirement references in ISO 13485:2016 Quality Management Systems	2019	AAMI	
9	14117	Active implantable medical devices - Electromagnetic compatibility - EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization devices	2019	AAMI	
10	14971	Medical devices-Application of risk management to medical devices	2019	AAMI	
11	23500-1	Preparation and quality management of fluids for haemodialysis and related therapies - Part 1: General requirements	2019	AAMI	
12	23500-2	Preparation and quality management of fluids for haemodialysis and related therapies - Part 2: Water treatment equipment for haemodialysis applications and related therapies	2019	AAMI	
13	23500-3	Preparation and quality management of fluids for haemodialysis and related therapies - Part 3: Water for haemodialysis and related therapies	2019	AAMI	
14	23500-4	Preparation and quality management of fluids for haemodialysis and related therapies - Part 4: Concentrates for haemodialysis and related therapies	2019	AAMI	
15	23500-5	Preparation and quality management of fluids for haemodialysis and related therapies - Part 5: Quality of dialysis fluid for haemodialysis and related therapies	2019	AAMI	
16	81060-2	Non-invasive sphygmomanometers - Part 2: Clinical investigation of automated measurement type	2019	AAMI	
17	CR500	Basic Introduction to the IEC 60601 Series	2019	AAMI	
18	EQ93	Medical equipment management - Vocabulary used in medical equipment programs	2019	AAMI	
19	2700-1	Medical Devices and Medical Systems - Essential safety and performance requirements for equipment comprising the patient-centric integrated clinical environment (ICE) - Part 1: General requirements and conceptual model	2019	AAMI	
20	2800-1	Standard for Safety for Medical Device Interoperability	2019	AAMI	
21	11138-7	Sterilization of health care products - Biological indicators - Guidance for the selection, use, and interpretation of results	2019	AAMI	
22	11607-1	Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems, and packaging - Incorporates Amendment 1: 2014	2019	AAMI	
23	11607-2	Packaging for terminally sterilized medical devices-Part 2: Validation requirements for forming, sealing, and assembly processes - Incorporates Amendment 1: 2014	2019	AAMI	
24	HIT1000-1	Safety and effectiveness of health IT software and systems-Part 1: Fundamental concepts, principles, and requirements	2018	AAMI	
25	80369-1	Small bore connectors for liquids and gases in healthcare applications - Part 1: General requirements	2018	AAMI	
26	80601-2-30	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers - Incorporating Amendment A1: 2013	2018	AAMI	
27	60601-2-4	Medical electrical equipment - Part 2-4: Particular requirements for basic safety and essential performance of cardiac defibrillators	2018	AAMI	
28	TIR21900	Guidance for uncertainty analysis regarding the application of ISO/TS 10974	2018	AAMI	

29	TIR77	Technical Information Report Sorbent-based regenerative hemodialysis systems	2018	AAMI	
30	TIR68	Low and intermediate-level disinfection in healthcare settings for medical devices and patient care equipment and sterile processing environmental surfaces	2018	AAMI	
31	SW91	Classification of defects in health software	2018	AAMI	
32	60601-2-19	Medical Electrical Equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators - Corrected 9 April 2012: Includes change to subclauses 201.4.3.101, 201.9.6.2.1.101, and 201.12.1.107	2016	AAMI	
33	60601-2-20	Medical Electrical Equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators - Corrected 9 April 2012: Includes change to subclauses 201.4.3.101 and 201.9.6.2.1.101	2016	AAMI	
34	60601-2-21	Medical Electrical Equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers	2016	AAMI	
35	60601-2-50	Medical Electrical Equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment	2016	AAMI	
36	13485	Medical devices-Quality management systems-Requirements for regulatory purposes	2016	AAMI	0
37	15225	Medical devices - Quality management - Medical device nomenclature data structure	2016	AAMI	0
38	80369-5	Small-bore connectors for liquids and gases in healthcare applicationsùPart 5: Connectors for limb cuff inflation applications	2016	AAMI	0
39	80369-6	Small-bore connectors for liquids and gases in healthcare applications ù Part 6: Connectors for neuraxial applications	2016	AAMI	0
40	80369-20	Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods	2016	AAMI	0
41	TIR14	Contract sterilization using ethylene oxide	2016	AAMI	0
42	TIR35	Sterilization of health care products - Radiation sterilization - Alternative sampling plans for verification dose experiments and sterilization dose audits - Former designation: AAMI ST31, AAMI ST32, and AAMI TIR5	2016	AAMI	0
43	TIR57	Principles for medical device securityùRisk management	2016	AAMI	0
44	TIR65	Sustainability of medical devicesùElements of a responsible product life cycle	2016	AAMI	0
45	TIR74	Change summary for ISO 11135:2014, Sterilization of health care productsùEthylene oxideùRequirements for the development, validation and routine control of a sterilization process for medical devices	2016	AAMI	0
46	TIR48	Quality Management System (QMS) Recommendations on the Application of the U.S. FDA___s CGMP Final Rule on Combination Products	2015	AAMI	0
47	ST91	Flexible and semi-rigid endoscope processing in health care facilities	2015	AAMI	0
48	62366-1	Medical devices Part 1: Application of usability engineering to medical devices	2015	AAMI	0
49	80369-20	Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods	2015	AAMI	0
50	CN6	Small-bore connectors for liquids and gases in healthcare applications - Part 6: Connectors for neuraxial applications	2015	AAMI	0
51	EQ89	Guidance for the use of medical equipment maintenance strategies and procedures	2015	AAMI	0
52	HA60601-1-11	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 - FDA REC	2015	AAMI	0
53	SPHC	Sterile Processing In Healthcare Facilities Preparing for Accreditation Surveys - 2nd Edition	2014	AAMI	0
54	SPVVQ	Basic Concepts in Sterilization Processes Verification, Validation, And Qualification	2014	AAMI	0
55	DUG	Dialysis Water and Dialysate Recommendations: A User Guide	2014	AAMI	0
56	80601-2-58	Medical electrical equipment - Part 2-58: Particular requirements for basic safety and essential performance of lens removal and vitrectomy devices for ophthalmic surgery	2014	AAMI	0
57	23500	Guidance for the preparation and quality management of fluids for hemodialysis and related therapies	2014	AAMI	0
58	26722	Water treatment equipment for hemodialysis and related therapies	2014	AAMI	0
59	60601-1-2	MEDICAL ELECTRICAL EQUIPMENT Part 1-2: General requirements for basic safety and essential performance Collateral Standard: Electromagnetic disturbances Requirements and tests	2014	AAMI	0

60	5841-2	Implants for surgery - Cardiac pacemakers - Part 2: Reporting of clinical performance of populations of pulse generators or leads	2014	AAMI	0
61	10993-3	Biological evaluation of medical devices-Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity	2014	AAMI	0
62	11135	Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices	2014	AAMI	0
63	11140-1	Sterilization of health care products-Chemical indicators-Part 1: General requirements	2014	AAMI	0
64	11663	Quality of dialysis fluid for hemodialysis and related therapies	2014	AAMI	0
65	13958	Concentrates for hemodialysis and related therapies	2014	AAMI	0
66	13959	Water for hemodialysis and related therapies	2014	AAMI	0
67	14708-1	Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and for information to be provided by the manufacturer	2014	AAMI	0
68	TIR58	Water testing methodologies	2014	AAMI	0
69	TIR60	Common mode rejection in ECG monitoring	2014	AAMI	0
70	TIR61	Generating reports for human factors design validation results for external cardiac defibrillators	2014	AAMI	0
71	TIR62	Generating reports for the purpose of submitting defibrillation waveform data for evaluation	2014	AAMI	0
72	TIR63	Management of loaned critical and semi-critical medical devices that require sterilization or high-level disinfection	2014	AAMI	0
73	TIR34	Water for the reprocessing of medical devices	2014	AAMI	0
74	TIR38	Medical device safety assurance case report guidance	2014	AAMI	0
75	TIR50	Post-market surveillance of use error management	2014	AAMI	0
76	TIR51	Human factors engineering Guidance for contextual inquiry	2014	AAMI	0
77	TIR52	Environmental Monitoring For Terminally Sterilized Healthcare Products	2014	AAMI	0
78	TIR55	Human factors engineering for processing medical devices	2014	AAMI	0
79	TIR80001-2-5	Application of risk management for ITnetworks incorporating medical devices Part 2-5: Application guidance Guidance on distributed alarm systems	2014	AAMI	0
80	TIR80001-2-6	Application of risk management for ITnetworks incorporating medical - Application guidance - Part 2-6: Guidance for responsibility agreements	2014	AAMI	0
81	TIR80001-2-7	Application of risk management for ITnetworks incorporating medical - Application guidance - Part 2-7: Guidance for Healthcare Delivery Organizations (HDOs) on how to selfassess their conformance with IEC 80001-1	2014	AAMI	0
82	TIR16775	Packaging for terminally sterilized medical devices - Guidance on the application of ISO 11607-1 and ISO 11607-2	2014	AAMI	0
83	TIR17137	Cardiovascular implants and extracorporeal systems Cardiovascular absorbable implants	2014	AAMI	0
84	TIR17665-3	Sterilization of health care products - Moist Heat - Guidance on the designation of a medical product to a product family and processing category for steam sterilization	2014	AAMI	0
85	TIR37137	Cardiovascular biological evaluation of medical devices - Guidance for absorbable implants	2014	AAMI	0
86	TIR56	Guidance for the development, validation and routine control of an ethylene oxide sterilization process utilizing flexible bag systems for the sterilization of medical devices	2013	AAMI	0
87	TIR37	Sterilization of health care products-Radiation-Guidance on sterilization of biologics and tissue-based products	2013	AAMI	0
88	TIR49	Design of training and instructional materials for medical devices used in non-clinical environments	2013	AAMI	0
89	TIR13004	Sterilization of health care products - Radiation - Substantiation of a selected sterilization dose: Method VDmax SD	2013	AAMI	0
90	ST77	Containment devices for reusable medical device sterilization	2013	AAMI	0
91	ST58	Chemical sterilization and high-level disinfection in health care facilities	2013	AAMI	0
92	ST8	Hospital steam sterilizers - FDA RECOGNIZED	2013	AAMI	0
93	ST15883-2	Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.	2013	AAMI	0
94	TIR24971	Medical devices - Guidance on the application of ISO 14971	2013	AAMI	0

95	11137-2	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose	2013	AAMI	0
96	5840-3	Cardiovascular implants - Cardiac valve prostheses - Part 3: Heart valve substitutes implanted by transcatheter techniques	2013	AAMI	0
97	81060-2	Non-invasive sphygmomanometers - Part 2: Clinical investigation of automated measurement type	2013	AAMI	0
98	AT6	Autologous transfusion devices	2013	AAMI	0
99	BFTF	Building for the Future Construction and Renovation of Sterile Processing Facilities	2013	AAMI	0
100	EQ56	Recommended practice for a medical equipment management program	2013	AAMI	0
101	EC53	ECG cables and leadwires	2013	AAMI	0
102	NS4	Transcutaneous electrical nerve stimulators	2013	AAMI	0
103	ID54	Enteral feeding set adapters and connectors	2012	AAMI	0
104	PB70	Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities - FDA RECOGNIZED	2012	AAMI	0
105	EC57	Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms	2012	AAMI	0
106	EQ56	Recommended practice for a medical equipment management program	2012	AAMI	0
107	BF64	Leukocyte reduction filters	2012	AAMI	0
108	BF7	Blood transfusion microfilters	2012	AAMI	0
109	60601-2-47	Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems	2012	AAMI	0
110	27185	Cardiac rhythm management devices - Symbols to be used with cardiac rhythm management device labels, and information to be supplied - General requirements	2012	AAMI	0
111	60601-1-2	MEDICAL ELECTRICAL EQUIPMENT Part 1-2: General requirements for basic safety and essential performance Collateral Standard: Electromagnetic disturbances Requirements and tests	2012	AAMI	0
112	60601-2-16	Medical electrical equipment, Part 2-16: Particular requirements for basic safety and essential performance of hemodialysis, hemodiafiltration and hemofiltration equipment	2012	AAMI	0
113	25539-2	Cardiovascular implants - Endovascular devices - Part 2: Vascular stents	2012	AAMI	0
114	5361	Anaesthetic and Respiratory Equipment-Tracheal Tubes and Connectors	2012	AAMI	0
115	11137-2	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose	2012	AAMI	0
116	10993-12	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	2012	AAMI	0
117	11658	Cardiovascular implants and extracorporeal systems - Blood/tissue contact surface modifications for extracorporeal perfusion systems	2012	AAMI	0
118	15223-1	Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied - Part 1: General requirements	2012	AAMI	0
119	14117	Active implantable medical devices - Electromagnetic compatibility - EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization devices	2012	AAMI	0
120	13408-7	Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products	2012	AAMI	0
121	13022	Medical products containing viable human cells - Application of risk management and requirements for processing practices	2012	AAMI	0
122	TIR62348	Assessment of the impact of the most significant changes in Amendment 1 to IEC 60601-1:2005 and mapping of the clauses of IEC 60601-1:2005 to the previous edition	2012	AAMI	0
123	ST15883-3	Washer-disinfectors - Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers	2012	AAMI	0
124	SW87	Application of quality management system concepts to medical device data systems - FDA RECOGNIZED	2012	AAMI	0
125	TIR29	GUIDE FOR PROCESS CONTROL IN RADIATION STERILIZATION	2012	AAMI	0
126	ST79 A3	NULL	2012	AAMI	0
127	TIR15499	Biological evaluation of medical devices Guidance on the conduct of biological evaluation within a risk management process	2012	AAMI	0

128	TIR10974	Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device	2012	AAMI	0
129	TIR44	Non-invasive blood pressure motion artifact - Testing and evaluation of NIBP device performance in the presence of motion artifact	2012	AAMI	0
130	TIR45	Guidance on the use of AGILE practices in the development of medical device software	2012	AAMI	0
131	TIR80001-2-1	Application of risk management for IT-networks incorporating medical devices - Part 2-1: Step by step risk management of medical IT-networks; Practical applications and examples	2012	AAMI	0
132	TIR80001-2-2	Application of risk management for IT-networks incorporating medical devices - Part 2-2: Guidance for the disclosure and communication of medical device security needs, risks and controls	2012	AAMI	0
133	TIR80001-2-3	Application of risk management for IT-networks incorporating medical devices - Part 2-3: Guidance for Wireless Networks	2012	AAMI	0
134	TIR80001-2-4	Application of risk management for IT-networks incorporating medical devices ___ Part 2-4: General implementation guidance for healthcare delivery organizations	2012	AAMI	0
135	TIR19218-2	Medical devices - Hierarchal coding structure for adverse events - Part 2: Evaluation codes	2012	AAMI	0
136	TIR23810	Cardiovascular implants and artificial organs - Checklist for preoperative extracorporeal circulation equipment setup	2012	AAMI	0
137	TIR12417	NULL	2011	AAMI	0
138	TIR19218-1	Medical devices _ Hierarchal coding structure for adverse events _ Part 1: Event-type codes	2011	AAMI	0
139	ST79	Comprehensive guide to steam sterilization and sterility assurance in health care facilities - Incorporates Amendment 1: 2010; Amendment 2: 2011; Amendment 3: 2012 and Amendment 4: 2013	2011	AAMI	0
140	ST67	Sterilization of health care products-Requirements and guidance for selecting a sterility assurance level (SAL) for products labeled sterile - FDA RECOGNIZED	2011	AAMI	0
141	ST72	Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing	2011	AAMI	0
142	TIR30	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices - FDA RECOGNIZED	2011	AAMI	0
143	13408-1	Aseptic processing of health care products - Part 1: General requirements - Incorporates Amendment 1: 2013	2011	AAMI	0
144	14155	Clinical investigation of medical devices for human subjects Good clinical practice - Corrected 16 December 2011: Includes change to subclause 7.3	2011	AAMI	0
145	14160	Sterilization of health care products - Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives - Requirements for characterization, development, validation and routine control of a sterilization pr	2011	AAMI	0
146	10993-14	Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics	2011	AAMI	0
147	10993-15	Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys	2011	AAMI	0
148	25539-3	NULL	2011	AAMI	0
149	AT6	Autologous transfusion devices	2011	AAMI	0
150	BP22	Blood pressure transducers - Incorporates Errata: 08/2004	2011	AAMI	0
151	EC12	Disposable ECG electrodes - FDA RECOGNIZED	2010	AAMI	0
152	DF80	Medical electrical equipment_ Part 2-4: Particular requirements for the safety of cardiac defibrillators (including automated external defibrillators)	2010	AAMI	0
153	NS28	Intracranial pressure monitoring devices - FDA RECOGNIZED; Incorporates Errata: 06/2001	2010	AAMI	0
154	ES60601-1	Medical electrical equipment-Part 1: General requirements for basic safety and essential performance - Consolidated Reprint C1: 2009; Incorporating Amendment 1: 2012; Amendment 2: 2010	2010	AAMI	0
155	80001-1	Application of risk management for IT Networks incorporating medical devices - Part 1: Roles, responsibilities and activities	2010	AAMI	0
156	80369-1	Small bore connectors for liquids and gases in healthcare applications - Part 1: General requirements	2010	AAMI	0
157	18472	Sterilization of health care products-Biological and chemical indicators-Test equipment	2010	AAMI	0
158	20857	Sterilization of health care products - Dry heat - Requirements for the development, validation and routine control of a sterilization process for medical devices	2010	AAMI	0

159	60601-2-4	Medical electrical equipment - Part 2-4: Particular requirements for basic safety and essential performance of cardiac defibrillators	2010	AAMI	0
160	10993-16	Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables	2010	AAMI	0
161	10993-13	Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices	2010	AAMI	0
162	11137-3	Sterilization of health care products-Radiation-Part 3: Guidance on dosimetric aspects	2010	AAMI	0
163	11138-1	Sterilization of health care products - Biological indicators - Part 1: General requirements	2010	AAMI	0
164	11138-2	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes	2010	AAMI	0
165	11137-1	Sterilization of health care products-Radiation-Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices - Incorporates Amendment 1: 2013	2010	AAMI	0
166	7198	Cardiovascular implants-Tubular vascular prostheses	2010	AAMI	0
167	8637	Cardiovascular implants and extracorporeal systems-Hemodialyzers, hemodiafilters, hemofilters and hemoconcentrators Amendment 1 Revision to Figure 2: Main fitting dimensions of dialysis fluid inlet and outlet ports - Incorporates Amendment 1: 2013	2010	AAMI	0
168	8638	Cardiovascular implants and extracorporeal systems - Extracorporeal blood circuit for hemodialyzers, hemodiafilters and hemofilters	2010	AAMI	0
169	10993-2	Biological evaluation of medical devices - Part 2: Animal welfare requirements	2010	AAMI	0
170	10993-6	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation	2010	AAMI	0
171	10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	2010	AAMI	0
172	10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	2010	AAMI	0
173	14708-5	NULL	2010	AAMI	0
174	15223-2	Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied - Part 2: Symbol development, selection and validation	2010	AAMI	0
175	14971	Medical devices-Application of risk management to medical devices	2010	AAMI	0
176	15225	Medical devices - Quality management - Medical device nomenclature data structure	2010	AAMI	0
177	11140-1	Sterilization of health care products-Chemical indicators-Part 1: General requirements	2010	AAMI	0
178	11607-2	Packaging for terminally sterilized medical devices-Part 2: Validation requirements for forming, sealing, and assembly processes - Incorporates Amendment 1: 2014	2010	AAMI	0
179	11138-5	Sterilization of health care products-Biological indicators-Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes	2010	AAMI	0
180	11607-1	Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems, and packaging - Incorporates Amendment 1: 2014	2010	AAMI	0
181	11138-3	Sterilization of health care products-Biological indicators-art 3: Biological indicators for moist heat sterilization processes	2010	AAMI	0
182	11138-4	Sterilization of health care products-Biological indicators-Part 4: Biological indicators for dry heat sterilization processes	2010	AAMI	0
183	ST72	Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing	2010	AAMI	0
184	TIR12	Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers	2010	AAMI	0
185	TIR18	Guidance on electromagnetic compatibility of medical devices in healthcare facilities	2010	AAMI	0
186	ST77	Containment devices for reusable medical device sterilization	2010	AAMI	0
187	ST81	Sterilization of medical devices-Information to be provided by the manufacturer for the processing of resterilizable medical devices	2010	AAMI	0
188	ST79 A1	NULL	2010	AAMI	0
189	ST40	Table-top dry heat (heated air) sterilization and sterility assurance in health care facilitie	2010	AAMI	0
190	ST50	Dry heat (heated air) sterilizers - FDA RECOGNIZED	2010	AAMI	0

191	ST55	Table-top steam sterilizers - FDA RECOGNIZED	2010	AAMI	0
192	ST58	Chemical sterilization and high-level disinfection in health care facilities	2010	AAMI	0
193	TIR42	Evaluation of particulates associated with vascular medical devices	2010	AAMI	0
194	TIR39	NULL	2009	AAMI	0
195	TIR40	NULL	2009	AAMI	0
196	TIR17665-2	Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1	2009	AAMI	0
197	TIR62296	Considerations of unaddressed safety aspects in the second edition of IEC 60601-1 and proposals for new requirements	2009	AAMI	0
198	TIR80002-1	NULL	2009	AAMI	0
199	ST24	Automatic, general purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities	2009	AAMI	0
200	ST15883-1	NULL	2009	AAMI	0
201	TIR16	Microbiological aspects of ethylene oxide sterilization	2009	AAMI	0
202	TIR14	Contract sterilization using ethylene oxide	2009	AAMI	0
203	TIR15	Physical aspects of ethylene oxide sterilization	2009	AAMI	0
204	TIR28	Product adoption and process equivalence for ethylene oxide sterilization	2009	AAMI	0
205	TIR62354	NULL	2009	AAMI	0
206	11737-2	Sterilization of medical devices Microbiological methods Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	2009	AAMI	0
207	15674	Cardiovascular implants and artificial organs - Hard shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags	2009	AAMI	0
208	15675	Cardiovascular implants and artificial organs - Cardiopulmonary bypass systems - Arterial blood line filters	2009	AAMI	0
209	14937	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	2009	AAMI	0
210	14161	Sterilization of health care products - Biological indicators - Guidance for the selection, use and interpretation of results	2009	AAMI	0
211	13485	Medical devices-Quality management systems-Requirements for regulatory purposes	2009	AAMI	0
212	10993-9	Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products	2009	AAMI	0
213	10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	2009	AAMI	0
214	10993-4	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood - Incorporates Amendment 1: 2006	2009	AAMI	0
215	10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2009	AAMI	0
216	7199	Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators)	2009	AAMI	0
217	10993-16	Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables	2009	AAMI	0
218	11137-2	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose	2009	AAMI	0
219	10993-3	Biological evaluation of medical devices-Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity	2009	AAMI	0
220	60601-2-2	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgery equipment and high frequency surgical accessories	2009	AAMI	0
221	60601-2-19	Medical Electrical Equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators - Corrected 9 April 2012: Includes change to subclauses 201.4.3.101, 201.9.6.2.1.101, and 201.12.1.107	2009	AAMI	0
222	17665-2	Sterilization of health care products _ Moist heat _ Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1	2009	AAMI	0
223	26722	Water treatment equipment for hemodialysis and related therapies	2009	AAMI	0
224	25539-1	Cardiovascular implants-Endovascular devices-Part 1: Endovascular prostheses Amendment 1: Test methods - Incorporates Amendment 1: 2005	2009	AAMI	0
225	25539-1 A1	NULL	2009	AAMI	0

226	80601-2-30	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers - Incorporating Amendment A1: 2013	2009	AAMI	0
227	60601-2-50	Medical Electrical Equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment	2009	AAMI	0
228	60601-2-20	Medical Electrical Equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators - Corrected 9 April 2012: Includes change to subclauses 201.4.3.101 and 201.9.6.2.1.101	2009	AAMI	0
229	60601-2-21	Medical Electrical Equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers	2009	AAMI	0
230	ID26	Medical electrical equipment-Part 2: Particular requirements for the safety of infusion pumps and controllers	2009	AAMI	0
231	HE74	Human factors design process for medical devices	2009	AAMI	0
232	HE75	Human factors engineering Design of medical devices	2009	AAMI	0
233	NS4	Transcutaneous electrical nerve stimulators	2009	AAMI	0
234	PB70	Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities - FDA RECOGNIZED	2009	AAMI	0
235	RD62	NULL	2009	AAMI	0
236	RD52	Dialysate for hemodialysis	2009	AAMI	0
237	RD47	Reprocessing of hemodialyzers - FDA RECOGNIZED	2008	AAMI	0
238	ST8	Hospital steam sterilizers - FDA RECOGNIZED	2008	AAMI	0
239	RD5	Hemodialysis systems	2008	AAMI	0
240	EC53A	NULL	2008	AAMI	0
241	EC57	Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms	2008	AAMI	0
242	EQ56	Recommended practice for a medical equipment management program	2008	AAMI	0
243	BE78 A1	NULL	2008	AAMI	0
244	BE78	Biological evaluation of medical devices Part 10: Tests for irritation and delayed-type hypersensitivity	2008	AAMI	0
245	22442-3	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	2008	AAMI	0
246	25539-2	Cardiovascular implants - Endovascular devices - Part 2: Vascular stents	2008	AAMI	0
247	22442-1	Medical devices utilizing animal tissues and their derivatives-Part 1: Application of risk management	2008	AAMI	0
248	22442-2	Medical devices utilizing animal tissues and their derivatives-Part 2: Controls on sourcing, collection and handling	2008	AAMI	0
249	60601-2-16	Medical electrical equipment, Part 2-16: Particular requirements for basic safety and essential performance of hemodialysis, hemodiafiltration and hemofiltration equipment	2008	AAMI	0
250	10993-17	Biological evaluation of medical devices - Part 17: Methods for the establishment of allowable limits for leachable substances	2008	AAMI	0
251	10993-7 E2010	NULL	2008	AAMI	0
252	10993-7	Biological evaluation of medical devices-Part 7: Ethylene oxide sterilization residuals	2008	AAMI	0
253	14155-1	Clinical investigation of medical devices for human subjects -- Part 1: General requirements	2008	AAMI	0
254	14155-2	Clinical investigation of medical devices for human subjects -- Part 2: Clinical investigation plans	2008	AAMI	0
255	14160	Sterilization of health care products - Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives - Requirements for characterization, development, validation and routine control of a sterilization pr	2008	AAMI	0
256	14708-3	NULL	2008	AAMI	0
257	14708-4	NULL	2008	AAMI	0
258	15882	Sterilization of health care products - Chemical indicators - Guidance for selection, use and interpretation of results	2008	AAMI	0
259	13408-1	Aseptic processing of health care products - Part 1: General requirements - Incorporates Amendment 1: 2013	2008	AAMI	0

260	TIR31	PROCESS CHALLENGE DEVICES/TEST PACKS FOR USE IN HEALTH CARD FACILITIES	2008	AAMI	0
261	TIR22 A1	NULL	2008	AAMI	0
262	TIR17	Compatibility of materials subject to sterilization	2008	AAMI	0
263	ST79 A1	NULL	2008	AAMI	0
264	ST65	Processing of reusable surgical textiles for use in health care facilities - FDA RECOGNIZED	2008	AAMI	0
265	ST41 E2010	NULL	2008	AAMI	0
266	ST41	Ethylene oxide sterilization in health care facilities: Safety and effectiveness - FDA RECOGNIZED	2008	AAMI	0
267	ST55	Table-top steam sterilizers - FDA RECOGNIZED	2008	AAMI	0
268	TIR11135-2	NULL	2008	AAMI	0
269	TIR36	Validation of software for regulated processes	2007	AAMI	0
270	TIR37	Sterilization of health care products-Radiation-Guidance on sterilization of biologics and tissue-based products	2007	AAMI	0
271	TIR34	Water for the reprocessing of medical devices	2007	AAMI	0
272	TIR22	Guidance for ANSI/AAMI/ISO 11607, Packaging for terminally sterilized medical devices_ Part 1 and Part 2:2006	2007	AAMI	0
273	TIR22 A1	NULL	2007	AAMI	0
274	11140-3	Sterilization of health care products - Chemical indicators - Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test	2007	AAMI	0
275	11140-4	Sterilization of health care products - Chemical indicators - Part 4: Class 2 indicators as an alternative to Bowie and Dick test for detection of steam penetration	2007	AAMI	0
276	11140-5	Sterilization of health care products - Chemical indicators - Part 5: Class 2 indicators for Bowie and Dick air removal test sheets and packs	2007	AAMI	0
277	14971	Medical devices-Application of risk management to medical devices	2007	AAMI	0
278	15223-1 A1	NULL	2007	AAMI	0
279	15223-1	Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied - Part 1: General requirements	2007	AAMI	0
280	10993-6	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation	2007	AAMI	0
281	11135-1	Sterilization of health care products _ Ethylene oxide _ Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices	2007	AAMI	0
282	11135-2	Sterilization of health care products _ Ethylene Oxide _ Part 2: Guidance on the application of ISO 11135-1	2007	AAMI	0
283	22442-3	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	2007	AAMI	0
284	22442-2	Medical devices utilizing animal tissues and their derivatives-Part 2: Controls on sourcing, collection and handling	2007	AAMI	0
285	22442-1	Medical devices utilizing animal tissues and their derivatives-Part 1: Application of risk management	2007	AAMI	0
286	BF7	Blood transfusion microfilters	2007	AAMI	0
287	BF64	Leukocyte reduction filters	2007	AAMI	0
288	81060-1	Non-invasive sphygmomanometers - Part 1: Requirements and test methods for nonautomated measurement type	2007	AAMI	0
289	62366	Medical devices _Application of usability engineering to medical devices - Incorporates Amendment 1: 2013	2007	AAMI	0
290	EC71	Standard communications protocol for computer-assisted electrocardiography	2007	AAMI	0
291	EC38	Ambulatory electrocardiographs	2007	AAMI	0
292	EC13	Cardiac monitors, heart rate meters, and alarms	2007	AAMI	0
293	EC11	Diagnostic electrocardiographic devices	2007	AAMI	0
294	RD16	Hemodialyzers	2007	AAMI	0
295	RD17	NULL	2007	AAMI	0

296	PC69	Active implantable medical devices_ Electromagnetic compatibility_ EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators	2007	AAMI	0
297	RD61	NULL	2006	AAMI	0
298	NS28	Intracranial pressure monitoring devices - FDA RECOGNIZED; Incorporates Errata: 06/2001	2006	AAMI	0
299	BP22	Blood pressure transducers - Incorporates Errata: 08/2004	2006	AAMI	0
300	62304	Medical device software - Software life cycle processes	2006	AAMI	0
301	60601-2-50	Medical Electrical Equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment	2006	AAMI	0
302	60601-2-2	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgery equipment and high frequency surgical accessories	2006	AAMI	0
303	BE83	Biological evaluation of medical devices-Part 18: Chemical characterization of materials	2006	AAMI	0
304	BE78	Biological evaluation of medical devices Part 10: Tests for irritation and delayed-type hypersensitivity	2006	AAMI	0
305	18472	Sterilization of health care products-Biological and chemical indicators-Test equipment	2006	AAMI	0
306	15225	Medical devices - Quality management - Medical device nomenclature data structure	2006	AAMI	0
307	10993-19	Biological evaluation of medical devices _ Part 19: Physicochemical, morphological, and topographical characterization of materials	2006	AAMI	0
308	11137-3	Sterilization of health care products-Radiation-Part 3: Guidance on dosimetric aspects	2006	AAMI	0
309	11137-2	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose	2006	AAMI	0
310	11137-1	Sterilization of health care products-Radiation-Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices - Incorporates Amendment 1: 2013	2006	AAMI	0
311	11138-3	Sterilization of health care products-Biological indicators-art 3: Biological indicators for moist heat sterilization processes	2006	AAMI	0
312	11138-2	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes	2006	AAMI	0
313	11138-1	Sterilization of health care products - Biological indicators - Part 1: General requirements	2006	AAMI	0
314	10993-4	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood - Incorporates Amendment 1: 2006	2006	AAMI	0
315	10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	2006	AAMI	0
316	10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	2006	AAMI	0
317	10993-2	Biological evaluation of medical devices - Part 2: Animal welfare requirements	2006	AAMI	0
318	17665-1	Sterilization of health care products-Moist heat-Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices	2006	AAMI	0
319	11607-1	Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems, and packaging - Incorporates Amendment 1: 2014	2006	AAMI	0
320	11138-5	Sterilization of health care products-Biological indicators-Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes	2006	AAMI	0
321	11138-4	Sterilization of health care products-Biological indicators-Part 4: Biological indicators for dry heat sterilization processes	2006	AAMI	0
322	11607-2	Packaging for terminally sterilized medical devices-Part 2: Validation requirements for forming, sealing, and assembly processes - Incorporates Amendment 1: 2014	2006	AAMI	0
323	11737-1	Sterilization of health care products-Microbiological methods-Part 1: Determination of the population of microorganisms on product	2006	AAMI	0
324	13408-3	Aseptic processing of health care products - Part 3: Lyophilization	2006	AAMI	0
325	13408-5	Aseptic processing of health care products - Part 5: Sterilization in place	2006	AAMI	0
326	SP10	Manual, electronic, or automated sphygmomanometers	2006	AAMI	0
327	ST79 A2	NULL	2006	AAMI	0

328	TIR35	Sterilization of health care products - Radiation sterilization - Alternative sampling plans for verification dose experiments and sterilization dose audits - Former designation: AAMI ST31, AAMI ST32, and AAMI TIR5	2006	AAMI	0
329	TIR11139	Sterilization of health care products - Vocabulary	2006	AAMI	0
330	TIR10993-19	Biological evaluation of medical devices - Part 19: Physico-chemical, morphological and topographical characterization of materials	2006	AAMI	0
331	TIR10993-20	Biological evaluation of medical devices - Part 20: Principles and methods for immunotoxicology testing of medical devices	2006	AAMI	0
332	TIR62348	Assessment of the impact of the most significant changes in Amendment 1 to IEC 60601-1:2005 and mapping of the clauses of IEC 60601-1:2005 to the previous edition	2006	AAMI	0
333	TIR19218	NULL	2005	AAMI	0
334	TIR16142	Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices - 2006 printing	2005	AAMI	0
335	TIR33	Sterilization of health care products - Radiation - Substantiation of a selected sterilization dose - Method VDmax	2005	AAMI	0
336	ST58	Chemical sterilization and high-level disinfection in health care facilities	2005	AAMI	0
337	TIR11	Selection and use of protective apparel and surgical drapes in health care facilities	2005	AAMI	0
338	13408-6	Aseptic processing of health care products - Part 6: Isolator systems - Incorporates Amendment 1: 2013	2005	AAMI	0
339	13408-4	Aseptic processing of health care products - Part 4: Clean-in-place technologies	2005	AAMI	0
340	11140-1	Sterilization of health care products-Chemical indicators-Part 1: General requirements	2005	AAMI	0
341	5840	Cardiovascular implants Cardiac valve prostheses	2005	AAMI	0
342	25539-1	Cardiovascular implants-Endovascular devices-Part 1: Endovascular prostheses Amendment 1: Test methods - Incorporates Amendment 1: 2005	2005	AAMI	0
343	AT6	Autologous transfusion devices	2005	AAMI	0
344	60601-2-27	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment - Includes Errata: May 31, 2012	2005	AAMI	0
345	EC12	Disposable ECG electrodes - FDA RECOGNIZED	2005	AAMI	0
346	ES60601-1	Medical electrical equipment-Part 1: General requirements for basic safety and essential performance - Consolidated Reprint C1: 2009; Incorporating Amendment 1: 2012; Amendment 2: 2010	2005	AAMI	0
347	ID54	Enteral feeding set adapters and connectors	2005	AAMI	0
348	II36	Medical electrical equipment Part 2: Particular requirements for safety of baby incubators	2004	AAMI	0
349	II51	Medical electrical equipment Part 2: Particular requirements for safety of transport incubators	2004	AAMI	0
350	RD52	Dialysate for hemodialysis	2004	AAMI	0
351	EQ56	Recommended practice for a medical equipment management program	2004	AAMI	0
352	8637	Cardiovascular implants and extracorporeal systems-Hemodialyzers, hemodiafilters, hemofilters and hemoconcentrators Amendment 1 Revision to Figure 2: Main fitting dimensions of dialysis fluid inlet and outlet ports - Incorporates Amendment 1: 2013	2004	AAMI	0
353	10993-12	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	2004	AAMI	0
354	10993-13	Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices	2004	AAMI	0
355	11737-3	Sterilization of medical devices -- Microbiological methods -- Part 3: Guidance on evaluation and interpretation of bioburden data	2004	AAMI	0
356	15223	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplie	2004	AAMI	0
357	TIR12	Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers	2004	AAMI	0
358	TIR14	Contract sterilization using ethylene oxide	2004	AAMI	0
359	TIR32	Medical device software risk management	2004	AAMI	0

360	ST50	Dry heat (heated air) sterilizers - FDA RECOGNIZED	2004	AAMI	0
361	ST40	Table-top dry heat (heated air) sterilization and sterility assurance in health care facilitie	2004	AAMI	0
362	TIR14969	Medical devices-Quality management systems- Guidance on the application of ISO 13485:2003	2004	AAMI	0
363	TIR60878	Graphical symbols for electrical equipment in medical practice	2003	AAMI	0
364	ST35	Safe handling and biological decontamination of reusable medical devices in health care facilities and in nonclinical settings	2003	AAMI	0
365	TIR30	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices - FDA RECOGNIZED	2003	AAMI	0
366	14155-2	Clinical investigation of medical devices for human subjects -- Part 2: Clinical investigation plans	2003	AAMI	0
367	13408-2	Aseptic processing of health care products - Part 2: Filtration	2003	AAMI	0
368	13485	Medical devices-Quality management systems-Requirements for regulatory purposes	2003	AAMI	0
369	14155-1	Clinical investigation of medical devices for human subjects -- Part 1: General requirements	2003	AAMI	0
370	10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2003	AAMI	0
371	10993-3	Biological evaluation of medical devices-Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity	2003	AAMI	0
372	EC57	Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms	2003	AAMI	0
373	DF80	Medical electrical equipment_ Part 2-4: Particular requirements for the safety of cardiac defibrillators (including automated external defibrillators)	2003	AAMI	0
374	SP10	Manual, electronic, or automated sphygmomanometers	2003	AAMI	0
375	RD5	Hemodialysis systems	2003	AAMI	0
376	PB70	Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities - FDA RECOGNIZED	2003	AAMI	0
377	25539-1	Cardiovascular implants-Endovascular devices-Part 1: Endovascular prostheses Amendment 1: Test methods - Incorporates Amendment 1: 2005	2003	AAMI	0
378	60601-2-4	Medical electrical equipment - Part 2-4: Particular requirements for basic safety and essential performance of cardiac defibrillators	2002	AAMI	0
379	RD47	Reprocessing of hemodialyzers - FDA RECOGNIZED	2002	AAMI	0
380	RD16	Hemodialyzers	2002	AAMI	0
381	EC13	Cardiac monitors, heart rate meters, and alarms	2002	AAMI	0
382	10993-17	Biological evaluation of medical devices - Part 17: Methods for the establishment of allowable limits for leachable substances	2002	AAMI	0
383	TIR29	GUIDE FOR PROCESS CONTROL IN RADIATION STERILIZATION	2002	AAMI	0
384	ST46	Steam sterilization and sterility assurance in health care facilities	2002	AAMI	0
385	ST63	Sterilization of health care products_Requirements for the development, validation, and routine control of an industrial sterilization process for medical devices_Dry heat	2002	AAMI	0
386	ST72	Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing	2002	AAMI	0
387	TIR28	Product adoption and process equivalence for ethylene oxide sterilization	2001	AAMI	0
388	TIR20	Parametric release for ethylene oxide sterilization	2001	AAMI	0
389	SW68	Medical device software _ Software life cycle processes	2001	AAMI	0
390	10993-14	Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics	2001	AAMI	0
391	10993-8	Biological evaluation of medical devices _Part 8: Selection and qualification of reference materials for biological tests	2001	AAMI	0
392	14937	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	2001	AAMI	0
393	15675	Cardiovascular implants and artificial organs - Cardiopulmonary bypass systems - Arterial blood line filters	2001	AAMI	0

394	15674	Cardiovascular implants and artificial organs - Hard shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags	2001	AAMI	0
395	EC11	Diagnostic electrocardiographic devices	2001	AAMI	0
396	BP22	Blood pressure transducers - Incorporates Errata: 08/2004	2001	AAMI	0
397	EC71	Standard communications protocol for computer-assisted electrocardiography	2001	AAMI	0
398	EC53	ECG cables and leadwires	2001	AAMI	0
399	HF18	Electrosurgical devices	2001	AAMI	0
400	60601-1-2	MEDICAL ELECTRICAL EQUIPMENT Part 1-2: General requirements for basic safety and essential performance Collateral Standard: Electromagnetic disturbances Requirements and tests	2001	AAMI	0
401	60601-2-47	Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems	2001	AAMI	0
402	60601-2-50	Medical Electrical Equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment	2000	AAMI	0
403	60601-2-21	Medical Electrical Equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers	2000	AAMI	0
404	60601-1-4	Medical Electrical Equipment - Part 1-4: General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems	2000	AAMI	0
405	PAC49	Pacemaker emergency intervention system	2000	AAMI	0
406	15843	Sterilization of health care products_ Radiation sterilization_ Product families and sampling plans for verification dose experiments and sterilization dose audits, and frequency of sterilization dose audits	2000	AAMI	0
407	15225	Medical devices - Quality management - Medical device nomenclature data structure	2000	AAMI	0
408	14161	Sterilization of health care products - Biological indicators - Guidance for the selection, use and interpretation of results	2000	AAMI	0
409	10993-15	Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys	2000	AAMI	0
410	TIR16	Microbiological aspects of ethylene oxide sterilization	2000	AAMI	0
411	TIR26	Ventricular assist and heart replacement systems	2000	AAMI	0
412	TIR23	Signal Averaging	1999	AAMI	0
413	TIR24	Acquisition and use of physiologic waveform databases for testing of medical devices	1999	AAMI	0
414	TIR19 A1	NULL	1999	AAMI	0
415	ST66	Sterilization of health care products Chemical indicators Part 2: Class 2 indicators for air removal test	1999	AAMI	0
416	10993-9	Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products	1999	AAMI	0
417	10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	1999	AAMI	0
418	60601-2-30	Medical Electrical Equipment - Part 2-30: Particular Requirements for the Safety, Including Essential Performance, of Automatic Cycling Non-Invasive Blood Pressure Monitoring Equipment	1999	AAMI	0
419	60601-2-2	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgery equipment and high frequency surgical accessories	1998	AAMI	0
420	EC38	Ambulatory electrocardiographs	1998	AAMI	0
421	7198	Cardiovascular implants-Tubular vascular prostheses	1998	AAMI	0
422	10993-13	Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices	1998	AAMI	0
423	14160	Sterilization of health care products - Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives - Requirements for characterization, development, validation and routine control of a sterilization pr	1998	AAMI	0
424	11737-2	Sterilization of medical devices Microbiological methods Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	1998	AAMI	0

425	TIR21	Systems Used to Forecast Remaining Pacemaker Battery Service Life	1998	AAMI	0
426	TIR13	Principles of industrial moist heat sterilization	1997	AAMI	0
427	TIR14	Contract sterilization using ethylene oxide	1997	AAMI	0
428	10993-16	Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables	1997	AAMI	0
429	7199	Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators)	1996	AAMI	0
430	5840	Cardiovascular implants Cardiac valve prostheses	1996	AAMI	0
431	13488	Quality systems -- Medical devices -- Particular requirements for the application of ISO9002	1996	AAMI	0
432	ID54	Enteral feeding set adapters and connectors	1996	AAMI	0
433	NS14	Implantable spinal cord stimulators	1995	AAMI	0
434	NS15	Implantable peripheral nerve stimulators	1995	AAMI	0
435	EC53	ECG cables and leadwires	1995	AAMI	0
436	10993-7	Biological evaluation of medical devices-Part 7: Ethylene oxide sterilization residuals	1995	AAMI	0
437	11137	Sterilization of health care products -- Requirements for validation and routine control -- Radiation sterilization	1995	AAMI	0
438	11134	Sterilization of health care products -- Requirements for validation and routine control -- Industrial moist heat sterilization	1994	AAMI	0
439	11135	Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices	1994	AAMI	0
440	BP22	Blood pressure transducers - Incorporates Errata: 08/2004	1994	AAMI	0
441	60601-1-3	Medical Electrical Equipment - Part 1: General Requirements for Safety 3. Collateral Standard: General Requirements for Radiation Protection in Diagnostic X-Ray Equipment	1994	AAMI	0
442	60601-2-21	Medical Electrical Equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers	1994	AAMI	0
443	60601-2-25	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs	1993	AAMI	0
444	ST37	Flash sterilization- Steam sterilization of patient care items for immediate use	1993	AAMI	0
445	TIR9	Evaluation of Clinical Systems for Invasive Blood Pressure Monitoring	1992	AAMI	0
446	60601-2-20	Medical Electrical Equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators - Corrected 9 April 2012: Includes change to subclauses 201.4.3.101 and 201.9.6.2.1.101	1990	AAMI	0
447	60601-2-19	Medical Electrical Equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators - Corrected 9 April 2012: Includes change to subclauses 201.4.3.101, 201.9.6.2.1.101, and 201.12.1.107	1990	AAMI	0
448	TIR4	Apnea monitoring by means of thoracic impedance pneumography	1989	AAMI	0