Medical Device Standards: FDA vs EU

Products that are in different markets need to comply with local health authority or notified body regulations or guidance. While countries are slowly harmonizing to achieve common standards goals, a large gap still exists complicating the process for manufacturers and increasing compliance costs as well.

As on May 2020, EU Harmonized Standards: 79

As on Dec 2019, FDA's List of Standards: 1354

Specialty Task Group	Count of Standards
Anesthesiology	48
Biocompatibility	55
Cardiovascular	52
Dental / ENT	86
General I (QS / RM)	35
General II (ES / EMC)	26
General Plastic Surgery / General Hospital	111
IVD	112
Materials	192
Nanotechnology	14
Neurology	7
ObGyn / Gastroenterology / Urology	35
Ophthalmic	51
Orthopedic	104
Physical Medicine	64
Radiology	120
Software / Informatics	91
Sterility	119
Tissue Engineering	32
Total	**1354**

List of Common Standards between FDA & Europe			
Sl. No.	**Standard Name**	**Specialty Task Group**	**Europe Standard**
1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	Biocompatibility	EN ISO 10993-1:2018
2	Biological evaluation of medical devices - Part 3: Tests for genotoxicity carcinogenicity and reproductive toxicity	Biocompatibility	EN ISO 10993-3:2014
3	Biological evaluation of medical devices--Part 4: Selection of tests for interactions with blood	Biocompatibility	EN ISO 10993-4:2017
4	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Biocompatibility	EN ISO 10993-5:2009
5	Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation	Biocompatibility	EN ISO 10993-6:2016
6	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009)]	Biocompatibility	EN ISO 10993-7:2008 +AC:2009
7	Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products	Biocompatibility	EN ISO 10993-9:2009
8	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Biocompatibility	EN ISO 10993-10:2010
9	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	Biocompatibility	EN ISO 10993-11:2018
10	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	Biocompatibility	EN ISO 10993-12:2012
11	Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices	Biocompatibility	EN ISO 10993-13:2010
12	Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics	Biocompatibility	EN ISO 10993-14:2009
13	Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables	Biocompatibility	EN ISO 10993-16:2017
14	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances	Biocompatibility	EN ISO 10993-17:2009
15	Implants for surgery -- Active implantable medical devices -- Part 1: General requirements for safety marking and for information to be provided by the manufacturer	Cardiovascular	ISO 14708-1

16	Medical devices - Symbols to be used with medical device labels labelling and information to be supplied - Part 1: General requirements	General I (QS/RM)	EN ISO 15223-1:2016
17	Medical devices - Application of risk management to medical devices	General I (QS/RM)	EN ISO 14971:2012
18	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	General I (QS/RM)	EN 60601-1-6:2010 +A1:2015
19	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	General I (QS/RM)	EN 60601-1-8:2007 +AC:2010+A11:2 017+prA2
20	Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]	General I (QS/RM)	EN 62366-1:2015 +AC:2016
21	C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 MOD)	General II (ES/EMC)	EN 60601-1:2006 + AC:2010 + A1:2013+A12: 2014
22	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	General II (ES/EMC)	EN 60601-1-2:2015
23	Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers	General II (ES/EMC)	EN 60601-1-10:2008 +A1:2015
24	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	General II (ES/EMC)	EN 60601-1-11:2015
25	Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment	General II (ES/EMC)	EN 60601-1-12:2015
26	Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles introducers for catheters and needles used for blood sampling	General Plastic Surgery / General Hospital	ISO 23908
27	Non-active surgical implants -- General requirements	Orthopedic	EN ISO 14630:2012
28	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment	Radiology	EN 60601-1-3:2008 +AC:2010+A11: 2016

29	Medical device software - Software life cycle processes	Software/Informatics	EN 62304:2018
30	Sterilization of health care products - Radiation - Part 1: Requirements for development validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2013)]	Sterility	EN ISO 11137-1:2015
31	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose	Sterility	EN ISO 11137-2:2015
32	Sterilization of health-care products - Ethylene oxide - Requirements for the development validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2018)]	Sterility	EN ISO 11135:2014
33	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials sterile barrier systems and packaging systems [Including: Amendment 1 (2014)]	Sterility	EN ISO 11607-1:2017
34	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming sealing and assembly processes [Including: Amendment 1 (2014)]	Sterility	EN ISO 11607-2:2017
35	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on product	Sterility	EN ISO 11737-1:2018
36	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition validation and maintenance of a sterilization process	Sterility	EN ISO 11737-2:2009
37	Aseptic processing of health care products - Part 1: General requirements [Including: Amendment 1 (2013)]	Sterility	EN ISO 13408-1:2015
38	Aseptic processing of health care products - Part 2: Sterilizing filtration	Sterility	EN ISO 13408-2:2018
39	Aseptic processing of health care products - Part 3: Lyophilization	Sterility	EN ISO 13408-3:2011
40	Aseptic processing of health care products - Part 4: Clean-in-place technologies	Sterility	EN ISO 13408-4:2011
41	Aseptic processing of health care products - Part 5: Sterilization-in-place	Sterility	EN ISO 13408-5:2011
42	Aseptic processing of health care products - Part 6: Isolator systems [Including: Amendment 1 (2013)]	Sterility	EN ISO 13408-6:2011+ A1:2013
43	Aseptic processing of health care products - Part 7: Alternate processes for medical devices and combination products	Sterility	EN ISO 13408-7:2015

44	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 process for medical devices	Sterility	EN ISO 14160:2011
45	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	Sterility	EN ISO 14937:2009
46	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices	Sterility	ISO 17664-2
47	Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ISO 17665-1	Sterility	EN ISO 17665-1:2006
48	Sterilization of health care products - Dry heat - Requirements for the development validation and routine control of a sterilization process for medical devices	Sterility	EN ISO 20857:2013
49	Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management	Tissue Engineering	EN ISO 22442-1:2015
50	Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing collection and handling.	Tissue Engineering	EN ISO 22442-2:2015
51	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.	Tissue Engineering	EN ISO 22442-3:2007

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