Standards Manager Web Standards List

AAMI-Association for the Advancement of Medical Instrumentation

Id	Number	Title	Year	Organization	Page
1	CR513	Guidance on radiation sterilization validation and routine control of single-use systems used for pharmaceutical and biopharmaceutical manufacturing	2024	AAMI	
2	TIR28	Product adoption and process equivalence for ethylene oxide sterilization	2024	AAMI	
3	TIR48	Quality Management System (QMS) Recommendations on the Application of the U.S. FDA___s CGMP Final Rule on Combination Products	2024	AAMI	
4	TIR99	Processing of dilators, transesophageal and ultrasound probes in health care facil ities	2024	AAMI	
5	TIR106	Microbiological methodsùUnderstanding and use of product bioburden data	2024	AAMI	
6	ST24	Automatic, general purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities	2024	AAMI	
7	11140-6	Steril ization of health care productsù Chemical indicatorsùPart 6: Type 2 indicators and process challenge devices for use in performance testing of small steam sterilizers	2024	AAMI	
8	TIR34971	Application of ISO 14971 to machine learning in artificial intelligenceùGuide	2023	AAMI	0
9	TIR57	Principles for medical device securityùRisk management	2023	AAMI	0
10	TIR63	Management of loaned critical and semi-critical medical devices that require sterilization or high-level disinfection	2023	AAMI	0
11	ST55	Table-top steam sterilizers - FDA RECOGNIZED	2023	AAMI	0
12	ST108	Water for the processing of medical devices	2023	AAMI	0
13	ST15883-1	Washer-disinfectors ù Part 1: General requirements, terms and definitions and tests	2023	AAMI	0
14	ST15883-3	Washer-disinfectors - Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers	2023	AAMI	0
15	SW96	Standard for medical device securityùSecurity risk management for device manufacturers	2023	AAMI	0
16	EQ89	Guidance for the use of medical equipment maintenance strategies and procedures	2023	AAMI	0
17	ISO 11137-3	NULL	2023	AAMI	0
18	ISO TIR16775	NULL	2023	AAMI	0
19	ISO TIR21387	NULL	2023	AAMI	0
20	ISO TIR22456	NULL	2022	AAMI	0
21	PB70	Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities - FDA RECOGNIZED	2022	AAMI	0
22	ISO TIR11137-4	NULL	2022	AAMI	0
23	ISO 15223-1	NULL	2022	AAMI	0
24	ISO 18472	NULL	2022	AAMI	0
25	HIT1000-1	Safety and effectiveness of health IT software and systems-Part 1: Fundamental concepts, principles, and requirements	2022	AAMI	0
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	0
27	2800-1-1	Standard for Risk Concerns for Interoperable Medical Products	2022	AAMI	0
28	2800-1-2	Standard for Interoperable Item Development Life Cycle	2022	AAMI	0
29	2800-1-3	Standard for Interoperable Item Integration Life Cycle	2022	AAMI	0
30	2800-1	Standard for Safety for Medical Device Interoperability	2022	AAMI	0

31	CR34971	Guidance on the Application of ISO 14971 to Artificial Intelligence and Machine Learning	2022	AAMI	0
32	ISO 5840-1	NULL	2022	AAMI	0
33	ISO 5840-2	NULL	2022	AAMI	0
34	ISO 5840-3	NULL	2022	AAMI	0
35	ST98	Cleaning validation of health care productsùRequirements for development and validation of a cleaning process for medical devices	2022	AAMI	0
36	TIR39	Guidance on selecting a microbial challenge and inoculation sites for sterilization validation of medical devices	2022	AAMI	0
37	UL 2800-1-1	Standard for Risk Concerns for Interoperable Medical Products	2022	AAMI	0
38	UL 2800-1-2	Standard for Interoperable Item Development Life Cycle	2022	AAMI	0
39	UL 2800-1-3	Standard for Interoperable Item Integration Life Cycle	2022	AAMI	0
40	UL 2800-1	Standard for Medical Device Interoperability	2022	AAMI	0
41	TIR104	Guidance on transferring health care products between radiation sterilization sources	2022	AAMI	0
42	TIR48	Quality Management System (QMS) Recommendations on the Application of the U.S. FDA___s CGMP Final Rule on Combination Products	2021	AAMI	0
43	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	0
44	TIR100	End-to-end microbiological quality and sterility assurance	2021	AAMI	0
45	IEC 62366-1	NULL	2021	AAMI	0
46	ST91	Flexible and semi-rigid endoscope processing in health care facilities	2021	AAMI	0
47	CR510	Quality Systems and Medical Devices	2021	AAMI	0
48	TIR101	Fluid delivery performance testing for infusion pumps	2021	AAMI	0
49	CN27	General requirements for Luer activated valves (LAVs) incorporated into medical devices for intravascular applications	2021	AAMI	0
50	TIR58	Water testing methodologies	2021	AAMI	0
51	PC76	Active implantable medical devicesùRequirements and test protocols for safety of patients with pacemakers and ICDs exposed to magnetic resonance imaging	2021	AAMI	0
52	TIR42	Evaluation of particulates associated with vascular medical devices	2021	AAMI	0
53	TIR43	Ultrapure dialysate for hemodialysis and related therapies	2021	AAMI	0
54	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
55	TIR105	Risk management guidance for combination products	2020	AAMI	0
56	TIR20416	Medical devicesù Post-market surveillance for manufacturers	2020	AAMI	0
57	TIR24971	Medical devices - Guidance on the application of ISO 14971	2020	AAMI	0
58	TIR12	Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers	2020	AAMI	0
59	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
60	13485	Medical devices-Quality management systems-Requirements for regulatory purposes	2020	AAMI	0
61	RD47	Reprocessing of hemodialyzers - FDA RECOGNIZED	2020	AAMI	0
62	MP80601-2-49	NULL	2020	AAMI	0
63	RT3	NULL	2020	AAMI	0
64	HIT1000-4	NULL	2020	AAMI	0
65	HIT1000-4(PS)	Safety and effectiveness of health IT software and systemsùPart 4: Application of human factors engineering	2020	AAMI	0
66	EC12	Disposable ECG electrodes - FDA RECOGNIZED	2020	AAMI	0

67	EC53	ECG cables and leadwires	2020	AAMI	0
68	EC57	Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms	2020	AAMI	0
69	IEC 80601-2-77	NULL	2020	AAMI	0
70	IEC 80601-2-78	NULL	2020	AAMI	0
71	ISO TIR24971	NULL	2020	AAMI	0
72	ISO TIR20416	NULL	2020	AAMI	0
73	ISO 14155	NULL	2020	AAMI	0
74	TIR49	Design of training and instructional materials for medical devices used in non-clinical environments	2020	AAMI	0
75	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	0
76	TIR69	Risk management of radio-frequency wireless coexistence for medical devices and systems	2020	AAMI	0
77	TIR71	Guidance for logging of alarm system data	2020	AAMI	0
78	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	0
79	TIR21	Systems Used to Forecast Remaining Pacemaker Battery Service Life	2020	AAMI	0
80	TIR17	Compatibility of materials subject to sterilization	2020	AAMI	0
81	ST79	Comprehensive guide to steam sterilization and sterility assurance in health care facilities	2020	AAMI	0
82	ISO 13485	NULL	2019	AAMI	0
83	ISO 14117	NULL	2019	AAMI	0
84	ISO 14971	NULL	2019	AAMI	0
85	ISO 11607-1	NULL	2019	AAMI	0
86	ISO 11607-2	NULL	2019	AAMI	0
87	ISO 11138-7	NULL	2019	AAMI	0
88	ISO 11737-2	NULL	2019	AAMI	0
89	ISO 11137-1	NULL	2019	AAMI	0
90	ISO 11137-2	NULL	2019	AAMI	0
91	ISO 10993-15	NULL	2019	AAMI	0
92	ISO 23500-1	NULL	2019	AAMI	0
93	ISO 23500-2	NULL	2019	AAMI	0
94	ISO 23500-3	NULL	2019	AAMI	0
95	ISO 23500-4	NULL	2019	AAMI	0
96	ISO 23500-5	NULL	2019	AAMI	0
97	ISO 81060-2	NULL	2019	AAMI	0
98	TIR9	Evaluation of Clinical Systems for Invasive Blood Pressure Monitoring	2019	AAMI	0
99	TIR23	Signal Averaging	2019	AAMI	0
100	TIR24	Acquisition and use of physiologic waveform databases for testing of medical devices	2019	AAMI	0
101	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
102	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
103	ST72	Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing	2019	AAMI	0
104	TIR38	Medical device safety assurance case report guidance	2019	AAMI	0

105	TIR75	Sorbent-based regenerative hemodialysis systems	2019	AAMI	0
106	TIR97	Principles for medical device security - Postmarket risk management for device manufacturers	2019	AAMI	0
107	TIR102	U.S. FDA 21 CFR mapping to the applicable regulatory requirement references in ISO 13485:2016 Quality Management Systems	2019	AAMI	0
108	14117	Active implantable medical devices - Electromagnetic compatibility - EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization devices	2019	AAMI	0
109	14971	Medical devices-Application of risk management to medical devices	2019	AAMI	0
110	23500-1	Preparation and quality management of fluids for haemodialysis and related therapies - Part 1: General requirements	2019	AAMI	0
111	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
112	23500-3	Preparation and quality management of fluids for haemodialysis and related therapies - Part 3: Water for haemodialysis and related therapies	2019	AAMI	0
113	23500-4	Preparation and quality management of fluids for haemodialysis and related therapies - Part 4: Concentrates for haemodialysis and related therapies	2019	AAMI	0
114	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
115	81060-2	Non-invasive sphygmomanometers - Part 2: Clinical investigation of automated measurement type	2019	AAMI	0
116	CR500	Basic Introduction to the IEC 60601 Series	2019	AAMI	0
117	EQ93	Medical equipment management - Vocabulary used in medical equipment programs	2019	AAMI	0
118	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
119	2800-1	Standard for Safety for Medical Device Interoperability	2019	AAMI	0
120	11138-7	Sterilization of health care products - Biological indicators - Guidance for the selection, use, and interpretation of results	2019	AAMI	0
121	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
122	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
123	HIT1000-1	Safety and effectiveness of health IT software and systems-Part 1: Fundamental concepts, principles, and requirements	2018	AAMI	0
124	80369-1	Small bore connectors for liquids and gases in healthcare applications - Part 1: General requirements	2018	AAMI	0
125	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
126	60601-2-4	Medical electrical equipment - Part 2-4: Particular requirements for basic safety and essential performance of cardiac defibrillators	2018	AAMI	0
127	TIR21900	Guidance for uncertainty analysis regarding the application of ISO/TS 10974	2018	AAMI	0
128	10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2018	AAMI	0
129	TIR77	Technical Information Report Sorbent-based regenerative hemodialysis systems	2018	AAMI	0
130	TIR68	Low and intermediate-level disinfection in healthcare settings for medical devices and patient care equipment and sterile processing environmental surfaces	2018	AAMI	0
131	SW91	Classification of defects in health software	2018	AAMI	0
132	13408-7	Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products	2018	AAMI	0
133	ST24	Automatic, general purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities	2018	AAMI	0
134	ST58	Chemical sterilization and high-level disinfection in health care facilities	2018	AAMI	0
135	ST65	Processing of reusable surgical textiles for use in health care facilities - FDA RECOGNIZED	2018	AAMI	0
136	ST77	Containment devices for reusable medical device sterilization	2018	AAMI	0

137	HE75	Human factors engineering Design of medical devices	2018	AAMI	0
138	11737-1	Sterilization of health care products-Microbiological methods-Part 1: Determination of the population of microorganisms on product	2018	AAMI	0
139	13408-2	Aseptic processing of health care products - Part 2: Filtration	2018	AAMI	0
140	ISO TIR10974	NULL	2018	AAMI	0
141	ISO 80369-1	NULL	2018	AAMI	0
142	ISO TIR21900	NULL	2018	AAMI	0
143	ST8	Hospital steam sterilizers - FDA RECOGNIZED	2018	AAMI	0
144	ISO 8637-2	NULL	2018	AAMI	0
145	ISO 8637-3	NULL	2018	AAMI	0
146	ISO 10993-1	NULL	2018	AAMI	0
147	ISO 13408-2	NULL	2018	AAMI	0
148	ISO 11737-1	NULL	2018	AAMI	0
149	ISO 13408-7	NULL	2018	AAMI	0
150	IEC 80601-2-30	NULL	2018	AAMI	0
151	ISO 5841-3	NULL	2018	AAMI	0
152	IEC 60601-2-16	NULL	2018	AAMI	0
153	IEC 60601-2-39	NULL	2018	AAMI	0
154	TIR10974	Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device	2018	AAMI	0
155	EQ93	NULL	2018	AAMI	0
156	ST40	Table-top dry heat (heated air) sterilization and sterility assurance in health care facilitie	2018	AAMI	0
157	ST41	Ethylene oxide sterilization in health care facilities: Safety and effectiveness - FDA RECOGNIZED	2018	AAMI	0
158	ST50	Dry heat (heated air) sterilizers - FDA RECOGNIZED	2018	AAMI	0
159	TIR40	Sterilization of health care productsùRadiationùGuidance on dose setting utilizing a Modified Method 2	2018	AAMI	0
160	TIR45	Guidance on the use of AGILE practices in the development of medical device software	2018	AAMI	0
161	TIR63	Management of loaned critical and semi-critical medical devices that require sterilization or high-level disinfection	2018	AAMI	0
162	TIR67	Promoting safe practices pertaining to the use of sterilant and disinfectant chemicals in health care facilities	2018	AAMI	0
163	TIR69	Risk management of radio-frequency wireless coexistence for medical devices and systems	2017	AAMI	0
164	TIR71	Guidance for logging of alarm system data	2017	AAMI	0
165	TIR72	Dialysis fluid chemical composition	2017	AAMI	0
166	TIR15499	Biological evaluation of medical devices Guidance on the conduct of biological evaluation within a risk management process	2017	AAMI	0
167	TIR59	Integrating human factors into design controls	2017	AAMI	0
168	TIR50	Post-market surveillance of use error management	2017	AAMI	0
169	TIR51	Human factors engineering Guidance for contextual inquiry	2017	AAMI	0
170	TIR52	Environmental Monitoring For Terminally Sterilized Healthcare Products	2017	AAMI	0
171	TIR55	Human factors engineering for processing medical devices	2017	AAMI	0
172	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
173	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
174	TIR29	GUIDE FOR PROCESS CONTROL IN RADIATION STERILIZATION	2017	AAMI	0

175	TIR30	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices - FDA RECOGNIZED	2017	AAMI	0
176	TIR34	Water for the reprocessing of medical devices	2017	AAMI	0
177	TIR39	Guidance on selecting a microbial challenge and inoculation sites for sterilization validation of medical devices	2017	AAMI	0
178	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
179	ST90	NULL	2017	AAMI	0
180	TIR16	Microbiological aspects of ethylene oxide sterilization	2017	AAMI	0
181	TIR17	Compatibility of materials subject to sterilization	2017	AAMI	0
182	TIR21	Systems Used to Forecast Remaining Pacemaker Battery Service Life	2017	AAMI	0
183	NS4	Transcutaneous electrical nerve stimulators	2017	AAMI	0
184	RT2	NULL	2017	AAMI	0
185	CI86	NULL	2017	AAMI	0
186	25539-1	Cardiovascular implants-Endovascular devices-Part 1: Endovascular prostheses Amendment 1: Test methods - Incorporates Amendment 1: 2005	2017	AAMI	0
187	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
188	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
189	IEC 60601-2-2	NULL	2017	AAMI	0
190	TIR80002-2	Medical device software - Part 2: Validation of software for medical device quality systems	2017	AAMI	0
191	ISO 8637-1	NULL	2017	AAMI	0
192	ISO 14708-3	NULL	2017	AAMI	0
193	ISO 10993-4	NULL	2017	AAMI	0
194	ISO 10993-16	NULL	2017	AAMI	0
195	ISO 10993-11	NULL	2017	AAMI	0
196	ISO 11138-1	NULL	2017	AAMI	0
197	ISO 11138-2	NULL	2017	AAMI	0
198	ISO 11138-3	NULL	2017	AAMI	0
199	ISO 11138-4	NULL	2017	AAMI	0
200	ISO 11138-5	NULL	2017	AAMI	0
201	ISO TIR80002-2	NULL	2017	AAMI	0
202	ISO 27185	NULL	2017	AAMI	0
203	ISO TIR15499	NULL	2017	AAMI	0
204	ISO 25539-1	NULL	2017	AAMI	0
205	ISO 16142-2	NULL	2017	AAMI	0
206	ISO 17664	NULL	2017	AAMI	0
207	13408-1	Aseptic processing of health care products - Part 1: General requirements - Incorporates Amendment 1: 2013	2017	AAMI	0
208	14708-3	Implants for surgeryùActive implantable medical devicesù Part 3: Implantable neurostimulators	2017	AAMI	0
209	16142-2	NULL	2017	AAMI	0
210	17664	NULL	2017	AAMI	0
211	11137-3	Sterilization of health care products-Radiation-Part 3: Guidance on dosimetric aspects	2017	AAMI	0

212	11138-1	Sterilization of health care products - Biological indicators - Part 1: General requirements	2017	AAMI	0
213	11138-2	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes	2017	AAMI	0
214	11138-3	Sterilization of health care products-Biological indicators-art 3: Biological indicators for moist heat sterilization processes	2017	AAMI	0
215	11138-4	Sterilization of health care products-Biological indicators-Part 4: Biological indicators for dry heat sterilization processes	2017	AAMI	0
216	11138-5	Sterilization of health care products-Biological indicators-Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes	2017	AAMI	0
217	TIR51	Human factors engineering Guidance for contextual inquiry	2017	AAMI	0
218	TIR63	Management of loaned critical and semi-critical medical devices that require sterilization or high-level disinfection	2017	AAMI	0
219	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
220	10993-4	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood - Incorporates Amendment 1: 2006	2017	AAMI	0
221	10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	2017	AAMI	0
222	7198	Cardiovascular implants-Tubular vascular prostheses	2016	AAMI	0
223	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
224	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
225	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
226	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
227	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
228	ST81	Sterilization of medical devices-Information to be provided by the manufacturer for the processing of resterilizable medical devices	2016	AAMI	0
229	TIR30	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices - FDA RECOGNIZED	2016	AAMI	0
230	TIR32	Medical device software risk management	2016	AAMI	0
231	TIR17665-2	Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1	2016	AAMI	0
232	7199	Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators)	2016	AAMI	0
233	10993-6	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation	2016	AAMI	0
234	18241	NULL	2016	AAMI	0
235	18242	NULL	2016	AAMI	0
236	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
237	15674	Cardiovascular implants and artificial organs - Hard shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags	2016	AAMI	0
238	15675	Cardiovascular implants and artificial organs - Cardiopulmonary bypass systems - Arterial blood line filters	2016	AAMI	0
239	15676	NULL	2016	AAMI	0
240	16142-1	NULL	2016	AAMI	0
241	13485	Medical devices-Quality management systems-Requirements for regulatory purposes	2016	AAMI	0
242	15225	Medical devices - Quality management - Medical device nomenclature data structure	2016	AAMI	0

243	80369-5	Small-bore connectors for liquids and gases in healthcare applicationsùPart 5: Connectors for limb cuff inflation applications	2016	AAMI	0
244	80369-6	Small-bore connectors for liquids and gases in healthcare applications ù Part 6: Connectors for neuraxial applications	2016	AAMI	0
245	80369-20	Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods	2016	AAMI	0
246	TIR14	Contract sterilization using ethylene oxide	2016	AAMI	0
247	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
248	TIR57	Principles for medical device securityùRisk management	2016	AAMI	0
249	TIR65	Sustainability of medical devicesùElements of a responsible product life cycle	2016	AAMI	0
250	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
251	ISO 15225	NULL	2016	AAMI	0
252	ISO 15674	NULL	2016	AAMI	0
253	ISO 15675	NULL	2016	AAMI	0
254	ISO 15676	NULL	2016	AAMI	0
255	ISO 18241	NULL	2016	AAMI	0
256	ISO 18242	NULL	2016	AAMI	0
257	ISO 80369-3	NULL	2016	AAMI	0
258	ISO 80369-5	NULL	2016	AAMI	0
259	ISO 80369-6	NULL	2016	AAMI	0
260	ISO 80369-7	NULL	2016	AAMI	0
261	ISO 22442-1	NULL	2016	AAMI	0
262	ISO 22442-2	NULL	2016	AAMI	0
263	ISO 22442-3	NULL	2016	AAMI	0
264	ISO TIR17665-2	NULL	2016	AAMI	0
265	ISO TIR17665-3	NULL	2016	AAMI	0
266	ISO TIR19024	NULL	2016	AAMI	0
267	ISO 16142-1	NULL	2016	AAMI	0
268	ISO TIR13004	NULL	2016	AAMI	0
269	ISO TIR22442-4	NULL	2016	AAMI	0
270	ISO 10993-6	NULL	2016	AAMI	0
271	ISO 14160	NULL	2016	AAMI	0
272	ISO 7198	NULL	2016	AAMI	0
273	ISO 7199	NULL	2016	AAMI	0
274	IEC TIR80002-3	NULL	2016	AAMI	0
275	IEC TIR80001-2-8	NULL	2016	AAMI	0
276	IEC TIR62366-2	NULL	2016	AAMI	0
277	IEC 60601-1-12	NULL	2016	AAMI	0

278	IEC 60601-2-47	NULL	2016	AAMI	0
279	IEC 60601-2-25	NULL	2016	AAMI	0
280	IEC 60601-2-27	NULL	2016	AAMI	0
281	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
282	TIR13004	Sterilization of health care products - Radiation - Substantiation of a selected sterilization dose: Method VDmax SD	2016	AAMI	0
283	TIR24971	Medical devices - Guidance on the application of ISO 14971	2016	AAMI	0
284	80601-2-58 AMD 1	NULL	2016	AAMI	0
285	22442-1	Medical devices utilizing animal tissues and their derivatives-Part 1: Application of risk management	2016	AAMI	0
286	22442-2	Medical devices utilizing animal tissues and their derivatives-Part 2: Controls on sourcing, collection and handling	2016	AAMI	0
287	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
288	60601-2-20 AMD 1	NULL	2016	AAMI	0
289	60601-2-21 AMD 1	NULL	2016	AAMI	0
290	60601-2-25	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs	2016	AAMI	0
291	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
292	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
293	60601-2-50 AMD 1	NULL	2016	AAMI	0
294	80369-3	NULL	2016	AAMI	0
295	80369-7	NULL	2016	AAMI	0
296	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
297	BP22	Blood pressure transducers - Incorporates Errata: 08/2004	2016	AAMI	0
298	ST55	Table-top steam sterilizers - FDA RECOGNIZED	2016	AAMI	0
299	TIR28	Product adoption and process equivalence for ethylene oxide sterilization	2016	AAMI	0
300	ST72	Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing	2016	AAMI	0
301	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
302	TIR15	Physical aspects of ethylene oxide sterilization	2016	AAMI	0
303	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
304	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
305	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
306	TIR23810	Cardiovascular implants and artificial organs - Checklist for preoperative extracorporeal circulation equipment setup	2015	AAMI	0
307	TIR65	Sustainability of medical devicesùElements of a responsible product life cycle	2015	AAMI	0
308	NS28	Intracranial pressure monitoring devices - FDA RECOGNIZED; Incorporates Errata: 06/2001	2015	AAMI	0

309	EC12	Disposable ECG electrodes - FDA RECOGNIZED	2015	AAMI	0
310	26782	NULL	2015	AAMI	0
311	60601-2-4	Medical electrical equipment - Part 2-4: Particular requirements for basic safety and essential performance of cardiac defibrillators	2015	AAMI	0
312	IEC TIR60878	NULL	2015	AAMI	0
313	ISO 5367	NULL	2015	AAMI	0
314	ISO 13408-5	NULL	2015	AAMI	0
315	ISO 14708-5	NULL	2015	AAMI	0
316	ISO 13408-3	NULL	2015	AAMI	0
317	ISO 12417-1	NULL	2015	AAMI	0
318	ISO 11140-3	NULL	2015	AAMI	0
319	ISO 11140-4	NULL	2015	AAMI	0
320	ISO 11140-5	NULL	2015	AAMI	0
321	ISO 8638	NULL	2015	AAMI	0
322	ISO 8836	NULL	2015	AAMI	0
323	ISO TIR23810	NULL	2015	AAMI	0
324	ISO TIR62354	NULL	2015	AAMI	0
325	ISO 25539-3	NULL	2015	AAMI	0
326	ISO 80369-20	NULL	2015	AAMI	0
327	ISO 20857	NULL	2015	AAMI	0
328	TIR48	Quality Management System (QMS) Recommendations on the Application of the U.S. FDA___s CGMP Final Rule on Combination Products	2015	AAMI	0
329	ST91	Flexible and semi-rigid endoscope processing in health care facilities	2015	AAMI	0
330	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
331	13408-5	Aseptic processing of health care products - Part 5: Sterilization in place	2015	AAMI	0
332	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
333	13408-3	Aseptic processing of health care products - Part 3: Lyophilization	2015	AAMI	0
334	8836	NULL	2015	AAMI	0
335	5367	NULL	2015	AAMI	0
336	5840-1	NULL	2015	AAMI	0
337	5840-2	NULL	2015	AAMI	0
338	TIR60878	Graphical symbols for electrical equipment in medical practice	2015	AAMI	0
339	TIR62354	General testing procedures for medical electrical equipment	2015	AAMI	0
340	TIR11	Selection and use of protective apparel and surgical drapes in health care facilities	2015	AAMI	0
341	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
342	ST15883-3	Washer-disinfectors - Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers	2015	AAMI	0
343	14708-5	Implants for surgeryùActive implantable medical devicesù Part 5: Circulatory support devices	2015	AAMI	0
344	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

345	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
346	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
347	134080-3	NULL	2015	AAMI	0
348	134080-5	NULL	2015	AAMI	0
349	25539-3	Cardiovascular implants ù Endovascular devices ù Part 3: Vena cava filters	2015	AAMI	0
350	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
351	8638	Cardiovascular implants and extracorporeal systems - Extracorporeal blood circuit for hemodialyzers, hemodiafilters and hemofilters	2015	AAMI	0
352	62366-1	Medical devices Part 1: Application of usability engineering to medical devices	2015	AAMI	0
353	80369-20	Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods	2015	AAMI	0
354	CN6	Small-bore connectors for liquids and gases in healthcare applications - Part 6: Connectors for neuraxial applications	2015	AAMI	0
355	EQ89	Guidance for the use of medical equipment maintenance strategies and procedures	2015	AAMI	0
356	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
357	SPHC	Sterile Processing In Healthcare Facilities Preparing for Accreditation Surveys - 2nd Edition	2014	AAMI	0
358	SPVVQ	Basic Concepts in Sterilization Processes Verification, Validation, And Qualification	2014	AAMI	0
359	DUG	Dialysis Water and Dialysate Recommendations: A User Guide	2014	AAMI	0
360	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
361	23500	Guidance for the preparation and quality management of fluids for hemodialysis and related therapies	2014	AAMI	0
362	26722	Water treatment equipment for hemodialysis and related therapies	2014	AAMI	0
363	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
364	5841-2	Implants for surgery - Cardiac pacemakers - Part 2: Reporting of clinical performance of populations of pulse generators or leads	2014	AAMI	0
365	10993-3	Biological evaluation of medical devices-Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity	2014	AAMI	0
366	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
367	11140-1	Sterilization of health care products-Chemical indicators-Part 1: General requirements	2014	AAMI	0
368	11663	Quality of dialysis fluid for hemodialysis and related therapies	2014	AAMI	0
369	13958	Concentrates for hemodialysis and related therapies	2014	AAMI	0
370	13959	Water for hemodialysis and related therapies	2014	AAMI	0
371	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
372	1340804	NULL	2014	AAMI	0
373	14161	Sterilization of health care products - Biological indicators - Guidance for the selection, use and interpretation of results	2014	AAMI	0
374	10993-2	Biological evaluation of medical devices - Part 2: Animal welfare requirements	2014	AAMI	0
375	10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	2014	AAMI	0
376	13408-4	Aseptic processing of health care products - Part 4: Clean-in-place technologies	2014	AAMI	0

377	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
378	10993-9	Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products	2014	AAMI	0
379	10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	2014	AAMI	0
380	10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	2014	AAMI	0
381	10993-13	Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices	2014	AAMI	0
382	TIR58	Water testing methodologies	2014	AAMI	0
383	TIR60	Common mode rejection in ECG monitoring	2014	AAMI	0
384	TIR61	Generating reports for human factors design validation results for external cardiac defibrillators	2014	AAMI	0
385	TIR62	Generating reports for the purpose of submitting defibrillation waveform data for evaluation	2014	AAMI	0
386	TIR63	Management of loaned critical and semi-critical medical devices that require sterilization or high-level disinfection	2014	AAMI	0
387	TIR34	Water for the reprocessing of medical devices	2014	AAMI	0
388	TIR38	Medical device safety assurance case report guidance	2014	AAMI	0
389	TIR50	Post-market surveillance of use error management	2014	AAMI	0
390	TIR51	Human factors engineering Guidance for contextual inquiry	2014	AAMI	0
391	TIR52	Environmental Monitoring For Terminally Sterilized Healthcare Products	2014	AAMI	0
392	TIR55	Human factors engineering for processing medical devices	2014	AAMI	0
393	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
394	TIR80001-2-6	Application of risk management for ITnetworks incorporating medical - Application guidance - Part 2-6: Guidance for responsibility agreements	2014	AAMI	0
395	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
396	TIR16775	Packaging for terminally sterilized medical devices - Guidance on the application of ISO 11607-1 and ISO 11607-2	2014	AAMI	0
397	TIR17137	Cardiovascular implants and extracorporeal systems Cardiovascular absorbable implants	2014	AAMI	0
398	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
399	TIR37137	Cardiovascular biological evaluation of medical devices - Guidance for absorbable implants	2014	AAMI	0
400	ISO 80601-2-35	NULL	2014	AAMI	0
401	ISO TIR37137	NULL	2014	AAMI	0
402	ISO TIR17137	NULL	2014	AAMI	0
403	ISO 10079-1	NULL	2014	AAMI	0
404	ISO 10079-2	NULL	2014	AAMI	0
405	ISO 10079-3	NULL	2014	AAMI	0
406	ISO 10651-4	NULL	2014	AAMI	0
407	ISO 10651-5	NULL	2014	AAMI	0
408	ISO 10993-9	NULL	2014	AAMI	0
409	ISO 10993-10	NULL	2014	AAMI	0
410	ISO 10993-5	NULL	2014	AAMI	0
411	ISO 10993-3	NULL	2014	AAMI	0
412	ISO 11135	NULL	2014	AAMI	0

413	ISO 10993-13	NULL	2014	AAMI	0
414	ISO 11195	NULL	2014	AAMI	0
415	ISO 13408-4	NULL	2014	AAMI	0
416	ISO 11140-1	NULL	2014	AAMI	0
417	ISO 14161	NULL	2014	AAMI	0
418	ISO 14408	NULL	2014	AAMI	0
419	ISO 14708-1	NULL	2014	AAMI	0
420	ISO 5841-2	NULL	2014	AAMI	0
421	ISO 5364	NULL	2014	AAMI	0
422	ISO 5366-1	NULL	2014	AAMI	0
423	ISO 5366-3	NULL	2014	AAMI	0
424	ISO 4135	NULL	2014	AAMI	0
425	ISO 5356-1	NULL	2014	AAMI	0
426	ISO 5361	NULL	2014	AAMI	0
427	IEC 80601-2-58	NULL	2014	AAMI	0
428	IEC TIR80001-2-5	NULL	2014	AAMI	0
429	IEC TIR80001-2-6	NULL	2014	AAMI	0
430	IEC TIR80001-2-7	NULL	2014	AAMI	0
431	CN3(PS)	Small-bore connectors for liquids and gases in healthcare applications ù Part 3: Connectors for enteral applications	2014	AAMI	0
432	IEC 60601-1-2	NULL	2014	AAMI	0
433	ST15883-1	Washer-disinfectors ù Part 1: General requirements, terms and definitions and tests	2014	AAMI	0
434	81060-1	Non-invasive sphygmomanometers - Part 1: Requirements and test methods for nonautomated measurement type	2013	AAMI	0
435	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
436	HE75	Human factors engineering Design of medical devices	2013	AAMI	0
437	ST24	Automatic, general purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities	2013	AAMI	0
438	ST65	Processing of reusable surgical textiles for use in health care facilities - FDA RECOGNIZED	2013	AAMI	0
439	ISO 13408-6	NULL	2013	AAMI	0
440	ISO 14937	NULL	2013	AAMI	0
441	ISO 81060-1	NULL	2013	AAMI	0
442	ISO 15882	NULL	2013	AAMI	0
443	ISO 17665-1	NULL	2013	AAMI	0
444	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
445	TIR37	Sterilization of health care products-Radiation-Guidance on sterilization of biologics and tissue-based products	2013	AAMI	0
446	TIR49	Design of training and instructional materials for medical devices used in non-clinical environments	2013	AAMI	0
447	TIR13004	Sterilization of health care products - Radiation - Substantiation of a selected sterilization dose: Method VDmax SD	2013	AAMI	0
448	ST77	Containment devices for reusable medical device sterilization	2013	AAMI	0
449	ST58	Chemical sterilization and high-level disinfection in health care facilities	2013	AAMI	0

450	ST8	Hospital steam sterilizers - FDA RECOGNIZED	2013	AAMI	0
451	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
452	13408-6	Aseptic processing of health care products - Part 6: Isolator systems - Incorporates Amendment 1: 2013	2013	AAMI	0
453	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
454	10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2013	AAMI	0
455	15882	Sterilization of health care products - Chemical indicators - Guidance for selection, use and interpretation of results	2013	AAMI	0
456	EC71	Standard communications protocol for computer-assisted electrocardiography	2013	AAMI	0
457	TIR24971	Medical devices - Guidance on the application of ISO 14971	2013	AAMI	0
458	134080-6	NULL	2013	AAMI	0
459	ID26	Medical electrical equipment-Part 2: Particular requirements for the safety of infusion pumps and controllers	2013	AAMI	0
460	11137-2	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose	2013	AAMI	0
461	5840-3	Cardiovascular implants - Cardiac valve prostheses - Part 3: Heart valve substitutes implanted by transcatheter techniques	2013	AAMI	0
462	81060-2	Non-invasive sphygmomanometers - Part 2: Clinical investigation of automated measurement type	2013	AAMI	0
463	AT6	Autologous transfusion devices	2013	AAMI	0
464	BFTF	Building for the Future Construction and Renovation of Sterile Processing Facilities	2013	AAMI	0
465	EQ56	Recommended practice for a medical equipment management program	2013	AAMI	0
466	EC53	ECG cables and leadwires	2013	AAMI	0
467	NS4	Transcutaneous electrical nerve stimulators	2013	AAMI	0
468	ID54	Enteral feeding set adapters and connectors	2012	AAMI	0
469	PB70	Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities - FDA RECOGNIZED	2012	AAMI	0
470	EC57	Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms	2012	AAMI	0
471	EQ56	Recommended practice for a medical equipment management program	2012	AAMI	0
472	BF64	Leukocyte reduction filters	2012	AAMI	0
473	BF7	Blood transfusion microfilters	2012	AAMI	0
474	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
475	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
476	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
477	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
478	25539-2	Cardiovascular implants - Endovascular devices - Part 2: Vascular stents	2012	AAMI	0
479	5361	Anaesthetic and Respiratory Equipment-Tracheal Tubes and Connectors	2012	AAMI	0
480	11137-2	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose	2012	AAMI	0
481	10993-12	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	2012	AAMI	0
482	11658	Cardiovascular implants and extracorporeal systems - Blood/tissue contact surface modifications for extracorporeal perfusion systems	2012	AAMI	0
483	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

484	14117	Active implantable medical devices - Electromagnetic compatibility - EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization devices	2012	AAMI	0
485	13408-7	Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products	2012	AAMI	0
486	13022	Medical products containing viable human cells - Application of risk management and requirements for processing practices	2012	AAMI	0
487	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
488	10993-17	Biological evaluation of medical devices - Part 17: Methods for the establishment of allowable limits for leachable substances	2012	AAMI	0
489	10993-7	Biological evaluation of medical devices-Part 7: Ethylene oxide sterilization residuals	2012	AAMI	0
490	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
491	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
492	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
493	ST15883-3	Washer-disinfectors - Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers	2012	AAMI	0
494	SW87	Application of quality management system concepts to medical device data systems - FDA RECOGNIZED	2012	AAMI	0
495	TIR29	GUIDE FOR PROCESS CONTROL IN RADIATION STERILIZATION	2012	AAMI	0
496	ST79 A3	NULL	2012	AAMI	0
497	TIR15499	Biological evaluation of medical devices Guidance on the conduct of biological evaluation within a risk management process	2012	AAMI	0
498	TIR10974	Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device	2012	AAMI	0
499	TIR44	Non-invasive blood pressure motion artifact - Testing and evaluation of NIBP device performance in the presence of motion artifact	2012	AAMI	0
500	TIR45	Guidance on the use of AGILE practices in the development of medical device software	2012	AAMI	0
501	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
502	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
503	TIR80001-2-3	Application of risk management for IT-networks incorporating medical devices - Part 2-3: Guidance for Wireless Networks	2012	AAMI	0
504	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
505	TIR19218-2	Medical devices - Hierarchal coding structure for adverse events - Part 2: Evaluation codes	2012	AAMI	0
506	TIR23810	Cardiovascular implants and artificial organs - Checklist for preoperative extracorporeal circulation equipment setup	2012	AAMI	0
507	ISO 25539-2	NULL	2012	AAMI	0
508	ISO TIR19218-2	NULL	2012	AAMI	0
509	ISO TIR62348	NULL	2012	AAMI	0
510	ISO 13022	NULL	2012	AAMI	0
511	ISO 11658	NULL	2012	AAMI	0
512	ISO 10993-12	NULL	2012	AAMI	0
513	ISO 10993-17	NULL	2012	AAMI	0
514	ISO 10993-7	NULL	2012	AAMI	0

515	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
516	IEC TIR62348	NULL	2012	AAMI	0
517	IEC TIR80001-2-1	NULL	2012	AAMI	0
518	IEC TIR80001-2-2	NULL	2012	AAMI	0
519	IEC TIR80001-2-3	NULL	2012	AAMI	0
520	IEC TIR80001-2-4	NULL	2012	AAMI	0
521	ISO 5362	NULL	2012	AAMI	0
522	IEC TIR61289	NULL	2011	AAMI	0
523	TIR61289	High frequency surgical equipment û Operation and maintenance	2011	AAMI	0
524	BE83	Biological evaluation of medical devices-Part 18: Chemical characterization of materials	2011	AAMI	0
525	TIR 19218-1	NULL	2011	AAMI	0
526	TIR43	Ultrapure dialysate for hemodialysis and related therapies	2011	AAMI	0
527	ISO 10993-14	NULL	2011	AAMI	0
528	ISO 14708-4	NULL	2011	AAMI	0
529	ISO TIR12417	NULL	2011	AAMI	0
530	TIR12417	NULL	2011	AAMI	0
531	TIR19218-1	Medical devices Hierarchal coding structure for adverse events Part 1: Event-type codes	2011	AAMI	0
532	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
533	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
534	ST72	Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing	2011	AAMI	0
535	TIR30	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices - FDA RECOGNIZED	2011	AAMI	0
536	14708-4	Implants for surgeryùActive implantable medical devicesù Part 4: Implantable infusion pumps	2011	AAMI	0
537	13408-1	Aseptic processing of health care products - Part 1: General requirements - Incorporates Amendment 1: 2013	2011	AAMI	0
538	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
539	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
540	10993-14	Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics	2011	AAMI	0
541	10993-15	Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys	2011	AAMI	0
542	25539-3	NULL	2011	AAMI	0
543	AT6	Autologous transfusion devices	2011	AAMI	0
544	BP22	Blood pressure transducers - Incorporates Errata: 08/2004	2011	AAMI	0
545	EC12	Disposable ECG electrodes - FDA RECOGNIZED	2010	AAMI	0
546	DF80	Medical electrical equipment_ Part 2-4: Particular requirements for the safety of cardiac defibrillators (including automated external defibrillators)	2010	AAMI	0

547	NS28	Intracranial pressure monitoring devices - FDA RECOGNIZED; Incorporates Errata: 06/2001	2010	AAMI	0
548	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
549	80001-1	Application of risk management for IT Networks incorporating medical devices - Part 1: Roles, responsibilities and activities	2010	AAMI	0
550	80369-1	Small bore connectors for liquids and gases in healthcare applications - Part 1: General requirements	2010	AAMI	0
551	18472	Sterilization of health care products-Biological and chemical indicators-Test equipment	2010	AAMI	0
552	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
553	60601-2-4	Medical electrical equipment - Part 2-4: Particular requirements for basic safety and essential performance of cardiac defibrillators	2010	AAMI	0
554	10993-16	Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables	2010	AAMI	0
555	10993-13	Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices	2010	AAMI	0
556	11137-3	Sterilization of health care products-Radiation-Part 3: Guidance on dosimetric aspects	2010	AAMI	0
557	11138-1	Sterilization of health care products - Biological indicators - Part 1: General requirements	2010	AAMI	0
558	11138-2	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes	2010	AAMI	0
559	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
560	7198	Cardiovascular implants-Tubular vascular prostheses	2010	AAMI	0
561	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
562	8638	Cardiovascular implants and extracorporeal systems - Extracorporeal blood circuit for hemodialyzers, hemodiafilters and hemofilters	2010	AAMI	0
563	10993-2	Biological evaluation of medical devices - Part 2: Animal welfare requirements	2010	AAMI	0
564	10993-6	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation	2010	AAMI	0
565	10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	2010	AAMI	0
566	10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	2010	AAMI	0
567	14708-5	NULL	2010	AAMI	0
568	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
569	14971	Medical devices-Application of risk management to medical devices	2010	AAMI	0
570	15225	Medical devices - Quality management - Medical device nomenclature data structure	2010	AAMI	0
571	11140-1	Sterilization of health care products-Chemical indicators-Part 1: General requirements	2010	AAMI	0
572	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
573	11138-5	Sterilization of health care products-Biological indicators-Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes	2010	AAMI	0
574	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
575	11138-3	Sterilization of health care products-Biological indicators-art 3: Biological indicators for moist heat sterilization processes	2010	AAMI	0
576	11138-4	Sterilization of health care products-Biological indicators-Part 4: Biological indicators for dry heat sterilization processes	2010	AAMI	0
577	5840	Cardiovascular implants_Cardiac valve prostheses	2010	AAMI	0

578	ST72	Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing	2010	AAMI	0
579	TIR12	Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers	2010	AAMI	0
580	TIR18	Guidance on electromagnetic compatibility of medical devices in healthcare facilities	2010	AAMI	0
581	ST77	Containment devices for reusable medical device sterilization	2010	AAMI	0
582	ST81	Sterilization of medical devices-Information to be provided by the manufacturer for the processing of resterilizable medical devices	2010	AAMI	0
583	ST79 A1	NULL	2010	AAMI	0
584	ST40	Table-top dry heat (heated air) sterilization and sterility assurance in health care facilitie	2010	AAMI	0
585	ST50	Dry heat (heated air) sterilizers - FDA RECOGNIZED	2010	AAMI	0
586	ST55	Table-top steam sterilizers - FDA RECOGNIZED	2010	AAMI	0
587	ST58	Chemical sterilization and high-level disinfection in health care facilities	2010	AAMI	0
588	TIR42	Evaluation of particulates associated with vascular medical devices	2010	AAMI	0
589	ISO 27186	NULL	2010	AAMI	0
590	RD52	Dialysate for hemodialysis	2010	AAMI	0
591	ISO 15223-2	NULL	2010	AAMI	0
592	ISO 10993-2	NULL	2010	AAMI	0
593	27186	NULL	2010	AAMI	0
594	IEC 80001-1	NULL	2010	AAMI	0
595	IEC TIR62296	NULL	2009	AAMI	0
596	IEC TIR62354	NULL	2009	AAMI	0
597	IEC TIR80002-1	NULL	2009	AAMI	0
598	80601-2-35	NULL	2009	AAMI	0
599	ISO 11663	NULL	2009	AAMI	0
600	ISO 26722	NULL	2009	AAMI	0
601	TIR39	NULL	2009	AAMI	0
602	TIR40	NULL	2009	AAMI	0
603	TIR17665-2	Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1	2009	AAMI	0
604	TIR62296	Considerations of unaddressed safety aspects in the second edition of IEC 60601-1 and proposals for new requirements	2009	AAMI	0
605	TIR80002-1	NULL	2009	AAMI	0
606	ST24	Automatic, general purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities	2009	AAMI	0
607	ST15883-1	NULL	2009	AAMI	0
608	TIR16	Microbiological aspects of ethylene oxide sterilization	2009	AAMI	0
609	TIR14	Contract sterilization using ethylene oxide	2009	AAMI	0
610	TIR15	Physical aspects of ethylene oxide sterilization	2009	AAMI	0
611	TIR28	Product adoption and process equivalence for ethylene oxide sterilization	2009	AAMI	0
612	TIR62354	NULL	2009	AAMI	0
613	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
614	15674	Cardiovascular implants and artificial organs - Hard shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags	2009	AAMI	0

615	15675	Cardiovascular implants and artificial organs - Cardiopulmonary bypass systems - Arterial blood line filters	2009	AAMI	0
616	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
617	14161	Sterilization of health care products - Biological indicators - Guidance for the selection, use and interpretation of results	2009	AAMI	0
618	13485	Medical devices-Quality management systems-Requirements for regulatory purposes	2009	AAMI	0
619	10993-9	Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products	2009	AAMI	0
620	10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	2009	AAMI	0
621	10993-4	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood - Incorporates Amendment 1: 2006	2009	AAMI	0
622	10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2009	AAMI	0
623	7199	Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators)	2009	AAMI	0
624	10993-16	Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables	2009	AAMI	0
625	11137-2	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose	2009	AAMI	0
626	10993-3	Biological evaluation of medical devices-Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity	2009	AAMI	0
627	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
628	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
629	17665-2	Sterilization of health care products _ Moist heat _ Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1	2009	AAMI	0
630	26722	Water treatment equipment for hemodialysis and related therapies	2009	AAMI	0
631	25539-1	Cardiovascular implants-Endovascular devices-Part 1: Endovascular prostheses Amendment 1: Test methods - Incorporates Amendment 1: 2005	2009	AAMI	0
632	25539-1 A1	NULL	2009	AAMI	0
633	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
634	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
635	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
636	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
637	ID26	Medical electrical equipment-Part 2: Particular requirements for the safety of infusion pumps and controllers	2009	AAMI	0
638	HE74	Human factors design process for medical devices	2009	AAMI	0
639	HE75	Human factors engineering _ Design of medical devices	2009	AAMI	0
640	NS4	Transcutaneous electrical nerve stimulators	2009	AAMI	0
641	PB70	Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities - FDA RECOGNIZED	2009	AAMI	0
642	RD62	NULL	2009	AAMI	0
643	RD52	Dialysate for hemodialysis	2009	AAMI	0
644	RD47	Reprocessing of hemodialyzers - FDA RECOGNIZED	2008	AAMI	0
645	ST8	Hospital steam sterilizers - FDA RECOGNIZED	2008	AAMI	0
646	RD5	Hemodialysis systems	2008	AAMI	0
647	EC53A	NULL	2008	AAMI	0

648	EC57	Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms	2008	AAMI	0
649	EQ56	Recommended practice for a medical equipment management program	2008	AAMI	0
650	BE78 A1	NULL	2008	AAMI	0
651	BE78	Biological evaluation of medical devices Part 10: Tests for irritation and delayed-type hypersensitivity	2008	AAMI	0
652	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
653	25539-2	Cardiovascular implants - Endovascular devices - Part 2: Vascular stents	2008	AAMI	0
654	22442-1	Medical devices utilizing animal tissues and their derivatives-Part 1: Application of risk management	2008	AAMI	0
655	22442-2	Medical devices utilizing animal tissues and their derivatives-Part 2: Controls on sourcing, collection and handling	2008	AAMI	0
656	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
657	10993-17	Biological evaluation of medical devices - Part 17: Methods for the establishment of allowable limits for leachable substances	2008	AAMI	0
658	10993-7 E2010	NULL	2008	AAMI	0
659	10993-7	Biological evaluation of medical devices-Part 7: Ethylene oxide sterilization residuals	2008	AAMI	0
660	14155-1	Clinical investigation of medical devices for human subjects -- Part 1: General requirements	2008	AAMI	0
661	14155-2	Clinical investigation of medical devices for human subjects -- Part 2: Clinical investigation plans	2008	AAMI	0
662	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
663	14708-3	NULL	2008	AAMI	0
664	14708-4	NULL	2008	AAMI	0
665	15882	Sterilization of health care products - Chemical indicators - Guidance for selection, use and interpretation of results	2008	AAMI	0
666	13408-1	Aseptic processing of health care products - Part 1: General requirements - Incorporates Amendment 1: 2013	2008	AAMI	0
667	5364	NULL	2008	AAMI	0
668	TIR31	PROCESS CHALLENGE DEVICES/TEST PACKS FOR USE IN HEALTH CARD FACILITIES	2008	AAMI	0
669	TIR22 A1	NULL	2008	AAMI	0
670	TIR17	Compatibility of materials subject to sterilization	2008	AAMI	0
671	ST79 A1	NULL	2008	AAMI	0
672	ST65	Processing of reusable surgical textiles for use in health care facilities - FDA RECOGNIZED	2008	AAMI	0
673	ST41 E2010	NULL	2008	AAMI	0
674	ST41	Ethylene oxide sterilization in health care facilities: Safety and effectiveness - FDA RECOGNIZED	2008	AAMI	0
675	ST55	Table-top steam sterilizers - FDA RECOGNIZED	2008	AAMI	0
676	TIR11135-2	NULL	2008	AAMI	0
677	SP10	Manual, electronic, or automated sphygmomanometers	2008	AAMI	0
678	DPM5	NULL	2007	AAMI	0
679	TIR36	Validation of software for regulated processes	2007	AAMI	0
680	TIR37	Sterilization of health care products-Radiation-Guidance on sterilization of biologics and tissue-based products	2007	AAMI	0
681	TIR34	Water for the reprocessing of medical devices	2007	AAMI	0
682	TIR22	Guidance for ANSI/AAMI/ISO 11607, Packaging for terminally sterilized medical devices Part 1 and Part 2:2006	2007	AAMI	0
683	TIR22 A1	NULL	2007	AAMI	0
684	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

685	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
686	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
687	14971	Medical devices-Application of risk management to medical devices	2007	AAMI	0
688	15223-1 A1	NULL	2007	AAMI	0
689	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
690	10993-6	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation	2007	AAMI	0
691	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
692	11135-2	Sterilization of health care products _ Ethylene Oxide _ Part 2: Guidance on the application of ISO 11135-1	2007	AAMI	0
693	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
694	22442-2	Medical devices utilizing animal tissues and their derivatives-Part 2: Controls on sourcing, collection and handling	2007	AAMI	0
695	22442-1	Medical devices utilizing animal tissues and their derivatives-Part 1: Application of risk management	2007	AAMI	0
696	BF7	Blood transfusion microfilters	2007	AAMI	0
697	BF64	Leukocyte reduction filters	2007	AAMI	0
698	81060-1	Non-invasive sphygmomanometers - Part 1: Requirements and test methods for nonautomated measurement type	2007	AAMI	0
699	62366	Medical devices _ Application of usability engineering to medical devices - Incorporates Amendment 1: 2013	2007	AAMI	0
700	EC71	Standard communications protocol for computer-assisted electrocardiography	2007	AAMI	0
701	EC38	Ambulatory electrocardiographs	2007	AAMI	0
702	EC13	Cardiac monitors, heart rate meters, and alarms	2007	AAMI	0
703	EC11	Diagnostic electrocardiographic devices	2007	AAMI	0
704	RD16	Hemodialyzers	2007	AAMI	0
705	RD17	NULL	2007	AAMI	0
706	PC69	Active implantable medical devices_ Electromagnetic compatibility_ EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators	2007	AAMI	0
707	RD61	NULL	2006	AAMI	0
708	NS28	Intracranial pressure monitoring devices - FDA RECOGNIZED; Incorporates Errata: 06/2001	2006	AAMI	0
709	BP22	Blood pressure transducers - Incorporates Errata: 08/2004	2006	AAMI	0
710	62304	Medical device software - Software life cycle processes	2006	AAMI	0
711	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
712	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
713	BE83	Biological evaluation of medical devices-Part 18: Chemical characterization of materials	2006	AAMI	0
714	BE78	Biological evaluation of medical devices _ Part 10: Tests for irritation and _ delayed-type hypersensitivity	2006	AAMI	0
715	18472	Sterilization of health care products-Biological and chemical indicators-Test equipment	2006	AAMI	0
716	15225	Medical devices - Quality management - Medical device nomenclature data structure	2006	AAMI	0
717	10993-19	Biological evaluation of medical devices _ Part 19: Physicochemical, morphological, and topographical characterization of materials	2006	AAMI	0
718	11137-3	Sterilization of health care products-Radiation-Part 3: Guidance on dosimetric aspects	2006	AAMI	0
719	11137-2	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose	2006	AAMI	0

720	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
721	11138-3	Sterilization of health care products-Biological indicators-art 3: Biological indicators for moist heat sterilization processes	2006	AAMI	0
722	11138-2	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes	2006	AAMI	0
723	11138-1	Sterilization of health care products - Biological indicators - Part 1: General requirements	2006	AAMI	0
724	10993-4	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood - Incorporates Amendment 1: 2006	2006	AAMI	0
725	10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	2006	AAMI	0
726	10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	2006	AAMI	0
727	10993-2	Biological evaluation of medical devices - Part 2: Animal welfare requirements	2006	AAMI	0
728	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
729	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
730	11138-5	Sterilization of health care products-Biological indicators-Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes	2006	AAMI	0
731	11138-4	Sterilization of health care products-Biological indicators-Part 4: Biological indicators for dry heat sterilization processes	2006	AAMI	0
732	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
733	11737-1	Sterilization of health care products-Microbiological methods-Part 1: Determination of the population of microorganisms on product	2006	AAMI	0
734	13408-3	Aseptic processing of health care products - Part 3: Lyophilization	2006	AAMI	0
735	13408-5	Aseptic processing of health care products - Part 5: Sterilization in place	2006	AAMI	0
736	SP10	Manual, electronic, or automated sphygmomanometers	2006	AAMI	0
737	ST79 A2	NULL	2006	AAMI	0
738	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
739	TIR11139	Sterilization of health care products - Vocabulary	2006	AAMI	0
740	TIR10993-19	Biological evaluation of medical devices - Part 19: Physico-chemical, morphological and topographical characterization of materials	2006	AAMI	0
741	TIR10993-20	Biological evaluation of medical devices - Part 20: Principles and methods for immunotoxicology testing of medical devices	2006	AAMI	0
742	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
743	5362	NULL	2006	AAMI	0
744	10651-5	NULL	2006	AAMI	0
745	IEC 60601-1-8	NULL	2006	AAMI	0
746	ISO TIR11139	NULL	2006	AAMI	0
747	ISO TIR10993-19	NULL	2006	AAMI	0
748	ISO TIR10993-20	NULL	2006	AAMI	0
749	ISO TIR16142	NULL	2005	AAMI	0
750	14408	NULL	2005	AAMI	0

751	TIR19218	NULL	2005	AAMI	0
752	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
753	TIR33	Sterilization of health care products - Radiation - Substantiation of a selected sterilization dose - Method VDmax	2005	AAMI	0
754	ST58	Chemical sterilization and high-level disinfection in health care facilities	2005	AAMI	0
755	TIR11	Selection and use of protective apparel and surgical drapes in health care facilities	2005	AAMI	0
756	13408-6	Aseptic processing of health care products - Part 6: Isolator systems - Incorporates Amendment 1: 2013	2005	AAMI	0
757	13408-4	Aseptic processing of health care products - Part 4: Clean-in-place technologies	2005	AAMI	0
758	11140-1	Sterilization of health care products-Chemical indicators-Part 1: General requirements	2005	AAMI	0
759	5840	Cardiovascular implants Cardiac valve prostheses	2005	AAMI	0
760	25539-1	Cardiovascular implants-Endovascular devices-Part 1: Endovascular prostheses Amendment 1: Test methods - Incorporates Amendment 1: 2005	2005	AAMI	0
761	AT6	Autologous transfusion devices	2005	AAMI	0
762	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
763	EC12	Disposable ECG electrodes - FDA RECOGNIZED	2005	AAMI	0
764	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
765	ID54	Enteral feeding set adapters and connectors	2005	AAMI	0
766	II36	Medical electrical equipment Part 2: Particular requirements for safety of baby incubators	2004	AAMI	0
767	II51	Medical electrical equipment Part 2: Particular requirements for safety of transport incubators	2004	AAMI	0
768	RD52	Dialysate for hemodialysis	2004	AAMI	0
769	EQ56	Recommended practice for a medical equipment management program	2004	AAMI	0
770	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
771	10993-12	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	2004	AAMI	0
772	10993-13	Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices	2004	AAMI	0
773	11737-3	Sterilization of medical devices -- Microbiological methods -- Part 3: Guidance on evaluation and interpretation of bioburden data	2004	AAMI	0
774	15223	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplie	2004	AAMI	0
775	TIR12	Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers	2004	AAMI	0
776	TIR14	Contract sterilization using ethylene oxide	2004	AAMI	0
777	TIR32	Medical device software risk management	2004	AAMI	0
778	ST50	Dry heat (heated air) sterilizers - FDA RECOGNIZED	2004	AAMI	0
779	ST40	Table-top dry heat (heated air) sterilization and sterility assurance in health care facilitie	2004	AAMI	0
780	TIR14969	Medical devices-Quality management systems- Guidance on the application of ISO 13485:2003	2004	AAMI	0
781	5356-1	NULL	2004	AAMI	0
782	ISO TIR14969	NULL	2004	AAMI	0
783	ISO 11737-3	NULL	2004	AAMI	0
784	TIR60878	Graphical symbols for electrical equipment in medical practice	2003	AAMI	0

785	ST35	Safe handling and biological decontamination of reusable medical devices in health care facilities and in nonclinical settings	2003	AAMI	0
786	TIR30	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices - FDA RECOGNIZED	2003	AAMI	0
787	14155-2	Clinical investigation of medical devices for human subjects -- Part 2: Clinical investigation plans	2003	AAMI	0
788	13408-2	Aseptic processing of health care products - Part 2: Filtration	2003	AAMI	0
789	13485	Medical devices-Quality management systems-Requirements for regulatory purposes	2003	AAMI	0
790	14155-1	Clinical investigation of medical devices for human subjects -- Part 1: General requirements	2003	AAMI	0
791	10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2003	AAMI	0
792	10993-3	Biological evaluation of medical devices-Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity	2003	AAMI	0
793	EC57	Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms	2003	AAMI	0
794	DF80	Medical electrical equipment_ Part 2-4: Particular requirements for the safety of cardiac defibrillators (including automated external defibrillators)	2003	AAMI	0
795	SP10	Manual, electronic, or automated sphygmomanometers	2003	AAMI	0
796	RD5	Hemodialysis systems	2003	AAMI	0
797	PB70	Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities - FDA RECOGNIZED	2003	AAMI	0
798	25539-1	Cardiovascular implants-Endovascular devices-Part 1: Endovascular prostheses Amendment 1: Test methods - Incorporates Amendment 1: 2005	2003	AAMI	0
799	60601-2-4	Medical electrical equipment - Part 2-4: Particular requirements for basic safety and essential performance of cardiac defibrillators	2002	AAMI	0
800	RD47	Reprocessing of hemodialyzers - FDA RECOGNIZED	2002	AAMI	0
801	RD16	Hemodialyzers	2002	AAMI	0
802	EC13	Cardiac monitors, heart rate meters, and alarms	2002	AAMI	0
803	10993-17	Biological evaluation of medical devices - Part 17: Methods for the establishment of allowable limits for leachable substances	2002	AAMI	0
804	TIR29	GUIDE FOR PROCESS CONTROL IN RADIATION STERILIZATION	2002	AAMI	0
805	ST46	Steam sterilization and sterility assurance in health care facilities	2002	AAMI	0
806	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
807	ST72	Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing	2002	AAMI	0
808	10651-4	NULL	2002	AAMI	0
809	ST44	Resistometers used for characterizing the performance of biological and chemical indicators	2002	AAMI	0
810	5366-3	NULL	2001	AAMI	0
811	4135	NULL	2001	AAMI	0
812	TIR28	Product adoption and process equivalence for ethylene oxide sterilization	2001	AAMI	0
813	TIR20	Parametric release for ethylene oxide sterilization	2001	AAMI	0
814	SW68	Medical device software Software life cycle processes	2001	AAMI	0
815	10993-14	Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics	2001	AAMI	0
816	10993-8	Biological evaluation of medical devices Part 8: Selection and qualification of reference materials for biological tests	2001	AAMI	0
817	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
818	15675	Cardiovascular implants and artificial organs - Cardiopulmonary bypass systems - Arterial blood line filters	2001	AAMI	0

819	15674	Cardiovascular implants and artificial organs - Hard shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags	2001	AAMI	0
820	EC11	Diagnostic electrocardiographic devices	2001	AAMI	0
821	BP22	Blood pressure transducers - Incorporates Errata: 08/2004	2001	AAMI	0
822	EC71	Standard communications protocol for computer-assisted electrocardiography	2001	AAMI	0
823	EC53	ECG cables and leadwires	2001	AAMI	0
824	HF18	Electrosurgical devices	2001	AAMI	0
825	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
826	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
827	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
828	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
829	60601-1-4	Medical Electrical Equipment - Part 1-4: General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems	2000	AAMI	0
830	PAC49	Pacemaker emergency intervention system	2000	AAMI	0
831	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
832	15225	Medical devices - Quality management - Medical device nomenclature data structure	2000	AAMI	0
833	14161	Sterilization of health care products - Biological indicators - Guidance for the selection, use and interpretation of results	2000	AAMI	0
834	10993-15	Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys	2000	AAMI	0
835	TIR16	Microbiological aspects of ethylene oxide sterilization	2000	AAMI	0
836	TIR26	Ventricular assist and heart replacement systems	2000	AAMI	0
837	5366-1	NULL	2000	AAMI	0
838	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	0
839	ST37	Flash sterilization- Steam sterilization of patient care items for immediate use	2000	AAMI	0
840	TIR4	Apnea monitoring by means of thoracic impedance pneumography	2000	AAMI	0
841	TIR9	Evaluation of Clinical Systems for Invasive Blood Pressure Monitoring	2000	AAMI	0
842	VP20-94	Cardiovascular implants_Vascular graft prostheses	2000	AAMI	0
843	ISO 10993-8	NULL	2000	AAMI	0
844	ISO 11134	NULL	2000	AAMI	0
845	ISO TIR15843	NULL	2000	AAMI	0
846	SP9	Non-automated sphygmomanometers	2000	AAMI	0
847	MDS	NULL	2000	AAMI	0
848	NS15	Implantable peripheral nerve stimulators	2000	AAMI	0
849	HE48	Human factors engineering guidelines and preferred practices for the design of medical devices	2000	AAMI	0
850	DF2	Cardiac defibrillator devices	2000	AAMI	0
851	DF39	Automatic external defibrillators and remote-control defibrillators	2000	AAMI	0

852	ST21	Sterilization of health care productsù Biological indicatorsùPart 2: Biological indicators for ethylene oxide sterilization	1999	AAMI	0
853	TIR25	Chemical indicatorsù Guidance for the selection, use, and interpretation of results	1999	AAMI	0
854	10079-1	NULL	1999	AAMI	0
855	10079-2	NULL	1999	AAMI	0
856	10079-3	NULL	1999	AAMI	0
857	TIR23	Signal Averaging	1999	AAMI	0
858	TIR24	Acquisition and use of physiologic waveform databases for testing of medical devices	1999	AAMI	0
859	TIR19 A1	NULL	1999	AAMI	0
860	ST66	Sterilization of health care products Chemical indicators Part 2: Class 2 indicators for air removal test	1999	AAMI	0
861	10993-9	Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products	1999	AAMI	0
862	10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	1999	AAMI	0
863	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
864	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
865	EC38	Ambulatory electrocardiographs	1998	AAMI	0
866	7198	Cardiovascular implants-Tubular vascular prostheses	1998	AAMI	0
867	10993-13	Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices	1998	AAMI	0
868	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
869	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
870	TIR21	Systems Used to Forecast Remaining Pacemaker Battery Service Life	1998	AAMI	0
871	TIR19	Guidance for ANSI/AAMI/ISO 1 0993-7:1 995, Biological evaluation of medical deicesùPart 7: Ethylene oxide sterilization residuals	1998	AAMI	0
872	ISO TIR15844	NULL	1998	AAMI	0
873	HDR	Current Concepts in Hemodialyzer Reprocessing	1998	AAMI	0
874	TIR13	Principles of industrial moist heat sterilization	1997	AAMI	0
875	TIR14	Contract sterilization using ethylene oxide	1997	AAMI	0
876	10993-16	Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables	1997	AAMI	0
877	7199	Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators)	1996	AAMI	0
878	5840	Cardiovascular implants Cardiac valve prostheses	1996	AAMI	0
879	13488	Quality systems -- Medical devices -- Particular requirements for the application of ISO9002	1996	AAMI	0
880	ID54	Enteral feeding set adapters and connectors	1996	AAMI	0
881	ISO 13488	NULL	1996	AAMI	0
882	NS14	Implantable spinal cord stimulators	1995	AAMI	0
883	NS15	Implantable peripheral nerve stimulators	1995	AAMI	0
884	EC53	ECG cables and leadwires	1995	AAMI	0
885	10993-7	Biological evaluation of medical devices-Part 7: Ethylene oxide sterilization residuals	1995	AAMI	0
886	11137	Sterilization of health care products -- Requirements for validation and routine control -- Radiation sterilization	1995	AAMI	0

887	11195	NULL	1995	AAMI	0
888	11134	Sterilization of health care products -- Requirements for validation and routine control -- Industrial moist heat sterilization	1994	AAMI	0
889	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
890	BP22	Blood pressure transducers - Incorporates Errata: 08/2004	1994	AAMI	0
891	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
892	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
893	60601-2-25	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs	1993	AAMI	0
894	ST37	Flash sterilization- Steam sterilization of patient care items for immediate use	1993	AAMI	0
895	ES1	NULL	1993	AAMI	0
896	TIR9	Evaluation of Clinical Systems for Invasive Blood Pressure Monitoring	1992	AAMI	0
897	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
898	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
899	TIR4	Apnea monitoring by means of thoracic impedance pneumography	1989	AAMI	0
900	TIR60-R2019	NULL	0	AAMI	0
901	TIR61-R2019	NULL	0	AAMI	0
902	TIR62-R2019	NULL	0	AAMI	0