Standards Manager Web Standards List

AAMI-Association for the Advancement of Medical Instrumentation

Id	Number	Title	Year	Organization	Page
1	EQ89	Guidance for the use of medical equipment maintenance strategies and procedures	2023	AAMI	
2	ISO 11137-3	NULL	2023	AAMI	
3	ISO TIR16775	NULL	2023	AAMI	
4	ISO TIR21387	NULL	2023	AAMI	
5	ST55	Table-top steam sterilizers - FDA RECOGNIZED	2023	AAMI	
6	ST108	Water for the processing of medical devices	2023	AAMI	
7	ST15883-1	Washer-disinfectors ù Part 1: General requirements, terms and definitions and tests	2023	AAMI	
8	ST15883-3	Washer-disinfectors - Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers	2023	AAMI	
9	SW96	Standard for medical device securityùSecurity risk management for device manufacturers	2023	AAMI	
10	TIR57	Principles for medical device securityùRisk management	2023	AAMI	
11	TIR63	Management of loaned critical and semi-critical medical devices that require sterilization or high-level disinfection	2023	AAMI	
12	TIR34971	Application of ISO 14971 to machine learning in artificial intelligenceùGuide	2023	AAMI	
13	UL 2800-1-1	Standard for Risk Concerns for Interoperable Medical Products	2022	AAMI	
14	UL 2800-1-2	Standard for Interoperable Item Development Life Cycle	2022	AAMI	
15	UL 2800-1-3	Standard for Interoperable Item Integration Life Cycle	2022	AAMI	
16	UL 2800-1	Standard for Medical Device Interoperability	2022	AAMI	
17	TIR104	Guidance on transferring health care products between radiation sterilization sources	2022	AAMI	
18	ST98	Cleaning validation of health care productsùRequirements for development and validation of a cleaning process for medical devices	2022	AAMI	
19	TIR39	Guidance on selecting a microbial challenge and inoculation sites for sterilization validation of medical devices	2022	AAMI	
20	ISO TIR22456	NULL	2022	AAMI	
21	PB70	Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities - FDA RECOGNIZED	2022	AAMI	
22	ISO TIR11137-4	NULL	2022	AAMI	
23	ISO 15223-1	NULL	2022	AAMI	
24	ISO 18472	NULL	2022	AAMI	
25	HIT1000-1	Safety and effectiveness of health IT software and systems-Part 1: Fundamental concepts, principles, and requirements	2022	AAMI	
26	2700-2-1	Medical devices and medical systemsùEssential safety and performance requirements for equipment comprising the patient-centric integrated clinical environment (ICE): Part 2-1: Particular requirements for forensic data logging	2022	AAMI	
27	2800-1-1	Standard for Risk Concerns for Interoperable Medical Products	2022	AAMI	
28	2800-1-2	Standard for Interoperable Item Development Life Cycle	2022	AAMI	
29	2800-1-3	Standard for Interoperable Item Integration Life Cycle	2022	AAMI	
30	2800-1	Standard for Safety for Medical Device Interoperability	2022	AAMI	
31	CR34971	Guidance on the Application of ISO 14971 to Artificial Intelligence and Machine Learning	2022	AAMI	

32	ISO 5840-1	NULL	2022	AAMI	
33	ISO 5840-2	NULL	2022	AAMI	
34	ISO 5840-3	NULL	2022	AAMI	
35	IEC 62366-1	NULL	2021	AAMI	
36	ST91	Flexible and semi-rigid endoscope processing in health care facilities	2021	AAMI	0
37	CR510	Quality Systems and Medical Devices	2021	AAMI	0
38	TIR101	Fluid delivery performance testing for infusion pumps	2021	AAMI	0
39	CN27	General requirements for Luer activated valves (LAVs) incorporated into medical devices for intravascular applications	2021	AAMI	0
40	TIR58	Water testing methodologies	2021	AAMI	0
41	TIR48	Quality Management System (QMS) Recommendations on the Application of the U.S. FDA___s CGMP Final Rule on Combination Products	2021	AAMI	
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	2021	AAMI	
43	TIR100	End-to-end microbiological quality and sterility assurance	2021	AAMI	
44	PC76	Active implantable medical devicesùRequirements and test protocols for safety of patients with pacemakers and ICDs exposed to magnetic resonance imaging	2021	AAMI	0
45	TIR42	Evaluation of particulates associated with vascular medical devices	2021	AAMI	0
46	TIR43	Ultrapure dialysate for hemodialysis and related therapies	2021	AAMI	0
47	TIR76	Sterilization of health care productsùRadiationù Substantiation of a selected sterilization dose at a specified sterility assurance level: Method VDmax SD-S	2021	AAMI	0
48	TIR105	Risk management guidance for combination products	2020	AAMI	0
49	TIR20416	Medical devicesù Post-market surveillance for manufacturers	2020	AAMI	0
50	TIR24971	Medical devices - Guidance on the application of ISO 14971	2020	AAMI	0
51	TIR12	Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers	2020	AAMI	0
52	14155	Clinical investigation of medical devices for human subjects Good clinical practice - Corrected 16 December 2011: Includes change to subclause 7.3	2020	AAMI	0
53	13485	Medical devices-Quality management systems-Requirements for regulatory purposes	2020	AAMI	0
54	RD47	Reprocessing of hemodialyzers - FDA RECOGNIZED	2020	AAMI	0
55	MP80601-2-49	NULL	2020	AAMI	0
56	RT3	NULL	2020	AAMI	0
57	HIT1000-4	NULL	2020	AAMI	0
58	TIR49	Design of training and instructional materials for medical devices used in non-clinical environments	2020	AAMI	
59	TIR66	Guidance for the creation of physiologic data and waveform databases to demonstrate reasonable assurance of the safety and effectiveness of alarm system algorithms	2020	AAMI	
60	TIR69	Risk management of radio-frequency wireless coexistence for medical devices and systems	2020	AAMI	
61	TIR71	Guidance for logging of alarm system data	2020	AAMI	
62	TIR41	Active implantable medical devicesù Guidance for designation of left ventricle and implantable cardioverter defibrillator lead connectors and pulse generator connector cavities for implantable pacemakers and implantable cardioverter defibrillators	2020	AAMI	
63	TIR21	Systems Used to Forecast Remaining Pacemaker Battery Service Life	2020	AAMI	
64	TIR17	Compatibility of materials subject to sterilization	2020	AAMI	
65	ST79	Comprehensive guide to steam sterilization and sterility assurance in health care facilities	2020	AAMI	
66	HIT1000-4(PS)	Safety and effectiveness of health IT software and systemsùPart 4: Application of human factors engineering	2020	AAMI	

67	EC12	Disposable ECG electrodes - FDA RECOGNIZED	2020	AAMI	
68	EC53	ECG cables and leadwires	2020	AAMI	
69	EC57	Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms	2020	AAMI	
70	IEC 80601-2-77	NULL	2020	AAMI	
71	IEC 80601-2-78	NULL	2020	AAMI	
72	ISO TIR24971	NULL	2020	AAMI	
73	ISO TIR20416	NULL	2020	AAMI	
74	ISO 14155	NULL	2020	AAMI	
75	ISO 13485	NULL	2019	AAMI	
76	ISO 14117	NULL	2019	AAMI	
77	ISO 14971	NULL	2019	AAMI	
78	ISO 11607-1	NULL	2019	AAMI	
79	ISO 11607-2	NULL	2019	AAMI	
80	ISO 11138-7	NULL	2019	AAMI	
81	ISO 11737-2	NULL	2019	AAMI	
82	ISO 11137-1	NULL	2019	AAMI	
83	ISO 11137-2	NULL	2019	AAMI	
84	ISO 10993-15	NULL	2019	AAMI	
85	ISO 23500-1	NULL	2019	AAMI	
86	ISO 23500-2	NULL	2019	AAMI	
87	ISO 23500-3	NULL	2019	AAMI	
88	ISO 23500-4	NULL	2019	AAMI	
89	ISO 23500-5	NULL	2019	AAMI	
90	ISO 81060-2	NULL	2019	AAMI	
91	TIR9	Evaluation of Clinical Systems for Invasive Blood Pressure Monitoring	2019	AAMI	0
92	TIR23	Signal Averaging	2019	AAMI	0
93	TIR24	Acquisition and use of physiologic waveform databases for testing of medical devices	2019	AAMI	0
94	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	2019	AAMI	0
95	ST67	Sterilization of health care products-Requirements and guidance for selecting a sterility assurance level (SAL) for products labeled sterile - FDA RECOGNIZED	2019	AAMI	0
96	ST72	Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing	2019	AAMI	0
97	TIR38	Medical device safety assurance case report guidance	2019	AAMI	0
98	TIR75	Sorbent-based regenerative hemodialysis systems	2019	AAMI	0
99	TIR97	Principles for medical device security - Postmarket risk management for device manufacturers	2019	AAMI	0
100	TIR102	U.S. FDA 21 CFR mapping to the applicable regulatory requirement references in ISO 13485:2016 Quality Management Systems	2019	AAMI	0
101	14117	Active implantable medical devices - Electromagnetic compatibility - EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization devices	2019	AAMI	0
102	14971	Medical devices-Application of risk management to medical devices	2019	AAMI	0
103	23500-1	Preparation and quality management of fluids for haemodialysis and related therapies - Part 1: General requirements	2019	AAMI	0
104	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	0

105	23500-3	Preparation and quality management of fluids for haemodialysis and related therapies - Part 3: Water for haemodialysis and related therapies	2019	AAMI	0
106	23500-4	Preparation and quality management of fluids for haemodialysis and related therapies - Part 4: Concentrates for haemodialysis and related therapies	2019	AAMI	0
107	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	0
108	81060-2	Non-invasive sphygmomanometers - Part 2: Clinical investigation of automated measurement type	2019	AAMI	0
109	CR500	Basic Introduction to the IEC 60601 Series	2019	AAMI	0
110	EQ93	Medical equipment management - Vocabulary used in medical equipment programs	2019	AAMI	0
111	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	0
112	2800-1	Standard for Safety for Medical Device Interoperability	2019	AAMI	0
113	11138-7	Sterilization of health care products - Biological indicators - Guidance for the selection, use, and interpretation of results	2019	AAMI	0
114	11607-1	Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems, and packaging - Incorporates Amendment 1: 2014	2019	AAMI	0
115	11607-2	Packaging for terminally sterilized medical devices-Part 2: Validation requirements for forming, sealing, and assembly processes - Incorporates Amendment 1: 2014	2019	AAMI	0
116	HIT1000-1	Safety and effectiveness of health IT software and systems-Part 1: Fundamental concepts, principles, and requirements	2018	AAMI	0
117	80369-1	Small bore connectors for liquids and gases in healthcare applications - Part 1: General requirements	2018	AAMI	0
118	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	0
119	60601-2-4	Medical electrical equipment - Part 2-4: Particular requirements for basic safety and essential performance of cardiac defibrillators	2018	AAMI	0
120	TIR21900	Guidance for uncertainty analysis regarding the application of ISO/TS 10974	2018	AAMI	0
121	10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2018	AAMI	0
122	TIR77	Technical Information Report Sorbent-based regenerative hemodialysis systems	2018	AAMI	0
123	TIR68	Low and intermediate-level disinfection in healthcare settings for medical devices and patient care equipment and sterile processing environmental surfaces	2018	AAMI	0
124	SW91	Classification of defects in health software	2018	AAMI	0
125	13408-7	Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products	2018	AAMI	0
126	ST24	Automatic, general purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities	2018	AAMI	0
127	ST58	Chemical sterilization and high-level disinfection in health care facilities	2018	AAMI	0
128	ST65	Processing of reusable surgical textiles for use in health care facilities - FDA RECOGNIZED	2018	AAMI	0
129	ST77	Containment devices for reusable medical device sterilization	2018	AAMI	0
130	HE75	Human factors engineering Design of medical devices	2018	AAMI	0
131	11737-1	Sterilization of health care products-Microbiological methods-Part 1: Determination of the population of microorganisms on product	2018	AAMI	0
132	13408-2	Aseptic processing of health care products - Part 2: Filtration	2018	AAMI	0
133	ISO TIR10974	NULL	2018	AAMI	
134	ISO 80369-1	NULL	2018	AAMI	
135	ISO TIR21900	NULL	2018	AAMI	
136	ST8	Hospital steam sterilizers - FDA RECOGNIZED	2018	AAMI	
137	ISO 8637-2	NULL	2018	AAMI	

138	ISO 8637-3	NULL	2018	AAMI	
139	ISO 10993-1	NULL	2018	AAMI	
140	ISO 13408-2	NULL	2018	AAMI	
141	ISO 11737-1	NULL	2018	AAMI	
142	ISO 13408-7	NULL	2018	AAMI	
143	IEC 80601-2-30	NULL	2018	AAMI	
144	ISO 5841-3	NULL	2018	AAMI	
145	IEC 60601-2-16	NULL	2018	AAMI	
146	IEC 60601-2-39	NULL	2018	AAMI	
147	TIR10974	Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device	2018	AAMI	0
148	EQ93	NULL	2018	AAMI	0
149	ST40	Table-top dry heat (heated air) sterilization and sterility assurance in health care facilitie	2018	AAMI	0
150	ST41	Ethylene oxide sterilization in health care facilities: Safety and effectiveness - FDA RECOGNIZED	2018	AAMI	0
151	ST50	Dry heat (heated air) sterilizers - FDA RECOGNIZED	2018	AAMI	0
152	TIR40	Sterilization of health care productsùRadiationùGuidance on dose setting utilizing a Modified Method 2	2018	AAMI	0
153	TIR45	Guidance on the use of AGILE practices in the development of medical device software	2018	AAMI	0
154	TIR63	Management of loaned critical and semi-critical medical devices that require sterilization or high-level disinfection	2018	AAMI	0
155	TIR67	Promoting safe practices pertaining to the use of sterilant and disinfectant chemicals in health care facilities	2018	AAMI	0
156	TIR69	Risk management of radio-frequency wireless coexistence for medical devices and systems	2017	AAMI	0
157	TIR71	Guidance for logging of alarm system data	2017	AAMI	0
158	TIR72	Dialysis fluid chemical composition	2017	AAMI	0
159	TIR15499	Biological evaluation of medical devices Guidance on the conduct of biological evaluation within a risk management process	2017	AAMI	0
160	TIR59	Integrating human factors into design controls	2017	AAMI	0
161	TIR50	Post-market surveillance of use error management	2017	AAMI	0
162	TIR51	Human factors engineering Guidance for contextual inquiry	2017	AAMI	0
163	TIR52	Environmental Monitoring For Terminally Sterilized Healthcare Products	2017	AAMI	0
164	TIR55	Human factors engineering for processing medical devices	2017	AAMI	0
165	TIR41	Active implantable medical devicesù Guidance for designation of left ventricle and implantable cardioverter defibrillator lead connectors and pulse generator connector cavities for implantable pacemakers and implantable cardioverter defibrillators	2017	AAMI	0
166	ST67	Sterilization of health care products-Requirements and guidance for selecting a sterility assurance level (SAL) for products labeled sterile - FDA RECOGNIZED	2017	AAMI	0
167	TIR29	GUIDE FOR PROCESS CONTROL IN RADIATION STERILIZATION	2017	AAMI	0
168	TIR30	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices - FDA RECOGNIZED	2017	AAMI	0
169	TIR34	Water for the reprocessing of medical devices	2017	AAMI	0
170	TIR39	Guidance on selecting a microbial challenge and inoculation sites for sterilization validation of medical devices	2017	AAMI	0
171	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	2017	AAMI	0
172	ST90	NULL	2017	AAMI	0
173	TIR16	Microbiological aspects of ethylene oxide sterilization	2017	AAMI	0
174	TIR17	Compatibility of materials subject to sterilization	2017	AAMI	0

175	TIR21	Systems Used to Forecast Remaining Pacemaker Battery Service Life	2017	AAMI	0
176	NS4	Transcutaneous electrical nerve stimulators	2017	AAMI	0
177	RT2	NULL	2017	AAMI	0
178	CI86	NULL	2017	AAMI	0
179	25539-1	Cardiovascular implants-Endovascular devices-Part 1: Endovascular prostheses Amendment 1: Test methods - Incorporates Amendment 1: 2005	2017	AAMI	0
180	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	2017	AAMI	0
181	TIR66	Guidance for the creation of physiologic data and waveform databases to demonstrate reasonable assurance of the safety and effectiveness of alarm system algorithms	2017	AAMI	0
182	IEC 60601-2-2	NULL	2017	AAMI	
183	TIR80002-2	Medical device software - Part 2: Validation of software for medical device quality systems	2017	AAMI	0
184	ISO 8637-1	NULL	2017	AAMI	
185	ISO 14708-3	NULL	2017	AAMI	
186	ISO 10993-4	NULL	2017	AAMI	
187	ISO 10993-16	NULL	2017	AAMI	
188	ISO 10993-11	NULL	2017	AAMI	
189	ISO 11138-1	NULL	2017	AAMI	
190	ISO 11138-2	NULL	2017	AAMI	
191	ISO 11138-3	NULL	2017	AAMI	
192	ISO 11138-4	NULL	2017	AAMI	
193	ISO 11138-5	NULL	2017	AAMI	
194	ISO TIR80002-2	NULL	2017	AAMI	
195	ISO 27185	NULL	2017	AAMI	
196	ISO TIR15499	NULL	2017	AAMI	
197	ISO 25539-1	NULL	2017	AAMI	
198	ISO 16142-2	NULL	2017	AAMI	
199	ISO 17664	NULL	2017	AAMI	
200	13408-1	Aseptic processing of health care products - Part 1: General requirements - Incorporates Amendment 1: 2013	2017	AAMI	0
201	14708-3	Implants for surgeryùActive implantable medical devicesù Part 3: Implantable neurostimulators	2017	AAMI	0
202	16142-2	NULL	2017	AAMI	0
203	17664	NULL	2017	AAMI	0
204	11137-3	Sterilization of health care products-Radiation-Part 3: Guidance on dosimetric aspects	2017	AAMI	0
205	11138-1	Sterilization of health care products - Biological indicators - Part 1: General requirements	2017	AAMI	0
206	11138-2	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes	2017	AAMI	0
207	11138-3	Sterilization of health care products-Biological indicators-art 3: Biological indicators for moist heat sterilization processes	2017	AAMI	0
208	11138-4	Sterilization of health care products-Biological indicators-Part 4: Biological indicators for dry heat sterilization processes	2017	AAMI	0
209	11138-5	Sterilization of health care products-Biological indicators-Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes	2017	AAMI	0
210	TIR51	Human factors engineering Guidance for contextual inquiry	2017	AAMI	0
211	TIR63	Management of loaned critical and semi-critical medical devices that require sterilization or high-level disinfection	2017	AAMI	0

212	27185	Cardiac rhythm management devices - Symbols to be used with cardiac rhythm management device labels, and information to be supplied - General requirements	2017	AAMI	0
213	10993-4	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood - Incorporates Amendment 1: 2006	2017	AAMI	0
214	10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	2017	AAMI	0
215	7198	Cardiovascular implants-Tubular vascular prostheses	2016	AAMI	0
216	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	0
217	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	0
218	60601-2-21	Medical Electrical Equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers	2016	AAMI	0
219	60601-2-50	Medical Electrical Equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment	2016	AAMI	0
220	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	2016	AAMI	0
221	ST81	Sterilization of medical devices-Information to be provided by the manufacturer for the processing of resterilizable medical devices	2016	AAMI	0
222	TIR30	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices - FDA RECOGNIZED	2016	AAMI	0
223	TIR32	Medical device software risk management	2016	AAMI	0
224	TIR17665-2	Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1	2016	AAMI	0
225	7199	Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators)	2016	AAMI	0
226	10993-6	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation	2016	AAMI	0
227	18241	NULL	2016	AAMI	0
228	18242	NULL	2016	AAMI	0
229	15223-1	Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied - Part 1: General requirements	2016	AAMI	0
230	15674	Cardiovascular implants and artificial organs - Hard shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags	2016	AAMI	0
231	15675	Cardiovascular implants and artificial organs - Cardiopulmonary bypass systems - Arterial blood line filters	2016	AAMI	0
232	15676	NULL	2016	AAMI	0
233	16142-1	NULL	2016	AAMI	0
234	13485	Medical devices-Quality management systems-Requirements for regulatory purposes	2016	AAMI	0
235	15225	Medical devices - Quality management - Medical device nomenclature data structure	2016	AAMI	0
236	80369-5	Small-bore connectors for liquids and gases in healthcare applicationsùPart 5: Connectors for limb cuff inflation applications	2016	AAMI	0
237	80369-6	Small-bore connectors for liquids and gases in healthcare applications ù Part 6: Connectors for neuraxial applications	2016	AAMI	0
238	80369-20	Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods	2016	AAMI	0
239	TIR14	Contract sterilization using ethylene oxide	2016	AAMI	0
240	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
241	TIR57	Principles for medical device securityùRisk management	2016	AAMI	0
242	TIR65	Sustainability of medical devicesùElements of a responsible product life cycle	2016	AAMI	0

243	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
244	ISO 15225	NULL	2016	AAMI	
245	ISO 15674	NULL	2016	AAMI	
246	ISO 15675	NULL	2016	AAMI	
247	ISO 15676	NULL	2016	AAMI	
248	ISO 18241	NULL	2016	AAMI	
249	ISO 18242	NULL	2016	AAMI	
250	ISO 80369-3	NULL	2016	AAMI	
251	ISO 80369-5	NULL	2016	AAMI	
252	ISO 80369-6	NULL	2016	AAMI	
253	ISO 80369-7	NULL	2016	AAMI	
254	ISO 22442-1	NULL	2016	AAMI	
255	ISO 22442-2	NULL	2016	AAMI	
256	ISO 22442-3	NULL	2016	AAMI	
257	ISO TIR17665-2	NULL	2016	AAMI	
258	ISO TIR17665-3	NULL	2016	AAMI	
259	ISO TIR19024	NULL	2016	AAMI	
260	ISO 16142-1	NULL	2016	AAMI	
261	ISO TIR13004	NULL	2016	AAMI	
262	ISO TIR22442-4	NULL	2016	AAMI	
263	ISO 10993-6	NULL	2016	AAMI	
264	ISO 14160	NULL	2016	AAMI	
265	ISO 7198	NULL	2016	AAMI	
266	ISO 7199	NULL	2016	AAMI	
267	IEC TIR80002-3	NULL	2016	AAMI	
268	IEC TIR80001-2-8	NULL	2016	AAMI	
269	IEC TIR62366-2	NULL	2016	AAMI	
270	IEC 60601-1-12	NULL	2016	AAMI	
271	IEC 60601-2-47	NULL	2016	AAMI	
272	IEC 60601-2-25	NULL	2016	AAMI	
273	IEC 60601-2-27	NULL	2016	AAMI	
274	TIR80001-2-8	Application of risk management for IT networks incorporating medical devices-Part 2-8: Application guidance-Guidance on standards for establishing the security capabilities identified in IEC 80001-2-2	2016	AAMI	0
275	TIR13004	Sterilization of health care products - Radiation - Substantiation of a selected sterilization dose: Method VDmax SD	2016	AAMI	0
276	TIR24971	Medical devices - Guidance on the application of ISO 14971	2016	AAMI	0
277	80601-2-58 AMD 1	NULL	2016	AAMI	0

278	22442-1	Medical devices utilizing animal tissues and their derivatives-Part 1: Application of risk management	2016	AAMI	0
279	22442-2	Medical devices utilizing animal tissues and their derivatives-Part 2: Controls on sourcing, collection and handling	2016	AAMI	0
280	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	2016	AAMI	0
281	60601-2-20 AMD 1	NULL	2016	AAMI	0
282	60601-2-21 AMD 1	NULL	2016	AAMI	0
283	60601-2-25	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs	2016	AAMI	0
284	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	2016	AAMI	0
285	60601-2-47	Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems	2016	AAMI	0
286	60601-2-50 AMD 1	NULL	2016	AAMI	0
287	80369-3	NULL	2016	AAMI	0
288	80369-7	NULL	2016	AAMI	0
289	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	2016	AAMI	0
290	BP22	Blood pressure transducers - Incorporates Errata: 08/2004	2016	AAMI	0
291	ST55	Table-top steam sterilizers - FDA RECOGNIZED	2016	AAMI	0
292	TIR28	Product adoption and process equivalence for ethylene oxide sterilization	2016	AAMI	0
293	ST72	Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing	2016	AAMI	0
294	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	2016	AAMI	0
295	TIR15	Physical aspects of ethylene oxide sterilization	2016	AAMI	0
296	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	2016	AAMI	0
297	TIR19024	Evaluation of CPB devices relative to their capabilities of reducing the transmission of gaseous microemboli (GME) to a patient during cardiopulmonary bypass	2016	AAMI	0
298	TIR22442-4	Medical devices utilizing animal tissues and their derivatives - Part 4: Principles for elimination and/or inactivation of transmissible spongiform encephalopathy (TSE) agents and validation assays for those processes	2016	AAMI	0
299	TIR23810	Cardiovascular implants and artificial organs - Checklist for preoperative extracorporeal circulation equipment setup	2015	AAMI	0
300	TIR65	Sustainability of medical devicesùElements of a responsible product life cycle	2015	AAMI	0
301	NS28	Intracranial pressure monitoring devices - FDA RECOGNIZED; Incorporates Errata: 06/2001	2015	AAMI	0
302	EC12	Disposable ECG electrodes - FDA RECOGNIZED	2015	AAMI	0
303	26782	NULL	2015	AAMI	0
304	60601-2-4	Medical electrical equipment - Part 2-4: Particular requirements for basic safety and essential performance of cardiac defibrillators	2015	AAMI	0
305	IEC TIR60878	NULL	2015	AAMI	
306	ISO 5367	NULL	2015	AAMI	
307	ISO 13408-5	NULL	2015	AAMI	
308	ISO 14708-5	NULL	2015	AAMI	
309	ISO 13408-3	NULL	2015	AAMI	

310	ISO 12417-1	NULL	2015	AAMI	
311	ISO 11140-3	NULL	2015	AAMI	
312	ISO 11140-4	NULL	2015	AAMI	
313	ISO 11140-5	NULL	2015	AAMI	
314	ISO 8638	NULL	2015	AAMI	
315	ISO 8836	NULL	2015	AAMI	
316	ISO TIR23810	NULL	2015	AAMI	
317	ISO TIR62354	NULL	2015	AAMI	
318	ISO 25539-3	NULL	2015	AAMI	
319	ISO 80369-20	NULL	2015	AAMI	
320	ISO 20857	NULL	2015	AAMI	
321	TIR48	Quality Management System (QMS) Recommendations on the Application of the U.S. FDA___s CGMP Final Rule on Combination Products	2015	AAMI	0
322	ST91	Flexible and semi-rigid endoscope processing in health care facilities	2015	AAMI	0
323	20857	Sterilization of health care products - Dry heat - Requirements for the development, validation and routine control of a sterilization process for medical devices	2015	AAMI	0
324	13408-5	Aseptic processing of health care products - Part 5: Sterilization in place	2015	AAMI	0
325	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	2015	AAMI	0
326	13408-3	Aseptic processing of health care products - Part 3: Lyophilization	2015	AAMI	0
327	8836	NULL	2015	AAMI	0
328	5367	NULL	2015	AAMI	0
329	5840-1	NULL	2015	AAMI	0
330	5840-2	NULL	2015	AAMI	0
331	TIR60878	Graphical symbols for electrical equipment in medical practice	2015	AAMI	0
332	TIR62354	General testing procedures for medical electrical equipment	2015	AAMI	0
333	TIR11	Selection and use of protective apparel and surgical drapes in health care facilities	2015	AAMI	0
334	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.	2015	AAMI	0
335	ST15883-3	Washer-disinfectors - Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers	2015	AAMI	0
336	14708-5	Implants for surgeryùActive implantable medical devicesù Part 5: Circulatory support devices	2015	AAMI	0
337	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	2015	AAMI	0
338	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	2015	AAMI	0
339	11140-5	Sterilization of health care products - Chemical indicators - Part 5: Class 2 indicators for Bowie and Dick air removal test sheets and packs	2015	AAMI	0
340	134080-3	NULL	2015	AAMI	0
341	134080-5	NULL	2015	AAMI	0
342	25539-3	Cardiovascular implants ù Endovascular devices ù Part 3: Vena cava filters	2015	AAMI	0
343	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	2015	AAMI	0

344	8638	Cardiovascular implants and extracorporeal systems - Extracorporeal blood circuit for hemodialyzers, hemodiafilters and hemofilters	2015	AAMI	0
345	62366-1	Medical devices Part 1: Application of usability engineering to medical devices	2015	AAMI	0
346	80369-20	Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods	2015	AAMI	0
347	CN6	Small-bore connectors for liquids and gases in healthcare applications - Part 6: Connectors for neuraxial applications	2015	AAMI	0
348	EQ89	Guidance for the use of medical equipment maintenance strategies and procedures	2015	AAMI	0
349	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
350	SPHC	Sterile Processing In Healthcare Facilities Preparing for Accreditation Surveys - 2nd Edition	2014	AAMI	0
351	SPVVQ	Basic Concepts in Sterilization Processes Verification, Validation, And Qualification	2014	AAMI	0
352	DUG	Dialysis Water and Dialysate Recommendations: A User Guide	2014	AAMI	0
353	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
354	23500	Guidance for the preparation and quality management of fluids for hemodialysis and related therapies	2014	AAMI	0
355	26722	Water treatment equipment for hemodialysis and related therapies	2014	AAMI	0
356	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
357	5841-2	Implants for surgery - Cardiac pacemakers - Part 2: Reporting of clinical performance of populations of pulse generators or leads	2014	AAMI	0
358	10993-3	Biological evaluation of medical devices-Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity	2014	AAMI	0
359	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
360	11140-1	Sterilization of health care products-Chemical indicators-Part 1: General requirements	2014	AAMI	0
361	11663	Quality of dialysis fluid for hemodialysis and related therapies	2014	AAMI	0
362	13958	Concentrates for hemodialysis and related therapies	2014	AAMI	0
363	13959	Water for hemodialysis and related therapies	2014	AAMI	0
364	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
365	1340804	NULL	2014	AAMI	0
366	14161	Sterilization of health care products - Biological indicators - Guidance for the selection, use and interpretation of results	2014	AAMI	0
367	10993-2	Biological evaluation of medical devices - Part 2: Animal welfare requirements	2014	AAMI	0
368	10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	2014	AAMI	0
369	13408-4	Aseptic processing of health care products - Part 4: Clean-in-place technologies	2014	AAMI	0
370	11737-2	Sterilization of medical devices Microbiological methods Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	2014	AAMI	0
371	10993-9	Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products	2014	AAMI	0
372	10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	2014	AAMI	0
373	10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	2014	AAMI	0
374	10993-13	Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices	2014	AAMI	0
375	TIR58	Water testing methodologies	2014	AAMI	0
376	TIR60	Common mode rejection in ECG monitoring	2014	AAMI	0

377	TIR61	Generating reports for human factors design validation results for external cardiac defibrillators	2014	AAMI	0
378	TIR62	Generating reports for the purpose of submitting defibrillation waveform data for evaluation	2014	AAMI	0
379	TIR63	Management of loaned critical and semi-critical medical devices that require sterilization or high-level disinfection	2014	AAMI	0
380	TIR34	Water for the reprocessing of medical devices	2014	AAMI	0
381	TIR38	Medical device safety assurance case report guidance	2014	AAMI	0
382	TIR50	Post-market surveillance of use error management	2014	AAMI	0
383	TIR51	Human factors engineering Guidance for contextual inquiry	2014	AAMI	0
384	TIR52	Environmental Monitoring For Terminally Sterilized Healthcare Products	2014	AAMI	0
385	TIR55	Human factors engineering for processing medical devices	2014	AAMI	0
386	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
387	TIR80001-2-6	Application of risk management for ITnetworks incorporating medical - Application guidance - Part 2-6: Guidance for responsibility agreements	2014	AAMI	0
388	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
389	TIR16775	Packaging for terminally sterilized medical devices - Guidance on the application of ISO 11607-1 and ISO 11607-2	2014	AAMI	0
390	TIR17137	Cardiovascular implants and extracorporeal systems Cardiovascular absorbable implants	2014	AAMI	0
391	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
392	TIR37137	Cardiovascular biological evaluation of medical devices - Guidance for absorbable implants	2014	AAMI	0
393	ISO 80601-2-35	NULL	2014	AAMI	
394	ISO TIR37137	NULL	2014	AAMI	
395	ISO TIR17137	NULL	2014	AAMI	
396	ISO 10079-1	NULL	2014	AAMI	
397	ISO 10079-2	NULL	2014	AAMI	
398	ISO 10079-3	NULL	2014	AAMI	
399	ISO 10651-4	NULL	2014	AAMI	
400	ISO 10651-5	NULL	2014	AAMI	
401	ISO 10993-9	NULL	2014	AAMI	
402	ISO 10993-10	NULL	2014	AAMI	
403	ISO 10993-5	NULL	2014	AAMI	
404	ISO 10993-3	NULL	2014	AAMI	
405	ISO 11135	NULL	2014	AAMI	
406	ISO 10993-13	NULL	2014	AAMI	
407	ISO 11195	NULL	2014	AAMI	
408	ISO 13408-4	NULL	2014	AAMI	
409	ISO 11140-1	NULL	2014	AAMI	
410	ISO 14161	NULL	2014	AAMI	
411	ISO 14408	NULL	2014	AAMI	
412	ISO 14708-1	NULL	2014	AAMI	
413	ISO 5841-2	NULL	2014	AAMI	
414	ISO 5364	NULL	2014	AAMI	

415	ISO 5366-1	NULL	2014	AAMI	
416	ISO 5366-3	NULL	2014	AAMI	
417	ISO 4135	NULL	2014	AAMI	
418	ISO 5356-1	NULL	2014	AAMI	
419	ISO 5361	NULL	2014	AAMI	
420	IEC 80601-2-58	NULL	2014	AAMI	
421	IEC TIR80001-2-5	NULL	2014	AAMI	
422	IEC TIR80001-2-6	NULL	2014	AAMI	
423	IEC TIR80001-2-7	NULL	2014	AAMI	
424	CN3(PS)	Small-bore connectors for liquids and gases in healthcare applications ù Part 3: Connectors for enteral applications	2014	AAMI	
425	IEC 60601-1-2	NULL	2014	AAMI	
426	ST15883-1	Washer-disinfectors ù Part 1: General requirements, terms and definitions and tests	2014	AAMI	0
427	81060-1	Non-invasive sphygmomanometers - Part 1: Requirements and test methods for nonautomated measurement type	2013	AAMI	0
428	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	2013	AAMI	0
429	HE75	Human factors engineering Design of medical devices	2013	AAMI	0
430	ST24	Automatic, general purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities	2013	AAMI	0
431	ST65	Processing of reusable surgical textiles for use in health care facilities - FDA RECOGNIZED	2013	AAMI	0
432	ISO 13408-6	NULL	2013	AAMI	
433	ISO 14937	NULL	2013	AAMI	
434	ISO 81060-1	NULL	2013	AAMI	
435	ISO 15882	NULL	2013	AAMI	
436	ISO 17665-1	NULL	2013	AAMI	
437	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
438	TIR37	Sterilization of health care products-Radiation-Guidance on sterilization of biologics and tissue-based products	2013	AAMI	0
439	TIR49	Design of training and instructional materials for medical devices used in non-clinical environments	2013	AAMI	0
440	TIR13004	Sterilization of health care products - Radiation - Substantiation of a selected sterilization dose: Method VDmax SD	2013	AAMI	0
441	ST77	Containment devices for reusable medical device sterilization	2013	AAMI	0
442	ST58	Chemical sterilization and high-level disinfection in health care facilities	2013	AAMI	0
443	ST8	Hospital steam sterilizers - FDA RECOGNIZED	2013	AAMI	0
444	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
445	13408-6	Aseptic processing of health care products - Part 6: Isolator systems - Incorporates Amendment 1: 2013	2013	AAMI	0
446	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	2013	AAMI	0
447	10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2013	AAMI	0
448	15882	Sterilization of health care products - Chemical indicators - Guidance for selection, use and interpretation of results	2013	AAMI	0
449	EC71	Standard communications protocol for computer-assisted electrocardiography	2013	AAMI	0
450	TIR24971	Medical devices - Guidance on the application of ISO 14971	2013	AAMI	0

451	134080-6	NULL	2013	AAMI	0
452	ID26	Medical electrical equipment-Part 2: Particular requirements for the safety of infusion pumps and controllers	2013	AAMI	0
453	11137-2	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose	2013	AAMI	0
454	5840-3	Cardiovascular implants - Cardiac valve prostheses - Part 3: Heart valve substitutes implanted by transcatheter techniques	2013	AAMI	0
455	81060-2	Non-invasive sphygmomanometers - Part 2: Clinical investigation of automated measurement type	2013	AAMI	0
456	AT6	Autologous transfusion devices	2013	AAMI	0
457	BFTF	Building for the Future Construction and Renovation of Sterile Processing Facilities	2013	AAMI	0
458	EQ56	Recommended practice for a medical equipment management program	2013	AAMI	0
459	EC53	ECG cables and leadwires	2013	AAMI	0
460	NS4	Transcutaneous electrical nerve stimulators	2013	AAMI	0
461	ID54	Enteral feeding set adapters and connectors	2012	AAMI	0
462	PB70	Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities - FDA RECOGNIZED	2012	AAMI	0
463	EC57	Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms	2012	AAMI	0
464	EQ56	Recommended practice for a medical equipment management program	2012	AAMI	0
465	BF64	Leukocyte reduction filters	2012	AAMI	0
466	BF7	Blood transfusion microfilters	2012	AAMI	0
467	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
468	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
469	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
470	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
471	25539-2	Cardiovascular implants - Endovascular devices - Part 2: Vascular stents	2012	AAMI	0
472	5361	Anaesthetic and Respiratory Equipment-Tracheal Tubes and Connectors	2012	AAMI	0
473	11137-2	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose	2012	AAMI	0
474	10993-12	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	2012	AAMI	0
475	11658	Cardiovascular implants and extracorporeal systems - Blood/tissue contact surface modifications for extracorporeal perfusion systems	2012	AAMI	0
476	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
477	14117	Active implantable medical devices - Electromagnetic compatibility - EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization devices	2012	AAMI	0
478	13408-7	Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products	2012	AAMI	0
479	13022	Medical products containing viable human cells - Application of risk management and requirements for processing practices	2012	AAMI	0
480	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
481	10993-17	Biological evaluation of medical devices - Part 17: Methods for the establishment of allowable limits for leachable substances	2012	AAMI	0
482	10993-7	Biological evaluation of medical devices-Part 7: Ethylene oxide sterilization residuals	2012	AAMI	0
483	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	2012	AAMI	0

484	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	2012	AAMI	0
485	11140-5	Sterilization of health care products - Chemical indicators - Part 5: Class 2 indicators for Bowie and Dick air removal test sheets and packs	2012	AAMI	0
486	ST15883-3	Washer-disinfectors - Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers	2012	AAMI	0
487	SW87	Application of quality management system concepts to medical device data systems - FDA RECOGNIZED	2012	AAMI	0
488	TIR29	GUIDE FOR PROCESS CONTROL IN RADIATION STERILIZATION	2012	AAMI	0
489	ST79 A3	NULL	2012	AAMI	0
490	TIR15499	Biological evaluation of medical devices Guidance on the conduct of biological evaluation within a risk management process	2012	AAMI	0
491	TIR10974	Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device	2012	AAMI	0
492	TIR44	Non-invasive blood pressure motion artifact - Testing and evaluation of NIBP device performance in the presence of motion artifact	2012	AAMI	0
493	TIR45	Guidance on the use of AGILE practices in the development of medical device software	2012	AAMI	0
494	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
495	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
496	TIR80001-2-3	Application of risk management for IT-networks incorporating medical devices - Part 2-3: Guidance for Wireless Networks	2012	AAMI	0
497	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
498	TIR19218-2	Medical devices - Hierarchal coding structure for adverse events - Part 2: Evaluation codes	2012	AAMI	0
499	TIR23810	Cardiovascular implants and artificial organs - Checklist for preoperative extracorporeal circulation equipment setup	2012	AAMI	0
500	ISO 25539-2	NULL	2012	AAMI	
501	ISO TIR19218-2	NULL	2012	AAMI	
502	ISO TIR62348	NULL	2012	AAMI	
503	ISO 13022	NULL	2012	AAMI	
504	ISO 11658	NULL	2012	AAMI	
505	ISO 10993-12	NULL	2012	AAMI	
506	ISO 10993-17	NULL	2012	AAMI	
507	ISO 10993-7	NULL	2012	AAMI	
508	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	2012	AAMI	0
509	IEC TIR62348	NULL	2012	AAMI	
510	IEC TIR80001-2-1	NULL	2012	AAMI	
511	IEC TIR80001-2-2	NULL	2012	AAMI	
512	IEC TIR80001-2-3	NULL	2012	AAMI	
513	IEC TIR80001-2-4	NULL	2012	AAMI	
514	ISO 5362	NULL	2012	AAMI	

515	IEC TIR61289	NULL	2011	AAMI	
516	TIR61289	High frequency surgical equipment û Operation and maintenance	2011	AAMI	0
517	BE83	Biological evaluation of medical devices-Part 18: Chemical characterization of materials	2011	AAMI	0
518	TIR 19218-1	NULL	2011	AAMI	0
519	TIR43	Ultrapure dialysate for hemodialysis and related therapies	2011	AAMI	0
520	ISO 10993-14	NULL	2011	AAMI	
521	ISO 14708-4	NULL	2011	AAMI	
522	ISO TIR12417	NULL	2011	AAMI	
523	TIR12417	NULL	2011	AAMI	0
524	TIR19218-1	Medical devices _ Hierarchal coding structure for adverse events _ Part 1: Event-type codes	2011	AAMI	0
525	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
526	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
527	ST72	Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing	2011	AAMI	0
528	TIR30	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices - FDA RECOGNIZED	2011	AAMI	0
529	14708-4	Implants for surgeryùActive implantable medical devicesù Part 4: Implantable infusion pumps	2011	AAMI	0
530	13408-1	Aseptic processing of health care products - Part 1: General requirements - Incorporates Amendment 1: 2013	2011	AAMI	0
531	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
532	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
533	10993-14	Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics	2011	AAMI	0
534	10993-15	Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys	2011	AAMI	0
535	25539-3	NULL	2011	AAMI	0
536	AT6	Autologous transfusion devices	2011	AAMI	0
537	BP22	Blood pressure transducers - Incorporates Errata: 08/2004	2011	AAMI	0
538	EC12	Disposable ECG electrodes - FDA RECOGNIZED	2010	AAMI	0
539	DF80	Medical electrical equipment_ Part 2-4: Particular requirements for the safety of cardiac defibrillators (including automated external defibrillators)	2010	AAMI	0
540	NS28	Intracranial pressure monitoring devices - FDA RECOGNIZED; Incorporates Errata: 06/2001	2010	AAMI	0
541	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
542	80001-1	Application of risk management for IT Networks incorporating medical devices - Part 1: Roles, responsibilities and activities	2010	AAMI	0
543	80369-1	Small bore connectors for liquids and gases in healthcare applications - Part 1: General requirements	2010	AAMI	0
544	18472	Sterilization of health care products-Biological and chemical indicators-Test equipment	2010	AAMI	0
545	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
546	60601-2-4	Medical electrical equipment - Part 2-4: Particular requirements for basic safety and essential performance of cardiac defibrillators	2010	AAMI	0
547	10993-16	Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables	2010	AAMI	0

548	10993-13	Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices	2010	AAMI	0
549	11137-3	Sterilization of health care products-Radiation-Part 3: Guidance on dosimetric aspects	2010	AAMI	0
550	11138-1	Sterilization of health care products - Biological indicators - Part 1: General requirements	2010	AAMI	0
551	11138-2	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes	2010	AAMI	0
552	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
553	7198	Cardiovascular implants-Tubular vascular prostheses	2010	AAMI	0
554	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
555	8638	Cardiovascular implants and extracorporeal systems - Extracorporeal blood circuit for hemodialyzers, hemodiafilters and hemofilters	2010	AAMI	0
556	10993-2	Biological evaluation of medical devices - Part 2: Animal welfare requirements	2010	AAMI	0
557	10993-6	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation	2010	AAMI	0
558	10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	2010	AAMI	0
559	10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	2010	AAMI	0
560	14708-5	NULL	2010	AAMI	0
561	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
562	14971	Medical devices-Application of risk management to medical devices	2010	AAMI	0
563	15225	Medical devices - Quality management - Medical device nomenclature data structure	2010	AAMI	0
564	11140-1	Sterilization of health care products-Chemical indicators-Part 1: General requirements	2010	AAMI	0
565	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
566	11138-5	Sterilization of health care products-Biological indicators-Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes	2010	AAMI	0
567	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
568	11138-3	Sterilization of health care products-Biological indicators-art 3: Biological indicators for moist heat sterilization processes	2010	AAMI	0
569	11138-4	Sterilization of health care products-Biological indicators-Part 4: Biological indicators for dry heat sterilization processes	2010	AAMI	0
570	5840	Cardiovascular implants Cardiac valve prostheses	2010	AAMI	0
571	ST72	Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing	2010	AAMI	0
572	TIR12	Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers	2010	AAMI	0
573	TIR18	Guidance on electromagnetic compatibility of medical devices in healthcare facilities	2010	AAMI	0
574	ST77	Containment devices for reusable medical device sterilization	2010	AAMI	0
575	ST81	Sterilization of medical devices-Information to be provided by the manufacturer for the processing of resterilizable medical devices	2010	AAMI	0
576	ST79 A1	NULL	2010	AAMI	0
577	ST40	Table-top dry heat (heated air) sterilization and sterility assurance in health care facilitie	2010	AAMI	0
578	ST50	Dry heat (heated air) sterilizers - FDA RECOGNIZED	2010	AAMI	0
579	ST55	Table-top steam sterilizers - FDA RECOGNIZED	2010	AAMI	0
580	ST58	Chemical sterilization and high-level disinfection in health care facilities	2010	AAMI	0

581	TIR42	Evaluation of particulates associated with vascular medical devices	2010	AAMI	0
582	ISO 27186	NULL	2010	AAMI	
583	RD52	Dialysate for hemodialysis	2010	AAMI	
584	ISO 15223-2	NULL	2010	AAMI	
585	ISO 10993-2	NULL	2010	AAMI	
586	27186	NULL	2010	AAMI	0
587	IEC 80001-1	NULL	2010	AAMI	
588	IEC TIR62296	NULL	2009	AAMI	
589	IEC TIR62354	NULL	2009	AAMI	
590	IEC TIR80002-1	NULL	2009	AAMI	
591	80601-2-35	NULL	2009	AAMI	0
592	ISO 11663	NULL	2009	AAMI	
593	ISO 26722	NULL	2009	AAMI	
594	TIR39	NULL	2009	AAMI	0
595	TIR40	NULL	2009	AAMI	0
596	TIR17665-2	Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1	2009	AAMI	0
597	TIR62296	Considerations of unaddressed safety aspects in the second edition of IEC 60601-1 and proposals for new requirements	2009	AAMI	0
598	TIR80002-1	NULL	2009	AAMI	0
599	ST24	Automatic, general purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities	2009	AAMI	0
600	ST15883-1	NULL	2009	AAMI	0
601	TIR16	Microbiological aspects of ethylene oxide sterilization	2009	AAMI	0
602	TIR14	Contract sterilization using ethylene oxide	2009	AAMI	0
603	TIR15	Physical aspects of ethylene oxide sterilization	2009	AAMI	0
604	TIR28	Product adoption and process equivalence for ethylene oxide sterilization	2009	AAMI	0
605	TIR62354	NULL	2009	AAMI	0
606	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
607	15674	Cardiovascular implants and artificial organs - Hard shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags	2009	AAMI	0
608	15675	Cardiovascular implants and artificial organs - Cardiopulmonary bypass systems - Arterial blood line filters	2009	AAMI	0
609	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
610	14161	Sterilization of health care products - Biological indicators - Guidance for the selection, use and interpretation of results	2009	AAMI	0
611	13485	Medical devices-Quality management systems-Requirements for regulatory purposes	2009	AAMI	0
612	10993-9	Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products	2009	AAMI	0
613	10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	2009	AAMI	0
614	10993-4	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood - Incorporates Amendment 1: 2006	2009	AAMI	0
615	10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2009	AAMI	0
616	7199	Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators)	2009	AAMI	0

617	10993-16	Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables	2009	AAMI	0
618	11137-2	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose	2009	AAMI	0
619	10993-3	Biological evaluation of medical devices-Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity	2009	AAMI	0
620	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
621	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
622	17665-2	Sterilization of health care products _ Moist heat _ Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1	2009	AAMI	0
623	26722	Water treatment equipment for hemodialysis and related therapies	2009	AAMI	0
624	25539-1	Cardiovascular implants-Endovascular devices-Part 1: Endovascular prostheses Amendment 1: Test methods - Incorporates Amendment 1: 2005	2009	AAMI	0
625	25539-1 A1	NULL	2009	AAMI	0
626	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
627	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
628	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
629	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
630	ID26	Medical electrical equipment-Part 2: Particular requirements for the safety of infusion pumps and controllers	2009	AAMI	0
631	HE74	Human factors design process for medical devices	2009	AAMI	0
632	HE75	Human factors engineering _ Design of medical devices	2009	AAMI	0
633	NS4	Transcutaneous electrical nerve stimulators	2009	AAMI	0
634	PB70	Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities - FDA RECOGNIZED	2009	AAMI	0
635	RD62	NULL	2009	AAMI	0
636	RD52	Dialysate for hemodialysis	2009	AAMI	0
637	RD47	Reprocessing of hemodialyzers - FDA RECOGNIZED	2008	AAMI	0
638	ST8	Hospital steam sterilizers - FDA RECOGNIZED	2008	AAMI	0
639	RD5	Hemodialysis systems	2008	AAMI	0
640	EC53A	NULL	2008	AAMI	0
641	EC57	Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms	2008	AAMI	0
642	EQ56	Recommended practice for a medical equipment management program	2008	AAMI	0
643	BE78 A1	NULL	2008	AAMI	0
644	BE78	Biological evaluation of medical devices _ Part 10: Tests for irritation and _ delayed-type hypersensitivity	2008	AAMI	0
645	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
646	25539-2	Cardiovascular implants - Endovascular devices - Part 2: Vascular stents	2008	AAMI	0
647	22442-1	Medical devices utilizing animal tissues and their derivatives-Part 1: Application of risk management	2008	AAMI	0
648	22442-2	Medical devices utilizing animal tissues and their derivatives-Part 2: Controls on sourcing, collection and handling	2008	AAMI	0
649	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

650	10993-17	Biological evaluation of medical devices - Part 17: Methods for the establishment of allowable limits for leachable substances	2008	AAMI	0
651	10993-7 E2010	NULL	2008	AAMI	0
652	10993-7	Biological evaluation of medical devices-Part 7: Ethylene oxide sterilization residuals	2008	AAMI	0
653	14155-1	Clinical investigation of medical devices for human subjects -- Part 1: General requirements	2008	AAMI	0
654	14155-2	Clinical investigation of medical devices for human subjects -- Part 2: Clinical investigation plans	2008	AAMI	0
655	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
656	14708-3	NULL	2008	AAMI	0
657	14708-4	NULL	2008	AAMI	0
658	15882	Sterilization of health care products - Chemical indicators - Guidance for selection, use and interpretation of results	2008	AAMI	0
659	13408-1	Aseptic processing of health care products - Part 1: General requirements - Incorporates Amendment 1: 2013	2008	AAMI	0
660	5364	NULL	2008	AAMI	0
661	TIR31	PROCESS CHALLENGE DEVICES/TEST PACKS FOR USE IN HEALTH CARD FACILITIES	2008	AAMI	0
662	TIR22 A1	NULL	2008	AAMI	0
663	TIR17	Compatibility of materials subject to sterilization	2008	AAMI	0
664	ST79 A1	NULL	2008	AAMI	0
665	ST65	Processing of reusable surgical textiles for use in health care facilities - FDA RECOGNIZED	2008	AAMI	0
666	ST41 E2010	NULL	2008	AAMI	0
667	ST41	Ethylene oxide sterilization in health care facilities: Safety and effectiveness - FDA RECOGNIZED	2008	AAMI	0
668	ST55	Table-top steam sterilizers - FDA RECOGNIZED	2008	AAMI	0
669	TIR11135-2	NULL	2008	AAMI	0
670	SP10	Manual, electronic, or automated sphygmomanometers	2008	AAMI	
671	DPM5	NULL	2007	AAMI	
672	TIR36	Validation of software for regulated processes	2007	AAMI	0
673	TIR37	Sterilization of health care products-Radiation-Guidance on sterilization of biologics and tissue-based products	2007	AAMI	0
674	TIR34	Water for the reprocessing of medical devices	2007	AAMI	0
675	TIR22	Guidance for ANSI/AAMI/ISO 11607, Packaging for terminally sterilized medical devices Part 1 and Part 2:2006	2007	AAMI	0
676	TIR22 A1	NULL	2007	AAMI	0
677	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
678	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
679	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
680	14971	Medical devices-Application of risk management to medical devices	2007	AAMI	0
681	15223-1 A1	NULL	2007	AAMI	0
682	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
683	10993-6	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation	2007	AAMI	0
684	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
685	11135-2	Sterilization of health care products _ Ethylene Oxide _ Part 2: Guidance on the application of ISO 11135-1	2007	AAMI	0

686	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
687	22442-2	Medical devices utilizing animal tissues and their derivatives-Part 2: Controls on sourcing, collection and handling	2007	AAMI	0
688	22442-1	Medical devices utilizing animal tissues and their derivatives-Part 1: Application of risk management	2007	AAMI	0
689	BF7	Blood transfusion microfilters	2007	AAMI	0
690	BF64	Leukocyte reduction filters	2007	AAMI	0
691	81060-1	Non-invasive sphygmomanometers - Part 1: Requirements and test methods for nonautomated measurement type	2007	AAMI	0
692	62366	Medical devices Application of usability engineering to medical devices - Incorporates Amendment 1: 2013	2007	AAMI	0
693	EC71	Standard communications protocol for computer-assisted electrocardiography	2007	AAMI	0
694	EC38	Ambulatory electrocardiographs	2007	AAMI	0
695	EC13	Cardiac monitors, heart rate meters, and alarms	2007	AAMI	0
696	EC11	Diagnostic electrocardiographic devices	2007	AAMI	0
697	RD16	Hemodialyzers	2007	AAMI	0
698	RD17	NULL	2007	AAMI	0
699	PC69	Active implantable medical devices_ Electromagnetic compatibility_ EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators	2007	AAMI	0
700	RD61	NULL	2006	AAMI	0
701	NS28	Intracranial pressure monitoring devices - FDA RECOGNIZED; Incorporates Errata: 06/2001	2006	AAMI	0
702	BP22	Blood pressure transducers - Incorporates Errata: 08/2004	2006	AAMI	0
703	62304	Medical device software - Software life cycle processes	2006	AAMI	0
704	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
705	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
706	BE83	Biological evaluation of medical devices-Part 18: Chemical characterization of materials	2006	AAMI	0
707	BE78	Biological evaluation of medical devices Part 10: Tests for irritation and delayed-type hypersensitivity	2006	AAMI	0
708	18472	Sterilization of health care products-Biological and chemical indicators-Test equipment	2006	AAMI	0
709	15225	Medical devices - Quality management - Medical device nomenclature data structure	2006	AAMI	0
710	10993-19	Biological evaluation of medical devices _ Part 19: Physicochemical, morphological, and topographical characterization of materials	2006	AAMI	0
711	11137-3	Sterilization of health care products-Radiation-Part 3: Guidance on dosimetric aspects	2006	AAMI	0
712	11137-2	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose	2006	AAMI	0
713	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
714	11138-3	Sterilization of health care products-Biological indicators-art 3: Biological indicators for moist heat sterilization processes	2006	AAMI	0
715	11138-2	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes	2006	AAMI	0
716	11138-1	Sterilization of health care products - Biological indicators - Part 1: General requirements	2006	AAMI	0
717	10993-4	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood - Incorporates Amendment 1: 2006	2006	AAMI	0
718	10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	2006	AAMI	0
719	10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	2006	AAMI	0
720	10993-2	Biological evaluation of medical devices - Part 2: Animal welfare requirements	2006	AAMI	0

721	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
722	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
723	11138-5	Sterilization of health care products-Biological indicators-Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes	2006	AAMI	0
724	11138-4	Sterilization of health care products-Biological indicators-Part 4: Biological indicators for dry heat sterilization processes	2006	AAMI	0
725	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
726	11737-1	Sterilization of health care products-Microbiological methods-Part 1: Determination of the population of microorganisms on product	2006	AAMI	0
727	13408-3	Aseptic processing of health care products - Part 3: Lyophilization	2006	AAMI	0
728	13408-5	Aseptic processing of health care products - Part 5: Sterilization in place	2006	AAMI	0
729	SP10	Manual, electronic, or automated sphygmomanometers	2006	AAMI	0
730	ST79 A2	NULL	2006	AAMI	0
731	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
732	TIR11139	Sterilization of health care products - Vocabulary	2006	AAMI	0
733	TIR10993-19	Biological evaluation of medical devices - Part 19: Physico-chemical, morphological and topographical characterization of materials	2006	AAMI	0
734	TIR10993-20	Biological evaluation of medical devices - Part 20: Principles and methods for immunotoxicology testing of medical devices	2006	AAMI	0
735	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
736	5362	NULL	2006	AAMI	0
737	10651-5	NULL	2006	AAMI	0
738	IEC 60601-1-8	NULL	2006	AAMI	0
739	ISO TIR11139	NULL	2006	AAMI	
740	ISO TIR10993-19	NULL	2006	AAMI	
741	ISO TIR10993-20	NULL	2006	AAMI	
742	ISO TIR16142	NULL	2005	AAMI	
743	14408	NULL	2005	AAMI	0
744	TIR19218	NULL	2005	AAMI	0
745	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
746	TIR33	Sterilization of health care products - Radiation - Substantiation of a selected sterilization dose - Method VDmax	2005	AAMI	0
747	ST58	Chemical sterilization and high-level disinfection in health care facilities	2005	AAMI	0
748	TIR11	Selection and use of protective apparel and surgical drapes in health care facilities	2005	AAMI	0
749	13408-6	Aseptic processing of health care products - Part 6: Isolator systems - Incorporates Amendment 1: 2013	2005	AAMI	0
750	13408-4	Aseptic processing of health care products - Part 4: Clean-in-place technologies	2005	AAMI	0
751	11140-1	Sterilization of health care products-Chemical indicators-Part 1: General requirements	2005	AAMI	0
752	5840	Cardiovascular implants_Cardiac valve prostheses	2005	AAMI	0

753	25539-1	Cardiovascular implants-Endovascular devices-Part 1: Endovascular prostheses Amendment 1: Test methods - Incorporates Amendment 1: 2005	2005	AAMI	0
754	AT6	Autologous transfusion devices	2005	AAMI	0
755	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
756	EC12	Disposable ECG electrodes - FDA RECOGNIZED	2005	AAMI	0
757	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
758	ID54	Enteral feeding set adapters and connectors	2005	AAMI	0
759	II36	Medical electrical equipment Part 2: Particular requirements for safety of baby incubators	2004	AAMI	0
760	II51	Medical electrical equipment Part 2: Particular requirements for safety of transport incubators	2004	AAMI	0
761	RD52	Dialysate for hemodialysis	2004	AAMI	0
762	EQ56	Recommended practice for a medical equipment management program	2004	AAMI	0
763	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
764	10993-12	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	2004	AAMI	0
765	10993-13	Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices	2004	AAMI	0
766	11737-3	Sterilization of medical devices -- Microbiological methods -- Part 3: Guidance on evaluation and interpretation of bioburden data	2004	AAMI	0
767	15223	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplie	2004	AAMI	0
768	TIR12	Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers	2004	AAMI	0
769	TIR14	Contract sterilization using ethylene oxide	2004	AAMI	0
770	TIR32	Medical device software risk management	2004	AAMI	0
771	ST50	Dry heat (heated air) sterilizers - FDA RECOGNIZED	2004	AAMI	0
772	ST40	Table-top dry heat (heated air) sterilization and sterility assurance in health care facilitie	2004	AAMI	0
773	TIR14969	Medical devices-Quality management systems- Guidance on the application of ISO 13485:2003	2004	AAMI	0
774	5356-1	NULL	2004	AAMI	0
775	ISO TIR14969	NULL	2004	AAMI	
776	ISO 11737-3	NULL	2004	AAMI	
777	TIR60878	Graphical symbols for electrical equipment in medical practice	2003	AAMI	0
778	ST35	Safe handling and biological decontamination of reusable medical devices in health care facilities and in nonclinical settings	2003	AAMI	0
779	TIR30	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices - FDA RECOGNIZED	2003	AAMI	0
780	14155-2	Clinical investigation of medical devices for human subjects -- Part 2: Clinical investigation plans	2003	AAMI	0
781	13408-2	Aseptic processing of health care products - Part 2: Filtration	2003	AAMI	0
782	13485	Medical devices-Quality management systems-Requirements for regulatory purposes	2003	AAMI	0
783	14155-1	Clinical investigation of medical devices for human subjects -- Part 1: General requirements	2003	AAMI	0
784	10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2003	AAMI	0
785	10993-3	Biological evaluation of medical devices-Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity	2003	AAMI	0
786	EC57	Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms	2003	AAMI	0

787	DF80	Medical electrical equipment_ Part 2-4: Particular requirements for the safety of cardiac defibrillators (including automated external defibrillators)	2003	AAMI	0
788	SP10	Manual, electronic, or automated sphygmomanometers	2003	AAMI	0
789	RD5	Hemodialysis systems	2003	AAMI	0
790	PB70	Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities - FDA RECOGNIZED	2003	AAMI	0
791	25539-1	Cardiovascular implants-Endovascular devices-Part 1: Endovascular prostheses Amendment 1: Test methods - Incorporates Amendment 1: 2005	2003	AAMI	0
792	60601-2-4	Medical electrical equipment - Part 2-4: Particular requirements for basic safety and essential performance of cardiac defibrillators	2002	AAMI	0
793	RD47	Reprocessing of hemodialyzers - FDA RECOGNIZED	2002	AAMI	0
794	RD16	Hemodialyzers	2002	AAMI	0
795	EC13	Cardiac monitors, heart rate meters, and alarms	2002	AAMI	0
796	10993-17	Biological evaluation of medical devices - Part 17: Methods for the establishment of allowable limits for leachable substances	2002	AAMI	0
797	TIR29	GUIDE FOR PROCESS CONTROL IN RADIATION STERILIZATION	2002	AAMI	0
798	ST46	Steam sterilization and sterility assurance in health care facilities	2002	AAMI	0
799	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
800	ST72	Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing	2002	AAMI	0
801	10651-4	NULL	2002	AAMI	0
802	ST44	Resistometers used for characterizing the performance of biological and chemical indicators	2002	AAMI	
803	5366-3	NULL	2001	AAMI	0
804	4135	NULL	2001	AAMI	0
805	TIR28	Product adoption and process equivalence for ethylene oxide sterilization	2001	AAMI	0
806	TIR20	Parametric release for ethylene oxide sterilization	2001	AAMI	0
807	SW68	Medical device software Software life cycle processes	2001	AAMI	0
808	10993-14	Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics	2001	AAMI	0
809	10993-8	Biological evaluation of medical devices Part 8: Selection and qualification of reference materials for biological tests	2001	AAMI	0
810	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
811	15675	Cardiovascular implants and artificial organs - Cardiopulmonary bypass systems - Arterial blood line filters	2001	AAMI	0
812	15674	Cardiovascular implants and artificial organs - Hard shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags	2001	AAMI	0
813	EC11	Diagnostic electrocardiographic devices	2001	AAMI	0
814	BP22	Blood pressure transducers - Incorporates Errata: 08/2004	2001	AAMI	0
815	EC71	Standard communications protocol for computer-assisted electrocardiography	2001	AAMI	0
816	EC53	ECG cables and leadwires	2001	AAMI	0
817	HF18	Electrosurgical devices	2001	AAMI	0
818	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
819	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

820	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
821	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
822	60601-1-4	Medical Electrical Equipment - Part 1-4: General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems	2000	AAMI	0
823	PAC49	Pacemaker emergency intervention system	2000	AAMI	0
824	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
825	15225	Medical devices - Quality management - Medical device nomenclature data structure	2000	AAMI	0
826	14161	Sterilization of health care products - Biological indicators - Guidance for the selection, use and interpretation of results	2000	AAMI	0
827	10993-15	Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys	2000	AAMI	0
828	TIR16	Microbiological aspects of ethylene oxide sterilization	2000	AAMI	0
829	TIR26	Ventricular assist and heart replacement systems	2000	AAMI	0
830	5366-1	NULL	2000	AAMI	0
831	ST33	Guidelines for the selection and use of reusable rigid container systems for ethylene oxide sterilization and steam sterilization in health care facilities	2000	AAMI	
832	ST37	Flash sterilization- Steam sterilization of patient care items for immediate use	2000	AAMI	
833	TIR4	Apnea monitoring by means of thoracic impedance pneumography	2000	AAMI	
834	TIR9	Evaluation of Clinical Systems for Invasive Blood Pressure Monitoring	2000	AAMI	
835	VP20-94	Cardiovascular implants_Vascular graft prostheses	2000	AAMI	
836	ISO 10993-8	NULL	2000	AAMI	
837	ISO 11134	NULL	2000	AAMI	
838	ISO TIR15843	NULL	2000	AAMI	
839	SP9	Non-automated sphygmomanometers	2000	AAMI	
840	MDS	NULL	2000	AAMI	
841	NS15	Implantable peripheral nerve stimulators	2000	AAMI	
842	HE48	Human factors engineering guidelines and preferred practices for the design of medical devices	2000	AAMI	
843	DF2	Cardiac defibrillator devices	2000	AAMI	
844	DF39	Automatic external defibrillators and remote-control defibrillators	2000	AAMI	
845	ST21	Sterilization of health care productsù Biological indicatorsùPart 2: Biological indicators for ethylene oxide sterilization	1999	AAMI	
846	TIR25	Chemical indicatorsù Guidance for the selection, use, and interpretation of results	1999	AAMI	
847	10079-1	NULL	1999	AAMI	0
848	10079-2	NULL	1999	AAMI	0
849	10079-3	NULL	1999	AAMI	0
850	TIR23	Signal Averaging	1999	AAMI	0
851	TIR24	Acquisition and use of physiologic waveform databases for testing of medical devices	1999	AAMI	0
852	TIR19 A1	NULL	1999	AAMI	0
853	ST66	Sterilization of health care products Chemical indicators Part 2: Class 2 indicators for air removal test	1999	AAMI	0
854	10993-9	Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products	1999	AAMI	0

855	10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	1999	AAMI	0
856	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
857	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
858	EC38	Ambulatory electrocardiographs	1998	AAMI	0
859	7198	Cardiovascular implants-Tubular vascular prostheses	1998	AAMI	0
860	10993-13	Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices	1998	AAMI	0
861	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
862	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
863	TIR21	Systems Used to Forecast Remaining Pacemaker Battery Service Life	1998	AAMI	0
864	TIR19	Guidance for ANSI/AAMI/ISO 1 0993-7:1 995, Biological evaluation of medical deicesùPart 7: Ethylene oxide sterilization residuals	1998	AAMI	
865	ISO TIR15844	NULL	1998	AAMI	
866	HDR	Current Concepts in Hemodialyzer Reprocessing	1998	AAMI	
867	TIR13	Principles of industrial moist heat sterilization	1997	AAMI	0
868	TIR14	Contract sterilization using ethylene oxide	1997	AAMI	0
869	10993-16	Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables	1997	AAMI	0
870	7199	Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators)	1996	AAMI	0
871	5840	Cardiovascular implants Cardiac valve prostheses	1996	AAMI	0
872	13488	Quality systems -- Medical devices -- Particular requirements for the application of ISO9002	1996	AAMI	0
873	ID54	Enteral feeding set adapters and connectors	1996	AAMI	0
874	ISO 13488	NULL	1996	AAMI	
875	NS14	Implantable spinal cord stimulators	1995	AAMI	0
876	NS15	Implantable peripheral nerve stimulators	1995	AAMI	0
877	EC53	ECG cables and leadwires	1995	AAMI	0
878	10993-7	Biological evaluation of medical devices-Part 7: Ethylene oxide sterilization residuals	1995	AAMI	0
879	11137	Sterilization of health care products -- Requirements for validation and routine control -- Radiation sterilization	1995	AAMI	0
880	11195	NULL	1995	AAMI	0
881	11134	Sterilization of health care products -- Requirements for validation and routine control -- Industrial moist heat sterilization	1994	AAMI	0
882	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
883	BP22	Blood pressure transducers - Incorporates Errata: 08/2004	1994	AAMI	0
884	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
885	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
886	60601-2-25	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs	1993	AAMI	0
887	ST37	Flash sterilization- Steam sterilization of patient care items for immediate use	1993	AAMI	0

888	ES1	NULL	1993	AAMI	
889	TIR9	Evaluation of Clinical Systems for Invasive Blood Pressure Monitoring	1992	AAMI	0
890	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
891	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
892	TIR4	Apnea monitoring by means of thoracic impedance pneumography	1989	AAMI	0
893	TIR60-R2019	NULL	0	AAMI	0
894	TIR61-R2019	NULL	0	AAMI	0
895	TIR62-R2019	NULL	0	AAMI	0