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EURASIAN ECONOMIC COMMISSION
BOARD

RECOMMENDATION

September 4, 2017 **No. 17** city of Moscow

On the list of standards, the application of which, on a voluntary basis, fully or partially ensures compliance of medical products with General Requirements for Safety and Efficacy of Medical Products, Requirements for Their Marking and Operational Documentation on Them

In accordance with paragraph 2 of Article 3, paragraph 4 of Article 4 and paragraph 4 of Article 7 of the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical products and Medical Equipment) within the Eurasian Economic Union dated December 23, 2014, and in accordance with paragraph 110 of the General Requirements for Safety and Efficacy of Medical Products, Requirements for Their Marking and Operational Documentation on Them approved by Decision No. 27 of the Council of the Eurasian Economic Commission dated February 12, 2016, the Board of the Eurasian Economic Commission **recommends** to the Member States of the Eurasian Economic Union:

upon expiration of 6 months from the date of publication of this Recommendation on the official website of the Eurasian Economic Union for registration of medical products in accordance with the Rules for Registration and Examination of Safety, Quality and Efficacy of Medical Products approved by Decision No. 46 of the Council of the Eurasian Economic Commission dated February 12, 2016, to apply a list of standards, the application of which, on a voluntary basis, fully or partially ensures the compliance of medical products with the General Requirements for Safety and Efficacy of Medical Products, Requirements for Their Marking and Operational Documentation on Them, according to the Annex;

to inform the authorised authorities of the Member States of the Eurasian Economic Union from the date of publication of this Recommendation on the official website of the Eurasian Economic Union on the need for the conformity assessment bodies (testing laboratories (centers)) of the Member States to work out the issue of updating the scope of accreditation, taking into account the standards included in this list.

Chairman of the Board of the
Eurasian Economic Commission T. Sargsyan

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Seal:
Eurasian Economic Commission. For documents

ANNEX
to Recommendation No. 17 of the Board of
the Eurasian Economic Commission
dated September 4, 2017

L I S T

of standards, the application of which, on a voluntary basis, fully or partially ensures compliance of medical products with the General Requirements for Safety and Efficacy of Medical Products, Requirements for Their Marking and Operational Documentation on Them

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
I. Standards applicable to medical products (except for in vitro diagnostics)						
1	ГОСТ 28271-89	Portable radiometric and dosimetric instruments. General technical requirements and test methods	06.05.2017		1.1.4-1.1.8, 1.3.1, 1.3.2	3
					1.1.4-1.1.8, 1.3.1, 1.3.2	4
					1.1.4-1.1.8, 1.3.1, 1.3.2	6
					1.1.4-1.1.8, 1.3.1, 1.3.2	7
					1.1.4-1.1.8, 1.3.1, 1.3.2	8
					2.1-2.10	31
					2.1-2.10	32
					2.1-2.10	33
2	ГОСТ 21643-82	Suture appliances, medical. General specifications	06.05.2017	31.12.2019	2.2,2.6-2.21,4.6-4.19	3
					2.26, 4.24	5
					2.2,2.6-2.21,4.6-4.19	6

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
3	ГОСТ 31214-2003	Medical products. Requirements for samples and documentation presented for toxicological tests, sanitary and chemical analyses, tests for sterility and pyrogenicity	06.05.2017	30.09.2017	4, 5, Annex B	13
					4, 5, Annex B	15
4	ГОСТ 31214-2016	Medical products. Requirements for samples and documentation presented for toxicological tests, sanitary and chemical researches, tests for sterility and pyrogenicity	01.10.2017		5, 6, Annex A	13
					5, 6, Annex A	15
5	ГОСТ 31509-2012	Medical elastic manufactured articles for the fixation and compression. General technical requirements. Test methods	06.05.2017		5,6	3
					5,6	4
					5,6	5
					5,6	6
					5,6	7
					5,6	8
					5,6	9
					5,6	12
6	ГОСТ 31515.3-2012 (EN 1060-3:1997, MOD)	Non-invasive sphygmomanometers (measuring devices of arterial pressure). Part 3. Supplementary requirements for electro-mechanical blood pressure measuring systems	06.05.2017	31.12.2019	7,8	3
					7,8	4
					7.5.1, 7.5.2, 8.9	5
					7,8	6
					7.6, 8.1	7

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					7,8	8
					9	9
					9.1	11
					7.3	23
					7.8,8.11,9.2	27
					7.4, 7.5, 7.11,8.4-8.7,	28
					8.9	
					7.2, 7.6, 7.9, 8.1, Annex A	31
					7.7	32
					6	33
					7.3, 8.2	38
					7.1	41
					7.1	42
					7.8, 7.11.3,8.11	49
					9.2	54
					9.1, 9.3	58
					9.2	65
7	ГОСТ 31576-2012	Evaluation of biological hazard of medical dental materials and articles. Classification and sampling	06.05.2017		3	13
					3	15
8	ГОСТ 31589-2012 (ISO 12870:1997, MOD)	Ophthalmic optics. Spectacle frames for corrective eyeglasses. General technical requirements and test methods	06.05.2017	31.12.2019	4-6	3
					4-6	4
					4-6	5
					4-6	6
					4-6	7
					4-6	8

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					4-6	9
					4-6	12
9	ГОСТ 31620-2012	Surgical sutures. General technical requirements. Test method	06.05.2017	31.12.2019	62-6.6	3
					62-6.6	6
10	ГОСТ EN 556-1-2011 (EN 556-1:2001, IDT)	Sterilization of medical products Requirements for medical products to be designated “sterile”. Part 1. Requirements for terminally sterilized medical products	06.05.2017		4.1	3
					4.1	16
					4.2	19
					4.1	58
11	ГОСТ IEC 60522-2011 (IEC 60522:1999, IDT)	X-ray tube assemblies. Methods for determination of the permanent filtration	06.05.2017		4,5	3
					4,5	4
					4,5	6
					4,5	8
12	ГОСТ IEC 60580-2011 (IEC 60580:2000, IDT)	Medical electrical equipment. Dose area product meters	06.05.2017		4,5,6	31
					4,5,6	32
					4,5,6	33
13	ГОСТ IEC 60601-2-22-2011 (IEC 60601-2-22:2007, IDT)	Medical electrical equipment. Part 2-22. Particular safety requirements to the operation of surgical, cosmetic, therapeutic and laser equipment	06.05.2017		201.4-201.17	3
					201.4-201.17	4
					201.4-201.17	5
					201.4-201.17	6
					201.4-201.17	7
					201.4-201.17	8
					201.11	12
					201.11	14
					201.11	15
					201.15	26
					201.16	27
					201.9, 201.11-201.13,	28

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.15, 201.17	
					201.11	29
					201.7	30
					201.12	31
					201.10	34
					201.10	35
					201.10	36
					201.10	37
					201.14	38
					201.13	39
					201.12	42
					201.17	43
					201.17	44
					201.8	45
					201.9	46
					201.9	47
					201.9	48
					201.8, 201.15	49
					201.15	50
					201.11	51
					201.12, 201.15	52
					201.12, 201.15	53
					201.12	54
					201.7	58
					201.7	65

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
14	ГОСТ IEC 60825-1-2013 (IEC 60825-1:2007, IDT)	Safety of laser products. Part 1. Equipment classification, requirements and user's guide	06.05.2017	31.12.2019	4-6, 7.2, 8, 9	34
					4-6, 7.2, 8, 9	35
15	ГОСТ ISO 10555-1-2011 (ISO 10555-1:1995, IDT)	Sterile, single-use intravascular catheters. Part 1. General technical reguirements	06.05.2017	31.12.2019	4,5	3
					4,5	4
					4,5	5
					4,5	6
					4,5	7
					4,5	12
					4,5	13
					5,6	27
					4,5	28
16	ГОСТ ISO 10555-5-2012 (ISO 10555-5:1996, IDT)	Sterile, single-use intravascular catheters. Part 5. Over-needle peripheral catheters	06.05.2017	31.12.2019	4, Annexes A, B, E	3
					4, Annexes A, B, E	4
					4, Annexes A, B, E	5
					4, Annexes A, B, E	6
					4, Annexes A, B, E	7
					4, Annexes A, B, E	12
					4, Annexes A, B, E	13
					4, Annexes A, B, E	27
					4, Annexes A, B, E	28
17	ГОСТ ISO 10993-11-2011(ISO 10993-11:2006, IDT)	Medical products. Biological evaluation of medical products. Part 11. Tests for systemic toxicity	06.05.2017		4-6	12
					4-6	13
					4-6	15
18	ГОСТ ISO 10993-1-2011 (ISO 10993-1:2003, IDT)	Medical products. Biological evaluation of medical products. Part 1. Evaluation and	06.05.2017	31.12.2019	4-7	12
					4-7	13

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1	2	3	4	5	6	7
		testing			4-7	15
19	ГОСТ ISO 10993-12-2015 (ISO 10993-12:2012, IDT)	Medical products. Biological evaluation of medical products. Part 12. Sample preparation and control materials	06.05.2017		4-11	13
					4-11	15
20	ГОСТ ISO 10993-13-2011 (ISO 10993-13:1998, IDT)	Medical products. Biological evaluation of medical products. Part 13. Identification and quantification of degradation products from polymeric medical products	06.05.2017	31.12.2019	4-6	12
					4-6	13
					4-6	15
21	ГОСТ ISO 10993-13-2016 (ISO 10993-13:2010, IDT)	Medical products. Biological evaluation of medical products. Part 13. Identification and quantification of degradation products from polymeric medical products	01.01.2018		4-6	12
					4-6	13
					4-6	15
22	ГОСТ ISO 10993-14-2011 (ISO 10993-14:2001, IDT)	Medical products. Biological evaluation of medical products. Part 14. Identification and quantification of degradation products from ceramics	06.05.2017		4-6	12
					4-6	13
					4-6	15
23	ГОСТ ISO 10993-15-2011 (ISO 10993-15:2000, IDT)	Medical products. Biological evaluation of medical products. Part 15. Identification	06.05.2017		4-9	12
					4-9	13

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1	2	3	4	5	6	7
		and quantification of degradation products from metals and alloys			4-9	15
24	ГОСТ ISO 10993-16-2011 (ISO 10993-16:1997, IDT)	Medical products. Biological evaluation of medical products. Part 16. Toxicokinetic study design for degradation products and leachables	06.05.2017	31.12.2019	4-5, Annex A	12
					4-5, Annex A	13
					4-5, Annex A	15
25	ГОСТ ISO 10993-16-2016 (ISO 10993-16:2010, IDT)	Medical products. Biological evaluation of medical products. Part 16. Toxicokinetic study design for degradation products and leachables	01.01.2018		4-5, Annex A	12
					4-5, Annex A	13
					4-5, Annex A	15
26	ГОСТ ISO 10993-17-2011 (ISO 10993-17:2002, IDT)	Medical products. Biological evaluation of medical products. Part 17. Establishment of allowable limits for leachable substances	06.05.2017		4-10	12
					4-10	13
					4-10	15
27	ГОСТ ISO 10993-18-2011 (ISO 10993-18:2005, IDT)	Medical products. Biological evaluation of medical products. Part 18. Chemical characterization of materials	06.05.2017		5-8, Annex A	12
					5-8, Annex A	13
					5-8, Annex A	15

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1	2	3	4	5	6	7
28	ГОСТ ISO 10993-3-2011 (ISO 10993-3:2003, IDT)	Medical products. Biological evaluation of medical products. Part 3. Tests for genotoxicity, carcinogenicity and reproductive toxicity	06.05.2017	31.12.2019	4-7	12
					4-7	13
					4-7	15
29	ГОСТ ISO 10993-4-2011 (ISO 10993-4:2002, IDT)	Medical products. Biological evaluation of medical products. Part 4. Selection of tests for interactions with blood	06.05.2017		6	12
					6	13
					6	15
30	ГОСТ ISO 10993-5-2011 (ISO 10993-5:1999, IDT)	Medical products. Biological evaluation of medical products. Part 5. Tests for in vitro cytotoxicity	06.05.2017	31.12.2019	4-10	12
					4-10	13
					4-10	15
31	ГОСТ ISO 10993-6-2011 (ISO 10993-6:2007, IDT)	Medical products. Biological evaluation of medical products. Part 6. Tests for local effects after implantation	06.05.2017		4-6, Annexes B, C, D	12
					4-6, Annexes B, C, D	13
					4-6, Annexes B, C, D	15
32	ГОСТ ISO 10993-7-2011 (ISO 10993-7:1995, IDT)	Medical products. Biological evaluation of medical products. Part 7. Ethylene oxide sterilization residuals	06.05.2017	31.12.2019	4,5	13
					4,5	15
33	ГОСТ ISO 10993-7-2016 (ISO	Medical products. Biological evaluation of	01.01.2018		4,5	13

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
	10993-7:2008, IDT)	medical products. Part 7. Ethylene oxide sterilization residuals			4,5	15
34	ГОСТ ISO 10993-9-2015 (ISO 10993-9:2009, IDT)	Medical products. Biological evaluation of medical products. Part 9. Framework for identification and quantification of potential degradation products	06.05.2017		4, 5, Annex A	12
					4, 5, Annex A	13
					4, 5, Annex A	15
35	ГОСТ ISO 11135-2012 (ISO 11135:1994, IDT)	Medical products. Validation and routine control of ethylene oxide sterilization	06.05.2017	31.12.2019	4-7	18
					4-7	19
36	ГОСТ ISO 11137-1-2011 (ISO 11137-1:2006, IDT)	Sterilization of health care products. Radiation. Part 1. Requirements for development, validation and routine control of a sterilization process for medical products	06.05.2017		4-12	18
					4-12	19
37	ГОСТ ISO 11137-2-2011 (ISO 11137-2:2006, IDT)	Sterilization of health care products. Radiation. Part 2. Establishing the sterilization dose	06.05.2017	31.12.2019	4-10	18
					4-10	19
38	ГОСТ ISO 11138-1-2012 (ISO 11138-1:1994, IDT)	Sterilization of health care products. Biological indicators. Part 1. Technical requirements	06.05.2017	31.12.2019	4-5, Annex A	3
					4-5, Annex A	5
					4-5, Annex A	6
					4-5, Annex A	9
					4-5, Annex A	11
					4-5, Annex A	13
					4-5, Annex A	14
					4-5, Annex A	65

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
39	ГОСТ ISO 11138-2-2012 (ISO 11138-2:1994, IDT)	Sterilization of health care products. Biological indicators. Part 2. Biological indicators for ethylene oxide sterilization	06.05.2017	31.12.2019	4-7	3
					4-7	5
					4-7	6
					4-7	9
					4-7	11
					4-7	13
					4-7	14
					4-7	65
40	ГОСТ ISO 11138-3-2012 (ISO 11138-3:1994, IDT)	Sterilization of health care products. Biological indicators. Part 3. Biological indicators for moist heat sterilization	06.05.2017	31.12.2019	4-10, Annex A	3
					4-10, Annex A	5
					4-10, Annex A	6
					4-10, Annex A	9
					4-10, Annex A	11
					4-10, Annex A	13
					4-10, Annex A	14
					4-10, Annex A	65
41	ГОСТ ISO 11140-1-2011 (ISO 11140-1:2005, IDT)	Sterilization of health care products. Chemical indicators. Part 1. General requirements	06.05.2017	31.12.2019	4.2-4.7, 5.5, 6.1,8	3
					4.2-4.7,5.5,64,8	5
					4.2-4.7,5.5,64,8	6
					5.8	9
					5.8	11
					4.2-4.7,5.5,64,8	13
					4.2-4.7, 5.5, 6.1,8	14
					4.2-437, 5.5, 6.1,8	65
42	ГОСТ ISO 11140-3-2011 (ISO 11140-3:2000, IDT)	Sterilization of health care products. Chemical indicators. Part 3. Class 2 indicators for steam penetration test sheets	06.05.2017	31.12.2019	4.1,6, 7,8.1	3
					4.1,6, 7,8.1	5
					4.1,6, 7,8.1	6
					4.1,6, 7,8.1	9
					4.1,6, 7,8.1	11
					4.1,6, 7,8.1	13
					4.1,6, 7,8.1	14
					4.1,6, 7,8.1	65

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
43	ГОСТ ISO 11737-1-2012 (ISO 11737-1:1995, IDT)	Sterilization of medical products. Microbiological methods. Part 1. Estimation of population of microorganisms on products	06.05.2017	31.12.2019	4-8	19
44	ГОСТ ISO 11737-2-2011 (ISO 11737-2:1998, IDT)	Sterilization of medical products. Microbiological methods. Part 2. Tests of sterility performed in the validation of a sterilization process	06.05.2017	31.12.2019	4-7	19
45	ГОСТ ISO 13485-2011 (ISO 13485:2003, IDT)	Medical products. Quality management systems. System requirements for regulatory purposes	06.05.2017	31.12.2019	4.1, 4.2, 5.1, 5.3-5.6, 6.4, 7.1-7.6, 8.2.2, 8.2.3, 8.2.4, 8.3, 8.4, 8.5.1-8.5.3	3
					4.1,4.2,54,5.3-5.6, 6.4, 74-7.6,8.2.2, 8.2.3, 8.2.4, 8.3, 8.4, 8.54-8.5.3	4
					44,4.2,54,5.3-5.6, 6.4, 74-7.6, 8.2.2, 8.2.3, 8.2.4, 8.3, 8.4, 8.54-8.5.3	5
					4.1, 4.2, 5.1, 5.3-5.6, 6.4, 7.1-7.6, 8.2.2, 8.2.3, 8.2.4, 8.3, 8.4, 8.5.1-8.5.3	6
					4.1, 4.2, 5.1, 5.3-5.6, 6.4, 7.1-7.6, 8.2.2, 8.2.3, 8.2.4, 8.3, 8.4, 8.5.1-8.5.3	7
					4.1, 4.2, 5.1, 5.3-5.6, 6.4, 7.1-7.6, 8.2.2, 8.2.3, 8.2.4, 8.3, 8.4, 8.5.1-8.5.3	8

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1	2	3	4	5	6	7
46	ГОСТ ISO 14160-2011 (ISO 14160:1998, IDT)	Sterilization of single-use medical products incorporating materials of animal origin. Validation and routine control of sterilization by liquid sterilants	06.05.2017	31.12.2019	4-7	18
					4-7	19
47	ГОСТ ISO 14971-2011 (ISO 14971:2007, IDT)	Medical products. Application of risk management to medical products	06.05.2017		1-9	3
					1-9	4
					1-9	5
					1-9	7
					6.4, 6.5, 7	8
48	ГОСТ ISO 7864-2011 (ISO 7864:1993, IDT)	Sterile hypodermic needles for single use	06.05.2017	31.12.2019	4-15	3
					4-15	4
					14	5
					4-15	6
					8, 15	9
					4-13	12
					4-13	14
					5,6, 14	15
					10, 14	16
					10, 14	18
					7-9, 13	27
					7, 8, 12, 13, 15	28
49	ГОСТ ISO 7886-1-2011 (ISO 7886-1:1993, IDT)	Sterile hypodermic syringes for single use. Part 1. Syringes for manual use	06.05.2017		5-14	3
					12-14	4
					15	5

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					12, 14, 15	6
					16	9
					16	11
					5, 6, 7, 8	12
					5-8, 15	13
					5-8, 14	15
					14	16
					15	18
					13	27
					9-11, 14.1	31
					12.3	
					9, 10, 14.1	33
					12.2	52
					12.1, 12.2, 14.3	53
					16	58
					15.1, 15.2	60
					16	65
50	ГОСТ ISO 7886-3-2011 (ISO 7886-3:2005, IDT)	Sterile hypodermic syringes for single use. Part 3. Auto-disabled syringes for fixed dose immunization	06.05.2017		5,6,7,8,10,11.1,12.1,12.2,13.1,13.2,14.1,14.2,14.3	3
					12.1,12.2,13.1,13.2,14.1,14.2,14.3	4
					14.4	5
					12.1,12.2,14.3,15.1	6
					16	9
					16	11
					5,6,7,8	12
					5,6,7,8,15.1,15.2	13
					5,6,7,8,14.2	15
					14.3	16
					15.1,15.2	18
					13.2	27

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					9,10,11.1,14.1	31
					10,11.1,11.2,12.1, 12.3	32
					9,10,14.1	33
					12.2	52
					12.1,12.2,14.3	53
					16	58
					15.1,15.2	60
					16	65
51	ГОСТ ISO 7886-4-2011(ISO 7886-4:2006, IDT)	Sterile hypodermic syringes for single use. Part 4. Syringes with re-use prevention feature	06.05.2017		6-15	3
					13-15	4
					16	5
					13, 15, 16	6
					17	9
					17	11
					6-9	12
					6-9, 16	13
					6-9, 15	15
					15	16
					16	18
					14	27
					10-12, 15.1	31
					11, 12, 13	32
					10, 11	33
					13	52
					13, 15	53
					17	58
					16	60
					17	65
52	ГОСТ ISO 8537-2011 (ISO 8537:2007, IDT)	Sterile single-use syringes, with or without needle, for insulin. Technical requirements and test methods	06.05.2017	31.12.2019	4-14, Annexes A-I	3
					4-14, Annexes A-I	4
					4-15	5
					4-14, Annexes A-I	6

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					16	9
					16	11
					4-14, Annexes A-I	12
					4-14, Annexes A-I	13
					4-14, Annexes A-I	15
					4-14, Annexes A-I	16
					15	18
					4-14, Annexes A-I	27
					9	32
					4-14, Annexes A-I	52
					4-14, Annexes A-I	53
					16	58
					16	60
53	ГОСТ ISO 9801-2011 (ISO 9801:1997, IDT)	Trial case lenses. Technical requirements and test methods	06.05.2017	31.12.2019	4,5	3
					4,5	4
					4,5	6
					4,5	7
					4,5	8
					4.2, 5.1	31
					4.2, 5.1	32
					4.2, 5.1	33
					6	58
					7	65
54	ГОСТ ISO/TS 10993-19-2011 (ISO/TS 10993-19:2006, IDT)	Medical products. Biological evaluation of medical products. Part 19. Tests of physico-chemical, morphological and topographical characterization of materials	06.05.2017		5-8	8
					5-8	15
55	ГОСТ ISO/TS 10993-20-2011 (ISO/TS 10993-20:2006, IDT)	Medical products. Biological evaluation of medical products. Part 20. Principles and methods for immunotoxicology testing of medical products	06.05.2017		4-7	8
					4-7	15
56	ГОСТ OIML R 76-1-2011 (OIML	State system for ensuring the uniformity of	06.05.2017		Annex A	31

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
	R76-1:2006, IDT)	measurements. Non-automatic weighing instruments. Part 1. Metrological and technical requirements. Tests			Annex A	32
					Annex A	33
57	ГОСТ ISO 14644-1-2002 (ISO 14644-1:1999, IDT)	Cleanrooms and associated controlled environments. Part 1. Classification of air cleanliness	06.05.2017	31.12.2019	3,4	20
58	ГОСТ ISO 14698-1-2005 (ISO 14698-1:2003, IDT)	Cleanrooms and associated controlled environments. Biocontamination control. Part 1. General principles and methods	06.05.2017		4-9	20
59	ГОСТ ISO 14698-2-2005 (ISO 14698-2:2003, IDT)	Cleanrooms and associated controlled environments. Biocontamination control. Part 2. Evaluation and interpretation of biocontamination data	06.05.2017		4	20
60	ГОСТ Р 50267.2.54-2013 (IEC 60601-2-54:2009, MOD)	Medical electrical equipment. Part 2-54. Particular safety requirements taking into account the main functional characteristics to the X-ray equipment for radiography and radioscopy	06.05.2017		201.4-201.17, 202, 203	3
					201.4-201.17, 202, 203	4
					201.4-201.17, 202,	5
					203	
					201.4-201.17, 202,	6
					203	
					201.4-201.17, 202,	7
					203	
					201.4-201.17, 202,	8
					203	
					201.11	12
					201.11	14
					201.11	15
					201.15	26
					201.16	27
					201.9, 201.11-201.13, 201.15,201.17, 202	28
					201.11	29

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.7	30
					201.12	31
					201.10, 203	34
					201.10, 203	35
					201.10	36
					201.10, 203	37
					201.14	38
					201.13	39
					201.12	42
					201.17, 202	43
					201.17, 202	44
					201.8	45
					201.9	46
					201.9	47
					201.9	48
					201.8,201.15	49
					201.15	50
					201.11	51
					201.12, 201.15	52
					201.12, 201.15	53
					201.12	54
					201.7	58
					201.7	65
61	ГОСТ Р 52459.27-2009 (EN 301 489-27:2004, MOD)	Electromagnetic compatibility of technical equipment. Radio communication equipment. Part 27. Specific requirements for ultra low power active medical implants and related peripheral devices	06.05.2017		4-7	28
					4-7	43
					4-7	44
62	ГОСТ Р 52459.31-2009 (EN 301 489-31:2005, MOD)	Electromagnetic compatibility of technical equipment. Radio communication	06.05.2017		4-7	28

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
		equipment. Part 31. Specific requirements for equipment in 9 kHz to 315 kHz band for ultra low power active medical implants and related peripheral devices			4-7	44
63	ГОСТ Р 52770-2007	Medical products. Safety requirements. Methods of sanitation-chemical and toxicological tests	06.05.2017	30.09.2017	4.3, 5, Annexes A, B	13
					4.3, 5, Annexes A, B	15
64	ГОСТ Р 52770-2016	Medical products. Safety requirements. Methods of sanitation-chemical and toxicological tests	01.10.2017		4.1-4.5, 5, 6, Annexes A, B, C	13
					4.1-4.5, 5, 6, Annexes A, B, C	15
65	ГОСТ Р 53469-2009 (ISO 8600-1:2005, MOD)	Optics and optical instruments. Medical endoscopes and endotherapy devices. Part 1. General requirements	06.05.2017	31.12.2019	5.2-5.6	3
					5.2-5.6	6
66	ГОСТ Р 54794-2011	Analyzers of the content of ethanol. General specifications	06.05.2017		5.2.1-5.2.3, 5.3, 7.4, 8.1, 8.3-8.5, 8.8, 9.1, 10, Annex A	3
					5.2.1-5.23,5.3,7.4, 8.1,83-8.5,8.8, 9.1, 10, Annex A	4
					5.2.1-5.23, 53,7.4, 8.1,83-8.5,8.8,9.1, 10,	5

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					Annex A	
					5.2.1-5.23,53,7.4, 8.1,83-8.5, 8.8, 9.1, 10, Annex A	6
					5.2.1-5.23,53, 7.4, 8.1,83-8.5,8.8, 9.1, 10, Annex A	7
					5.2.1-5.23,53,7.4, 8.1,83-8.5, 8.8, 9.1, 10, Annex A	8
					5.2.1	31
					5.2.1	32
					5.2.1	33
					10	65
67	ГОСТ Р 8.605-2004 (IEC/TR 61206:1993, MOD)	State system for ensuring the uniformity of measurements. Medical diagnostic ultrasonic equipment. General requirements for the measurement methods of continuous-wave doppler equipment	06.05.2017		4,5	3
					4,5	32
					4,5	38
					4,5	52
					4,5	53
					4,5	54
68	ГОСТ Р ИСО 10328-2007 (ISO 10328:2006, IDT)	Prosthetics. Structural testing of lower-limb prostheses. Requirements and test methods	06.05.2017	31.12.2019	4-16	3
					4-16	4
					4-16	5
					4-16	6
					4-16	7
69	ГОСТ Р ИСО 10651-4-2015 (ISO 10651-4:2002, IDT)	Lung ventilators. Part 4. Particular safety requirements for operator-powered resuscitators taking into account the main fuctional characteristics	06.05.2017		4-10	3
					4-10	4
					5.4, 5.5, 7.1	5
					44-4.3,4.5-4.7, 5.2-5.4, 6.1-6.7, 7.1, 7.2	6
					5.1-5.5,74	7
					9.1	8

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
70	ГОСТ Р ИСО 10993-2-2009 (ISO 10993-2:2006, IDT)	Standardization in the Russian Federation. Medical products. Biological evaluation of medical products. Part 2. Animal welfare requirements	06.05.2017	31.12.2019	4.5, 4.8 "a", "c", "c", "d1", "d2", "d8"	3
					4.5, 4.8 "a", "c", "c", "d1", "d2", "d8"	6
71	ГОСТ Р ИСО 11334-1-2010 (ISO 11334-1:2007, IDT)	Assistive products for walking manipulated by one arm. Requirements and test methods. Part 1. Elbow crutches	06.05.2017		4,5	3
					4,5	4
					4,5	5
					4,5	6
					4,5	7
					4,5	8
					6	9
					4,5	12
					4,5	46
					4,5	55
					4,5	56
					4,5	57
					6	58
					6	65
72	ГОСТ Р ИСО 12866-2011 (ISO 12866:1999, IDT)	State system for ensuring the uniformity of measurements. Ophthalmic perimeters. Technical requirements and test methods	06.05.2017		4.2-4.4, 5	3
					4.2-4.4, 5	4
					4.2-4.4, 5	6
					4.2-4.4, 5	8
					4.2-4.4, 5	31
					4.2-4.4, 5	32
73	ГОСТ Р ИСО 13408-1-2000 (ISO 13408-1:1998, IDT)	Aseptic processing of health care products. Part 1: General reguirements	06.05.2017	31.12.2019	3-21	18
					3-21	19
74	ГОСТ Р ИСО 13408-2-2007 (ISO 13408-2:2003, IDT)	Aseptic processing of health care products. Part 2. Filtration	06.05.2017		4-12	18
					4-12	19
75	ГОСТ Р ИСО 13408-3-2011 (ISO 13408-3:2006, IDT)	Aseptic processing of health care products. Part 3. Lyophilization	06.05.2017		4-9	18
					4-9	19
76	ГОСТ Р ИСО 13408-4-2011 (ISO 13408-4:2005, IDT)	Aseptic processing of health care products. Part 4. Clean-in-place technologies	06.05.2017		4-9	18
					4-9	19

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
77	ГОСТ Р ИСО 13408-5-2011 (ISO 13408-5:2006, IDT)	Aseptic processing of health care products. Part 5. Sterilization in place	06.05.2017		4-9	18
					4-9	19
78	ГОСТ Р ИСО 13408-6-2009 (ISO 13408-6:2005, IDT)	Aseptic processing of health care products. Part 6. Isolator systems	06.05.2017		4-9	18
					4-9	19
79	ГОСТ Р ИСО 14155-2014 (ISO 14155:2011, IDT)	Clinical investigations. Good clinical practice	06.05.2017		4-9, Annex A	3
					4-9, Annex A	6
					4-9, Annex A	8
80	ГОСТ Р ИСО 14630-2011 (ISO 14630:2008, IDT)	Non-active surgical implants. General requirements	06.05.2017	31.12.2019	4-8	3
					4-8	4
					4, 5, 7, 8, 10	5
					4-10	6
					4-8	7
					5,7	8
					4-8	12
					4, 6-8, 10	13
					6, 7,8	14
					9, 10	16
					9, 10	18
					9, 10	19
					9, 10	20
					9, 10	21
					6	22
					6	23
					5, 6, 11	27
					4, 5,6	28
					9	58
					9, 10	60
81	ГОСТ Р ИСО 14937-2012 (ISO 14937:2009, IDT)	Sterilization of health care products. General criteria for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical products	06.05.2017		4-12	18
					4-12	19

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
82	ГОСТ Р ИСО 15032-2001 (ISO 15032:2000, IDT)	Prostheses. Structural testing of hip units	06.05.2017		4-9	3
					4-9	4
					4-9	5
					4-9	6
					4-9	7
					4-9	8
					4-9	9
					4-9	12
83	ГОСТ Р ИСО 15223-1-2014 (ISO 15223-1:2012, IDT)	Medical products. Symbols to be used with medical product labels, labelling and information to be supplied. Part 1. General requirements	06.05.2017		4	11
					5.1-5.4	58
					5.2.7	60
84	ГОСТ Р ИСО 15882-2012 (ISO 15882:2008, IDT)	Sterilization of health care products. Chemical indicators. Guidance for selection, use and interpretation of results	06.05.2017		3-11	18
					3-11	19
85	ГОСТ Р ИСО 16061-2011 (ISO 16061:2008, IDT)	Instrumentation for use in association with non-active surgical implants. General requirements	06.05.2017	31.12.2019	4-8	3
					4-8	4
					4, 5, 7, 8, 10	5
					4-10	6
					4-8	7
					5,7	8
					4-8	12
					4, 6-8, 10	13
					6, 7,8	14
					9, 10	16
					9, 10	18
					9, 10	19

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					9, 10	20
					9, 10	21
					6	22
					6	23
					5, 6, 11	27
					4, 5,6	28
					9	58
					9, 10	60
86	ГОСТ Р ИСО 16201-2010 (ISO 16201:2006, IDT)	Technical aids for persons with disability. Environmental control systems for daily living	06.05.2017		4-6	3
					4-6	4
					4-6	5
					4-6	6
					4-6	7
					4.1	8
					4.3	12
					4.2,6	27
					6	28
					6	29
					5.1	38
					6	43
					6	45
					6	46
					6	49
					6	51
					5.2	54
87	ГОСТ Р ИСО 17664-2012 (ISO 17664:2004, IDT)	Sterilization of medical products. Information to be provided by the manufacturer for the processing of resterilizable medical products	06.05.2017		3-6	58
					3-6	65
88	ГОСТ Р ИСО 17665-1-2016 (ISO 17665-1:2006, IDT)	Sterilization of health care products. Moist heat. Part 1. Requirements for	01.03.2017		4-12	18
					4-12	19

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
		development, validation and routine control of a sterilization process for medical product				
89	ГОСТ Р ИСО 20857-2016 (ISO 20857:2010, IDT)	Sterilization of health care products. Dry heat. Requirements for the development, validation and routine control of a sterilization process for medical products	01.03.2017		4-12	18
					4-12	19
90	ГОСТ Р ИСО 21534-2013 (ISO 21534:2007, IDT)	Non-active surgical implants. Joint replacement implants. Specific requirements	06.05.2017		4-8	3
					4-8	4
					4, 5, 7, 8, 10	5
					4-10	6
					4-8	7
					5,7	8
					4-8	12
					4, 6-8, 10	13
					6, 7,8	14
					9, 10	16
					9, 10	18
					9, 10	19
					9, 10	20
					9, 10	21
					6	22
					6	23
					5,6, 11	27
					4, 5,6	28
					9	58
					9, 10	60
					9	65
91	ГОСТ Р ИСО 21535-2013 (ISO 21535:2007, IDT)	Non-active surgical implants. Joint replacement implants. Specific requirements for hip-joint replacement implants	06.05.2017		4-8	3
					4-8	4
					4, 5, 7, 8, 10	5
					4-10	6

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					4-8	7
					5,7	8
					4-8	12
					4, 6-8, 10	13
					6, 7,8	14
					9, 10	16
					9, 10	18
					9, 10	19
					9, 10	20
					9, 10	21
					6	22
					6	23
					5,6, 11	27
					4, 5,6	28
					9	58
					9, 10	60
					9	65
92	ГОСТ Р ИСО 21536-2013 (ISO 21536:2007, IDT)	Non-active surgical implants. Joint replacement implants. Specific requirements for knee-joint replacement implants	06.05.2017		4-8	3
					4-8	4
					4, 5,7, 8, 10	5
					4-10	6
					4-8	7
					5,7	8
					4-8	12
					4, 6-8, 10	13
					6, 7,8	14
					9, 10	16
					9, 10	18
					8, 9, 10	19
					8,9	20
					9, 10	21

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					6	22
					6	23
					5, 6, 11	27
					4, 5,6	28
					9	58
					9, 10	60
					9,11	65
93	ГОСТ Р ИСО 22442-1-2011 (ISO 22442-1:2007, IDT)	Medical products utilizing animal tissues and their derivatives. Part 1. Application of risk management	06.05.2017	31.12.2019	4.1-4.6, Annex C	12
					4.1-4.6, Annex C	13
					4.1-4.6, Annex C	16
					4.1-4.6, Annex C	23
94	ГОСТ Р ИСО 22442-2-2011 (ISO 22442-2:2007, IDT)	Medical products utilizing animal tissues and their derivatives. Part 2. Controls on sourcing, collection and handling	06.05.2017	31.12.2019	4-8, Annex A	12
					4-8, Annex A	13
					4-8, Annex A	16
					4-8, Annex A	23
95	ГОСТ Р ИСО 22442-3-2011 (ISO 22442-3:2007, IDT)	Medical products utilizing animal tissues and their derivatives. Part 3. Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy agents	06.05.2017		4-9, Annex A	12
					4-9, Annex A	13
					4-9, Annex A	16
					4-9, Annex A	23
96	ГОСТ Р ИСО 22523-2007 (ISO 22523:2006, IDT)	External limb prostheses and external orthoses. Requirements and test methods	06.05.2017		4-14	3
					4-14	4
					4-14	5
					4-14	6
					4-14	7
					4-14	8
					13	9
					5.1, 5.2	12
					5.2, 13, 14	13
					5.2.2, 5.4	14
					5.2, 5.3	16
					14	21

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					12.1, 13	27
					7, 9, 11.1, 12.2, 12.3	28
					5.1, 8.2, 8.4	29
					8.3	38
					8.1, 8.2	40
					7	43
					8	45
					11, 12	46
					6	47
					6	48
					8.2, 11.2	49
					9	51
					8.5	53
					13.1, 13.2	54
					13	58
					13	65
97	ГОСТ Р ИСО 22675-2009 (ISO 22675:2006, IDT)	Prosthetics. Testing of ankle-foot devices and foot units. Requirements and test methods	06.05.2017	31.12.2019	5-10, 15, 16, 17	4
					5-10, 15, 16, 17	7
					5, 20, 21	9
					5,20,21	27
					5-10, 15, 16, 17	46
					20	58
98	ГОСТ Р ИСО 25424-2013 (ISO 25424:2009, IDT)	Sterilization of medical products. Low temperature steam and formaldehyde. Requirements for development, validation and routine control of a sterilization process for medical products	06.05.2017		4-12	18
					4-12	19
99	ГОСТ Р ИСО 25539-1-2012 (ISO 25539-1:2003, IDT)	Cardiovascular implants. Endovascular devices. Part 1. Endovascular prostheses	06.05.2017		4-10	3
					4-10	4
					5, 8, 10.1	5
					4, 5, 7, 8, 10.1	6
					4, 5,7	7

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					7	8
					4-8	12
					5-9, 10.1	13
					5-7, 10.1	14
					9	16
					9, 10.1	18
					9, 10.1	19
					6, 10.1	22
					6,9	23
					5, 7, 10.2, 10.3	27
					5, 6,7	28
					10.2	58
					10.2	60
					10.3	65
100	ГОСТ Р ИСО 25539-2-2012 (ISO 25539-2:2008, IDT)	Cardiovascular implants. Endovascular devices. Part 2. Vascular stents	06.05.2017	31.12.2019	4-8, 10-12	3
					4-8, 10	4
					4-8, 10-12	5
					4-8, 10-12	6
					4-8, 10-12	7
					6-8	8
101	ГОСТ Р ИСО 7396-1-2011 (ISO 7396-1:2007, IDT)	Medical gas pipeline systems. Part 1. Pipeline systems for compressed medical gases and vacuum	06.05.2017	31.12.2019	4, 5.1-5.2.7, 6, 7, 8, 11, 12.1-12.4	3
					4, 5.1-5.2.7, 5.3.1-5.3.4,5.8-5.10, 6, 7, 8, 11, 12.1-12.4, 12.6.2-12.6.9	4
					5.2.7, 5.2.8,5.34-5.3.4,5.4, 5.5.1,5.5.2.12, 5.5.2.10,5.5.3, 5.6,5.74-5.7.7,5.8- 5.10, 6, 7, 11, 12.1- 12.4, 12.6.2-12.6.9	6

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					4.4.2, 5.1-5.2.7, 6, 7.3, 11,13,	7
					13	9
					4, 4.3.3,43.6, 5.3.7, 5.3.8	12
					4.3.7, 43.8,5.5.2.1-5.5.2.10,5.5.3,5.6, 12.6.10, 12.6.11, 12.6.12, 12.6.13, 12.6.14	13
					4	14
					5.2.7, 5.3.4,5.5.2.11, 5.5.3, 5.6, 5.7.8-5.7.9, 12.5.2, 12.6.1, 12.6.2-12.6.9	15
					5.7.1-5.7.7	16
					9	27
					4.3.4, 4.3.9,5.5.2.12, 7.2.5, 7.2.6, 9.3, 12.5.1, 12.5.2	28
					43.2, 4.3.4, 4.3.5, 43.6,53.7,5.6, 7.1, 12.5.1, 12.5.2	29
					6, 9.3, 9.3, 11.1.3, 4.3.4	41
					9.3	43
					9.3, 11.1.3	45
					4.3.4, 4.3.6, 5.3.5, 5.3.6, 7.1, 12.5.1, 12.5.2, 12.6.1	46
					5.5.2.13,5.7.10	47
					12.6.15-12.6.16,9	49
					5.1-5.2.7, 5.7.1-5.7.7, 6, 12.6.15-12.6.16	52

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					5.1-5.2.7, 6	53
					6	54
					13	58
					13,9	65
102	ГОСТ Р ИСО 80601-2-12-2013 (ISO 80601-2-12:2011, IDT)	Medical electrical equipment. Part 2-12. Particular safety requirements to lung ventilators for intensive care taking into account the main functional characteristics	06.05.2017		201.4-201.17, 201.101-201.108, 202, 206, 208	3
					201.4-201.17, 201.101-201.108, 202, 206, 208	4
					201.7	5
					201.4-201.17, 201.101-201.108, 202, 206, 208	6
					201.12.1,201.12.4, 201.13,201.15, 201.102, 201.105	7
					201.103	8
					201.7, 201.16	9
					201.9, 201.11	12
					201.11	13
					201.11	14
					201.11,201.13	15
					201.11	16
					201.11	20
					201.7	21
					201.15	26

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.8,201.9, 201.11, 201.14, 201.15, 201.16, 201.101, 201.102, 201.106, 201.108	27
					201.8,201.9, 201.12, 201.15,201.101, 201.106, 201.108, 202, 206	28
					201.8, 201.11,201.12, 201.15	29
					201.7	30
					201.12	31
					201.12	32
					201.7	33
					201.10, 201.12, 201.17, 202	34
					201.14	38
					201.13	39
					201.11.8	40
					201.12, 201.11.8	41
					201.12.4, 201.12, 208	42
					201.17, 202	43
					201.17, 202	44
					201.8, 201.15, 201.16	45
					201.9, 201.15,201.16	46
					201.9, 201.16	47
					201.9, 201.16	48
					201.7, 201.8, 201.15, 201.16, 201.101	49

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.15	50
					201.11,201.15,	52
					201.16	
					201.12, 201.101	53
					201.7	60
					201.7, 201.16	65
103	ГОСТ Р ИСО 80601-2-13-2013 (ISO 80601-2-13:2011, IDT)	Medical electrical equipment. Part 2-13. Particular safety requirements to anesthetic workstations taking into account the main functional characteristics	06.05.2017		201.4-201.17, 201.101-201.107, 202, 203,206, 208-211	3
						4
						5
						6
						7
						8
					201.11	12
					201.11	14
					201.11	15
					201.15	26

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.16	27
					201.9, 201.11-201.13, 201.15, 201.17, 202, 206	28
					201.11	29
					201.7	30
					201.12	31
					201.10	34
					201.10	35
					201.10	36
					201.10	37
					201.14	38
					201.13	39
					201.12	42
					201.17, 202	43
					201.17, 202	44
					201.8	45
					201.9	46
					201.9	47
					201.9	48
					201.8, 201.15	49
					201.15	50
					201.11	51
					201.12, 201.15	52
					201.12, 201.15	53
					201.12	54
					201.7	58
					201.7	65
104	ГОСТ Р ИСО 80601-2-55-2015 (ISO 80601-2-55:2011, IDT)	Medical electrical equipment. Part 2-55. Particular safety requirements to respiratory gas monitors taking into	06.05.2017		201.11.6.4-201.11.6.6	13
					201.11.6.4, 201.11.6.8	14
					201.11.6.4	15

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
		account the main functional characteristics				
					201.11.6.6, 201.11.6.7, 201.105	16
					201.11.6.7	19
					201.7.2.101, 201.7.2.4.101, 201.7.2.13.101, 201.12.1.102, 201.102, 201.103,208	27
					201.9, 201.101,202, 206	28
					201.11	29
					201.12.1,201.101	31
					201.7, 201.12.1.103, 201.12.1.104, 206, 208	32
					201.7.4.3	33
					202	36
					201.14	38
					208	42
					202	43
					201.8	45
					201.9	46
					201.9	47
					201.9	48
					201.8, 201.15, 201.103	49
					201.11	51
					201.104	54
					201.7.9.1	58
					201.7.2.17.101	60
					201.7, 201.12	65
105	ГОСТ Р МЭК 60601-1-2010 (IEC 60601-1:2005, IDT)	Medical electrical equipment. Part 1. General safety requirements taking into	06.05.2017		4-17	3
					4-17	4

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
		account the main functional characteristics			4-17	5
					4-17	6
					4-17	7
					4-17	8
					11	12
					11	14
					11	15
					15	26
					16	27
					9, 11-13, 15, 17	28
					11	29
					7	30
					12	31
					10	34
					10	35
					10	36
					10	37
					14	38
					13	39
					12	42
					17	43
					17	44
					8	45
					9	46
					9	47
					9	48
					8, 15	49
					15	50
					11	51
					12, 15	52
					12, 15	53
					12	54

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					7, 12, 16	55
					7, 12, 16	56
					7, 12, 16	57
					7	58
					7	65
106	ГОСТ Р МЭК 60601-1-2-2014 (IEC 60601-1-2:2007, IDT)	Medical electrical equipment. Part 1-2. General safety requirements taking into account the main functional characteristics. Collateral standard. Electromagnetic compatibility. Requirements and tests	06.05.2017	31.12.2019		28
					4-6 (not applicable unchanged to implantable products)	
					4-6 (not applicable unchanged to implantable products)	43
					4-6 (not applicable unchanged to implantable products)	44
107	ГОСТ Р МЭК 60601-1-3-2013 (IEC 60601-1-3:2008, IDT)	Medical electrical equipment. Part 1-3. General safety requirements taking into account the main functional characteristics. Collateral standard. Radiation protection in diagnostic X-ray equipment.	06.05.2017		4-13	3
					4-13	4
					4-13	5
					4-13	6
					4-13	7
					4-13	8
					4-13	34
					4-13	35
					4-13	37
108	ГОСТ Р МЭК 60601-1-6-2014 (IEC 60601-1-6:2010, IDT)	Medical electrical equipment. Part 1-6. General safety requirements taking into account the main functional characteristics. Collateral standard. Usability	06.05.2017		4-5	28
					4-5	32
					4-5	55
					4-5	56
					4-5	57
109	ГОСТ Р МЭК 60601-2-1-2013 (IEC 60601-2-1:2009, IDT)	Medical electrical equipment. Part 2-1. Particular safety requirements taking into	06.05.2017		201.4-201.17, 206	3
					201.4-201.17, 206	4

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
		account the main functional characteristics to electron accelerators operating within the range from 1 to 50 MeV				
					201.4-201.17, 206	5
					201.4-201.17, 206	6
					201.4-201.17, 206	7
					201.4-201.17, 206	8
					201.11	12
					201.11	14
					201.11	15
					201.15	26
					201.16	27
					201.9, 201.11-201.13, 201.15,201.17, 206	28
					201.11	29
					201.7	30
					201.12	31
					201.10	34
					201.10	35
					201.10	36
					201.10	37
					201.14	38
					201.13	39
					201.12	42
					201.17	43
					201.15	44
					201.8	45
					201.9	46
					201.9	47
					201.9	48
					201.8, 201.15	49
					201.15	50

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.11	51
					201.12, 201.15	52
					201.12, 201.15	53
					201.12	54
					201.7	58
					201.7	65
110	ГОСТ Р МЭК 60601-2-16-2016 (IEC 60601-2-16:2012, IDT)	Medical electrical equipment. Part 2-16. Particular safety requirements taking into account the main functional characteristics to haemodialysis, haemodiafiltration and haemofiltration	06.05.2017		201.4-201.17, 202, 208,210,211	3
					201.4-201.17, 202, 208,210,211	4
					201.4-201.17, 202, 208,210,211	5
					201.4-201.17, 202, 208,210,211	6
					201.4-201.17, 202, 208,210,211	7
					201.4-201.17, 202, 208,210,211	8
					201.11	12
					201.11	14
					201.11	15
					201.15	26
					201.16	27
					201.9, 201.11-201.13, 201.15,201.17, 202	28
					201.11	29
					201.7	30
					201.12	31
					201.10	34
					201.10	35
					201.10	36
					201.10	37

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.14	38
					201.13	39
					201.12	42
					201.17, 202	43
					201.17, 202	44
					201.8	45
					201.9	46
					201.9	47
					201.9	48
					201.8, 201.15	49
					201.15	50
					201.11	51
					201.12, 201.15	52
					201.12, 201.15	53
					201.12	54
					201.7	58
					201.7	65
111	ГОСТ Р МЭК 60601-2-18-2014 (IEC 60601-2-18:2009, IDT)	Medical electrical equipment. Part 2-18. Particular safety requirements taking into account the main functional characteristics to endoscopic equipment	06.05.2017		201.4-201.17, 202	3
					201.4-201.17, 202	4
					201.4-201.17, 202	5
					201.4-201.17, 202	6
					201.4-201.17, 202	7
					201.4-201.17, 202	8
					201.11	12
					201.11	14
					201.11	15
					201.15	26
					201.16	27
					201.9, 201.11-201.13,	28
					201.15, 201.17, 202	
					201.11	29
					201.7	30

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.12	31
					201.10	34
					201.10	35
					201.10	36
					201.10	37
					201.14	38
					201.13	39
					201.12	42
					201.17, 202	43
					201.17, 202	44
					201.8	45
					201.9	46
					201.9	47
					201.9	48
					201.8, 201.15	49
					201.15	50
					201.11	51
					201.12, 201.15	52
					201.12, 201.15	53
					201.12	54
					201.7	58
					201.7	65
112	ГОСТ Р МЭК 60601-2-19-2011 (IEC 60601-2-19:2009, IDT)	Medical electrical equipment. Part 2-19. Particular safety requirements taking into account the main functional characteristics to infant incubators	06.05.2017		201.4-201.17, 202, 210	3
					201.4-201.17, 202, 210	4
					201.4-201.17, 202, 210	5

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.4-201.17, 202, 210	6
					201.4-201.17, 202, 210	7
					201.4-201.17, 202, 210	8
					201.11	12
					201.11	14
					201.11	15
					201.15	26
					201.16	27
					201.9, 201.11-201.13, 201.15,201.17, 202, 210	28
					201.11	29
					201.7	30
					201.12	31
					201.10	34
					201.10	35
					201.10	36
					201.10	37
					201.14	38
					201.13	39
					201.12	42
					201.17, 202	43
					201.17, 202	44
					201.8	45
					201.9	46
					201.9	47
					201.9	48
					201.8, 201.15	49
					201.15	50
					201.11	51

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.12, 201.15	52
					201.12, 201.15	53
					201.12	54
					201.7,210	58
					201.7,210	65
113	ГОСТ Р МЭК 60601-2-20-2011 (IEC 60601-2-20:2009, IDT)	Medical electrical equipment. Part 2-20. Particular safety requirements taking into account the main functional characteristics to infant transport incubators	06.05.2017		201.4-201.17, 202, 210	3
					201.4-201.17, 202, 210	4
					201.4-201.17, 202, 210	5
					201.4-201.17, 202, 210	6
					201.4-201.17, 202, 210	7
					201.4-201.17, 202, 210	8
					201.11	12
					201.11	14
					201.11	15
					201.15	26
					201.16	27
					201.9, 201.11-201.13, 201.15,201.17, 202, 210	28
					201.11	29
					201.7	30
					201.12	31
					201.10	34
					201.10	35
					201.10	36
					201.10	37
					201.14	38
					201.13	39
					201.12	42
					201.17, 202	43
					201.17, 202	44
					201.8	45
					201.9	46

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.9	47
					201.9	48
					201.8, 201.15	49
					201.15	50
					201.11	51
					201.12, 201.15	52
					201.12, 201.15	53
					201.12	54
					201.7,210	58
					201.7,210	65
114	ГОСТ Р МЭК 60601-2-21-2013 (IEC 60601-2-21:2009, IDT)	Medical electrical equipment. Part 2-21. Particular safety requirements taking into account the main functional characteristics to infant radiant warmers	06.05.2017		201.4-201.17, 202, 210	3
					201.4-201.17, 202, 210	4
					201.4-201.17, 202, 210	5
					201.4-201.17, 202, 210	6
					201.4-201.17, 202, 210	7
					201.4-201.17, 202, 210	8
					201.11	12
					201.11	14
					201.11	15
					201.15	26
					201.16	27
					201.9, 201.11-201.13, 201.15,201.17, 202, 210	28
					201.11	29
					201.7	30
					201.12	31
					201.10	34
					201.10	35
					201.10	36
					201.10	37
					201.14	38
					201.13	39

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.12	42
					201.17, 202	43
					201.17, 202	44
					201.8	45
					201.9	46
					201.9	47
					201.9	48
					201.8, 201.15	49
					201.15	50
					201.11	51
					201.12, 201.15	52
					201.12, 201.15	53
					201.12	54
					201.7,210	58
					201.7,210	65
115	ГОСТ Р МЭК 60601-2-2-2013 (IEC 60601-2-2:2009, IDT)	Medical electrical equipment. Part 2-2. Particular safety requirements taking into account the main functional characteristics to high frequency surgical equipment and high frequency surgical accessories	06.05.2017		201.4-201.17, 202, 208	3
					201.4-201.17, 202, 208	4
					201.4-201.17, 202, 208	5
					201.4-201.17, 202, 208	6
					201.4-201.17, 202, 208	7
					201.4-201.17, 202, 208	8
					201.11	12
					201.11	14
					201.11	15
					201.15	26
					201.16	27
					201.9, 201.11-201.13, 201.15, 201.17, 202	28
					201.11	29
					201.7	30

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.12	31
					201.10	34
					201.10	35
					201.10	36
					201.10	37
					201.14	38
					201.13	39
					201.12	42
					201.17, 202	43
					201.17, 202	44
					201.8	45
					201.9	46
					201.9	47
					201.9	48
					201.8, 201.15	49
					201.15	50
					201.11	51
					201.12, 201.15	52
					201.12, 201.15	53
					201.12	54
					201.7	58
					201.7	65
116	ГОСТ Р МЭК 60601-2-25-2016 (IEC 60601-2-25:2011, IDT)	Medical electrical equipment. Part 2-25. Particular safety requirements taking into account the main functional characteristics to electrocardiographs	06.05.2017		201.4-201.17, 202	3
					201.4-201.17, 202	4
					201.4-201.17, 202	5
					201.4-201.17, 202	6
					201.4-201.17, 202	7
					201.4-201.17, 202	8
					201.11	12
					201.11	14
					201.11	15
					201.15	26

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.16	27
					201.9, 201.11-201.13, 201.15, 201.17, 202	28
					201.11	29
					201.7	30
					201.12	31
					201.10	34
					201.10	35
					201.10	36
					201.10	37
					201.14	38
					201.13	39
					201.12	42
					201.17, 202	43
					201.17, 202	44
					201.8	45
					201.9	46
					201.9	47
					201.9	48
					201.8,201.15	49
					201.15	50
					201.11	51
					201.12, 201.15	52
					201.12, 201.15	53
					201.12	54
					201.9, 201.11-201.13,	28
					201.15, 201.17, 202	
					201.11	29
					201.7	30
					201.12	31
					201.10	34
					201.10	35

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.10	36
					201.10	37
					201.14	38
					201.13	39
					201.12	42
					201.17, 202	43
					201.17, 202	44
					201.8	45
					201.9	46
					201.9	47
					201.9	48
					201.8,201.15	49
					201.15	50
					201.11	51
					201.12, 201.15	52
					201.12, 201.15	53
					201.12	54
					201.10	35
					201.10	36
					201.10	37
					201.14	38
					201.13	39
					201.12	42
					201.17, 202	43
					201.17, 202	44
					201.8	45
					201.9	46
					201.9	47
					201.9	48
					201.8, 201.15	49
					201.15	50
					201.11	51

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.12, 201.15	52
					201.12, 201.15	53
					201.12	54
					201.7	58
					201.7	65
117	ГОСТ Р МЭК ЕС 60601-2-27-20163 (IEC 60601-2-27:2011, IDT)	Medical electrical equipment. Part 2-27. Particular safety requirements taking into account the main functional characteristics to electrocardiographic monitoring equipment	06.05.2017		201.4-201.17, 202, 208	3
					201.4-201.17, 202, 208	4
					201.4-201.17, 202, 208	5
					201.4-201.17, 202, 208	6
					201.4-201.17, 202, 208	7
					201.4-201.17, 202, 208	8
					201.11	12
					201.11	14
					201.11	15
					201.15	26
					201.16	27
					201.9, 201.11-201.13, 201.15, 201.17, 202	28
					201.11	29
					201.7	30
					201.12	31
					201.10	34
					201.10	35
					201.10	36
					201.10	37
					201.14	38
					201.13	39
					201.12	42

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.17, 202	43
					201.17, 202	44
					201.8	45
					201.9	46
					201.9	47
					201.9	48
					201.8,201.15	49
					201.15	50
					201.11	51
					201.12, 201.15	52
					201.12, 201.15	53
					201.12	54
					201.7	58
					201.7	65
118	ГОСТ Р МЭК 60601-2-28-2013 (IEC 60601-2-28:2010, IDT)	Medical electrical equipment. Part 2-28. Particular safety requirements taking into account the main functional characteristics to X-ray tube assemblies for medical diagnostics	06.05.2017		201.4-201.17, 203	3
					201.4-201.17, 203	4
					201.4-201.17, 203	5
					201.4-201.17, 203	6
					201.4-201.17, 203	7
					201.4-201.17, 203	8
					201.11	12
					201.11	14
					201.11	15
					201.15	26
					201.16	27
					201.9, 201.11-201.13,	28
					201.15, 201.17	
					201.11	29
					201.7	30
					201.12	31
					201.10	34
					201.10	35

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.10	36
					201.10	37
					201.14	38
					201.13	39
					201.12	42
					201.17	43
					201.17	44
					201.8	45
					201.9	46
					201.9	47
					201.9	48
					201.8,201.15	49
					201.15	50
					201.11	51
					201.12, 201.15	52
					201.12, 201.15	53
					201.12	54
					201.7	58
					201.7	65
119	ГОСТ Р МЭК 60601-2-29-2013 (IEC 60601-2-29:2008, IDT)	Medical electrical equipment. Part 2-29. Particular safety requirements taking into account the main functional characteristics to radiotherapy simulators	06.05.2017		201.4-201.17	3
					201.4-201.17	4
					201.4-201.17	5
					201.4-201.17	6
					201.4-201.17	7
					201.4-201.17	8
					201.11	12
					201.11	14
					201.11	15
					201.15	26
					201.16	27
					201.9, 201.11-201.13, 201.15,201.17	28

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.11	29
					201.7	30
					201.12	31
					201.10	34
					201.10	35
					201.10	36
					201.10	37
					201.14	38
					201.13	39
					201.12	42
					201.17	43
					201.17	44
					201.8	45
					201.9	46
					201.9	47
					201.9	48
					201.8,201.15	49
					201.15	50
					201.11	51
					201.12, 201.15	52
					201.12, 201.15	53
					201.12	54
					201.7	58
					201.7	65
120	ГОСТ Р МЭК 60601-2-33-2013 (IEC 60601-2-33:2010, IDT)	Medical electrical equipment. Part 2-33. Particular safety requirements taking into account the main functional characteristics to magnetic resonance equipment for medical diagnostics	06.05.2017		201.4-201.17, 202	3
					201.4-201.17, 202	4
					201.4-201.17, 202	5
					201.4-201.17, 202	6
					201.4-201.17, 202	7
					201.4-201.17, 202	8
					201.11	12
					201.11	14

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.11	15
					201.15	26
					201.16	27
					201.9, 201.11-201.13, 201.15, 201.17, 202	28
					201.11	29
					201.7	30
					201.12	31
					201.10	34
					201.10	35
					201.10	36
					201.10	37
					201.14	38
					201.13	39
					201.12	42
					201.17, 202	43
					201.17, 202	44
					201.8	45
					201.9	46
					201.9	47
					201.9	48
					201.8, 201.15	49
					201.15	50
					201.11	51
					201.12, 201.15	52
					201.12, 201.15	53
					201.12	54
					201.7	58
					201.7	65
121	ГОСТ Р МЭК 60601-2-36-2016 (IEC 60601-2-36:2014, IDT)	Medical electrical equipment. Part 2-36. Particular safety requirements taking into account the main functional characteristics	06.05.2017		201.4-201.17, 202	3
					201.4-201.17, 202	4
					201.4-201.17, 202	5

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
		to equipment for extracorporeally induced lithotripsy			201.4-201.17, 202	6
					201.4-201.17, 202	7
					201.4-201.17, 202	8
					201.11	12
					201.11	14
					201.11	15
					201.15	26
					201.16	27
					201.9, 201.11-201.13, 201.15,201.17, 202	28
					201.11	29
					201.7	30
					201.12	31
					201.10	34
					201.10	35
					201.10	36
1	2	3	4	5	6	7
					201.10	37
					201.14	38
					201.13	39
					201.12	42
					201.17, 202	43
					201.17, 202	44
					201.8	45
					201.9	46
					201.9	47
					201.9	48
					201.8, 201.15	49
					201.15	50
					201.11	51
					201.12, 201.15	52
					201.12, 201.15	53

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.12	54
					201.7	58
					201.7	65
122	ГОСТ Р МЭК 60601-2-37-2009 (IEC 60601-2-37:2007, IDT)	Medical electrical equipment. Part 2-37. Particular safety requirements taking into account the main functional characteristics to ultrasonic medical diagnostic and monitoring equipment	06.05.2017		201.4-201.17, 202.6	3
					201.4-201.17, 202.6	4
					201.4-201.17, 202.6	5
					201.4-201.17, 202.6	6
					201.4-201.17, 202.6	7
					201.4-201.17, 202.6	8
					201.11	12
					201.11	14
					201.11	15
					201.15	26
					201.16	27
					201.9, 201.11-201.13, 201.15,201.17, 202.6	28
					201.11	29
					201.7	30
					201.12	31
					201.10	34
					201.10	35
					201.10	36
					201.10	37
					201.14	38
					201.13	39
					201.12	42
					201.17, 202.6	43
					201.17, 202.6	44
					201.8	45
					201.9	46
					201.9	47
					201.9	48

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.8,201.15	49
					201.15	50
					201.11	51
					201.12, 201.15	52
					201.12, 201.15	53
					201.12	54
					201.7	58
					201.7	65
123	ГОСТ Р МЭК 60601-2-41-2014 (IEC 60601-2-41:2009, IDT)	Medical electrical equipment. Part 2-41. Particular safety requirements taking into account the main functional characteristics to surgical luminaires for diagnostics	06.05.2017		201.4-201.17	3
					201.4-201.17	4
					201.4-201.17	5
					201.4-201.17	6
					201.4-201.17	7
					201.4-201.17	8
					201.11	12
					201.11	14
					201.11	15
					201.15	26
					201.16	27
					201.9, 201.11-201.13,	28
					201.15, 201.17	
					201.11	29
					201.7	30
					201.12	31
					201.10	34
					201.10	35
					201.10	36
					201.10	37
					201.14	38
					201.13	39
					201.12	42
					201.17	43

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.17	44
					201.8	45
					201.9	46
					201.9	47
					201.9	48
					201.8, 201.15	49
					201.15	50
					201.11	51
					201.12, 201.15	52
					201.12, 201.15	53
					201.12	54
					201.7	58
					201.7	65
124	ГОСТ Р МЭК 60601-2-4-2013 (IEC 60601-2-4:2010, IDT)	Medical electrical equipment. Part 2-4. Particular safety requirements taking into account the main functional characteristics to cardio-defibrillators	06.05.2017		201.4-201.17,	3
					201.101-201.109, 202	
					201.4-201.17,	4
					201.101-201.109, 202	
					201.4-201.17, 201.101-201.109, 202	5
					201.4-201.17, 201.101-201.109, 202	6
					201.4-201.17, 201.101-201.109, 202	7
					201.4-201.17, 201.101-201.109, 202	8
					201.11	12
					201.11	14
					201.11	15
					201.15	26
					201.16	27
					201.9, 201.11-201.13, 201.15,201.17, 202	28

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.11	29
					201.7	30
					201.12	31
					201.10	34
					201.10	35
					201.10	36
					201.10	37
					201.14	38
					201.13	39
					201.12	42
					201.17, 202	43
					201.17, 202	44
					201.8	45
					201.9	46
					201.9	47
					201.9	48
					201.8, 201.15	49
					201.15	50
					201.11	51
					201.12, 201.15	52
					201.12, 201.15	53
					201.12	54
					201.7	58
					201.7	65
125	ГОСТ Р МЭК 60601-2-43-2013 (IEC 60601-2-43:2010, IDT)	Medical electrical equipment. Part 2-43. Particular safety requirements taking into account the main functional characteristics to the X-ray equipment for interventional procedures	06.05.2017		201.4-201.17, 202, 203	3
					201.4-201.17, 202, 203	4
					201.4-201.17, 202, 203	5
					201.4-201.17, 202, 203	6
					201.4-201.17, 202, 203	7
					201.4-201.17, 202, 203	8
					201.11	12
					201.11	14

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.11	15
					201.15	26
					201.16	27
					201.9, 201.11-201.13, 201.15, 201.17, 202	28
					201.11	29
					201.7	30
					201.12	31
					201.10, 203	34
					201.10, 203	35
					201.10	36
					201.10, 203	37
					201.14	38
					201.13	39
					201.12	42
					201.17, 202	43
					201.17, 202	44
					201.8	45
					201.9	46
					201.9	47
					201.9	48
					201.8,201.15	49
					201.15	50
					201.11	51
					201.12, 201.15	52
					201.12, 201.15	53
					201.12	54
					201.7	58
					201.7	65
126	ГОСТ Р МЭК 60601-2-44-2013 (IEC 60601-2-44:2009, IDT)	Medical electrical equipment. Part 2-44. Particular safety requirements taking into account the main functional characteristics	06.05.2017		201.4-201.17, 203	3
					201.4-201.17, 203	4
					201.4-201.17, 203	5

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
		to X-ray equipment for computed tomography			201.4-201.17, 203	6
					201.4-201.17, 203	7
					201.4-201.17, 203	8
					201.11	12
					201.11	14
					201.11	15
					201.15	26
					201.16	27
					201.9, 201.11-201.13,	28
					201.15, 201.17	
					201.11	29
					201.7	30
					201.12	31
					201.10, 203	34
					201.10, 203	35
					201.10	36
					201.10, 203	37
					201.14	38
					201.13	39
					201.12	42
					201.17	43
					201.17	44
					201.8	45
					201.9	46
					201.9	47
					201.9	48
					201.8, 201.15	49
					201.15	50
					201.11	51
					201.12, 201.15	52
					201.12, 201.15	53
					201.12	54

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.7	58
					201.7	65
127	ГОСТ Р МЭК 60601-2-45-2014 (IEC 60601-2-45:2011, IDT)	Medical electrical equipment. Part 2-45. Particular safety requirements taking into account the main functional characteristics to mammographic X-ray equipment and mammographic stereotactic devices	06.05.2017		201.4-201.17, 202, 203	3
					201.4-201.17, 202,	4
					203	
					201.4-201.17, 202, 203	5
					201.4-201.17, 202, 203	6
					201.4-201.17, 202, 203	7
					201.4-201.17, 202,	8
					203	
					201.11	12
					201.11	14
					201.11	15
					201.15	26
					201.16	27
					201.9, 201.11-201.13, 201.15,201.17, 202	28
					201.11	29
					201.7	30
					201.12	31
					201.10, 203	34
					201.10, 203	35
					201.10	36
					201.10, 203	37
					201.14	38
					201.13	39
					201.12	42
					201.17, 202	43
					201.17, 202	44
					201.8	45
					201.9	46

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.9	47
					201.9	48
					201.8, 201.15	49
					201.15	50
					201.11	51
					201.12, 201.15	52
					201.12, 201.15	53
					201.12	54
					201.7	58
					201.7	65
128	ГОСТ Р МЭК 60601-2-46-2014 (IEC 60601-2-46:2010, IDT)	Medical electrical equipment. Part 2-46. Particular safety requirements taking into account the main functional characteristics to operating tables	06.05.2017		201.4-201.17, 202	3
					201.4-201.17, 202	4
					201.4-201.17, 202	5
					201.4-201.17, 202	6
					201.4-201.17, 202	7
					201.4-201.17, 202	8
					201.11	12
					201.11	14
					201.11	15
					201.15	26
					201.16	27
					201.9, 201.11-201.13, 201.15, 201.17, 202	28
					201.11	29
					201.7	30
					201.12	31
					201.10	34
					201.10	35
					201.10	36
					201.10	37
					201.14	38
					201.13	39

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.12	42
					201.17, 202	43
					201.17, 202	44
					201.8	45
					201.9	46
					201.9	47
					201.9	48
					201.8, 201.15	49
					201.15	50
					201.11	51
					201.12, 201.15	52
					201.12, 201.15	53
					201.12	54
					201.7	58
					201.7	65
129	ГОСТ Р МЭК 60601-2-47-2015 (IEC 60601-2-47:2012, IDT)	Medical electrical equipment. Part 2-47. Particular safety requirements taking into account the main functional characteristics to ambulatory electrocardiographic systems	06.05.2017		201.4-201.17	3
					201.4-201.17	4
					201.4-201.17	5
					201.4-201.17	6
					201.4-201.17	7
					201.4-201.17	8
					201.11	12
					201.11	14
					201.11	15
					201.15	26
					201.16	27
					201.9, 201.11-201.13,	28
					201.15,201.17	
					201.11	29
					201.7	30
					201.12	31
					201.10	34

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.10	35
					201.10	36
					201.10	37
					201.14	38
					201.13	39
					201.12	42
					201.17	43
					201.17	44
					201.8	45
					201.9	46
					201.9	47
					201.9	48
					201.8,201.15	49
					201.15, 201.17, 202	
					201.11	29
					201.7	30
					201.12	31
					201.10	34
					201.10	35
					201.10	36
					201.10	37
					201.14	38
					201.13	39
					201.12	42
					201.17, 202	43
					201.17, 202	44
					201.8	45
					201.9	46
					201.9	47
					201.9	48
					201.8, 201.15	49
					201.15	50

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.11	51
					201.12, 201.15	52
					201.12, 201.15	53
					201.12	54
					201.7	58
					201.7	65
130	ГОСТ Р МЭК 60601-2-49-2015 (IEC 60601-2-49:2011, IDT)	Medical electrical equipment. Part 2-49. Particular safety requirements taking into account the main functional characteristics to multifunction patient monitoring equipment	06.05.2017		201.4-201.17, 202, 208	3
					201.4-201.17, 202, 208	4
					201.4-201.17, 202, 208	5
					201.4-201.17, 202, 208	6
					201.4-201.17, 202, 208	7
					201.4-201.17, 202, 208	8
					201.11	12
					201.11	14
					201.11	15
					201.15	26
					201.16	27
					201.9, 201.11-201.13, 201.15, 201.17, 202	28
					201.11	29
					201.7	30
					201.12	31
					201.10	34
					201.10	35
					201.10	36
					201.10	37
					201.14	38
					201.13	39

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.12	42
					201.17, 202	43
					201.17, 202	44
					201.8	45
					201.9	46
					201.9	47
					201.9	48
					201.8,201.15	49
					201.15	50
					201.11	51
					201.12, 201.15	52
					201.12, 201.15	53
					201.12	54
					201.7	58
					201.7	65
131	ГОСТ Р МЭК 60601-2-50-2012 (IEC 60601-2-50:2009, IDT)	Medical electrical equipment. Part 2-50. Particular safety requirements taking into account the main functional characteristics to infant phototherapy equipment	06.05.2017		201.4-201.17, 202	3
					201.4-201.17, 202	4
					201.4-201.17, 202	5
					201.4-201.17, 202	6
					201.4-201.17, 202	7
					201.4-201.17, 202	8
					201.11	12
					201.11	14
					201.11	15
					201.15	26
					201.16	27
					201.9, 201.11-201.13, 201.15, 201.17, 202	28
					201.11	29
					201.7	30
					201.12	31
					201.10	34

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.10	35
					201.10	36
					201.10	37
					201.14	38
					201.13	39
					201.12	42
					201.17, 202	43
					201.17, 202	44
					201.8	45
					201.9	46
					201.9	47
					201.9	48
					201.8,201.15	49
					201.15	50
					201.11	51
					201.12, 201.15	52
					201.12, 201.15	53
					201.12	54
					201.7	58
					201.7	65
132	ГОСТ Р МЭК 60601-2-63-2015 (IEC 60601-2-63:2012, IDT)	Medical electrical equipment. Part 2-63. Particular safety requirements taking into account the main functional characteristics to dental extra-oral X-ray equipment	06.05.2017		201.4-201.17, 202, 203	3
					201.4-201.17, 202, 203	4
					201.4-201.17, 202, 203	5
					201.4-201.17, 202, 203	6
					201.4-201.17, 202, 203	7
					201.4-201.17, 202, 203	8
					201.11	12
					201.11	14
					201.11	15
					201.15	26
					201.16	27
					201.9, 201.11-201.13,	28

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.15,201.17, 202	
					201.11	29
					201.7	30
					201.12	31
					201.10, 203	34
					201.10, 203	35
					201.10	36
					201.10, 203	37
					201.14	38
					201.13	39
					201.12	42
					201.17, 202	43
					201.17, 202	44
					201.8	45
					201.9	46
					201.9	47
					201.9	48
					201.8, 201.15	49
					201.15	50
					201.11	51
					201.12, 201.15	52
					201.12, 201.15	53
					201.12	54
					201.7	58
					201.7	65
133	ГОСТ Р МЭК 60601-2-65-2015 (IEC 60601-2-65:2012, IDT)	Medical electrical equipment. Part 2-65. Particular safety requirements taking into account the main functional characteristics to dental intra-oral X-ray equipment	06.05.2017		201.4-201.17, 202, 202.101,203	3
					201.4-201.17, 202, 202.101,203	4
					201.4-201.17, 202, 202.101,203	5
					201.4-201.17, 202,	6

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					202.101,203	
					201.4-201.17, 202, 202.101,203	7
					201.4-201.17, 202, 202.101,203	8
					201.11	12
					201.11	14
					201.11	15
					201.15	26
					201.16	27
					201.9, 201.11-201.13, 201.15, 201.17, 202	28
					201.11	29
					201.7	30
					201.12	31
					201.10, 203	34
					201.10, 203	35
					201.10	36
					201.10, 203	37
					201.14	38
					201.13	39
					201.12	42
					201.17, 202	43
					201.17, 202	44
					201.8	45
					201.9	46
					201.9	47
					201.9	48
					201.8, 201.15	49
					201.15	50
					201.11	51
					201.12, 201.15	52

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.12, 201.15	53
					201.12	54
					201.7	58
					201.7	65
134	ГОСТ Р МЭК 60627-2005 (IEC 60627:2001, IDT)	Diagnostic X-ray imaging equipment. Characteristics of general purpose and mammographic anti-scatter grids	06.05.2017	31.12.2019	4-6	3
					4-6	4
					4-6	6
					4-6	8
135	ГОСТ Р МЭК 62083-2013 (IEC 62083:2009, IDT)	Medical electrical equipment. Requirements for the safety of radiotherapy treatment planning systems	06.05.2017		4-16	3
					4-16	4
					4-16	6
					4-16	8
136	ГОСТ Р МЭК 62220-1-2-2010 (IEC 62220-1-2:2007, IDT)	Medical electrical equipment. Characteristics of digital X-ray imaging devices. Part 1-2. Determination of the detective quantum efficiency. Detectors used in mammography	06.05.2017		4-8	3
					4-8	4
					4-8	6
					4-8	8
137	ГОСТ Р МЭК 62220-1-3-2013 (IEC 62220-1-3:2008, IDT)	Medical electrical equipment. Characteristics of digital X-ray imaging devices. Part 1-3. Determination of the detective quantum efficiency. Detectors used in dynamic imaging	06.05.2017		4-8	3
					4-8	4
					4-8	6
					4-8	8
138	ГОСТ Р МЭК 62304-2013 (IEC 62304:2006, IDT)	Medical products. Software. Lifecycle processes	06.05.2017		4-9	3
					4-9	4
					4-9	5
					4-9	8
					4-9	38
139	ГОСТ Р МЭК 62366-2013 (IEC 62366:2007, IDT)	Medical products. Application of usability engineering to medical products	06.05.2017	31.12.2019	4-7	8
					4-7	32
					4-7	33
					4-7	50
					4-7	55

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					4-7	56
					4-7	57
140	СТ РК 2.189-2010 (IEC/TR 61206:1993, MOD)	Medical diagnostic ultrasonic equipment. General requirements for the measurement methods of continuous-wave Doppler equipment	06.05.2017		5,6	3
					5,6	32
					5,6	38
					5,6	52
					5,6	53
					5,6	54
141	СТ РК ГОСТ Р ИСО 10328-2010 (ISO 10328:2006, IDT)	Prosthetics. Structural testing of lower-limb prostheses. Requirements and test methods	06.05.2017	31.12.2019	4-16	3
					4-16	4
					4-16	5
					4-16	6
					4-16	7
142	СТ РК ГОСТ Р ИСО 15032-2008 (ISO 15032:2000, IDT)	Prostheses. Structural testing of hip units	06.05.2017		4-9	3
					4-9	4
					4-9	5
					4-9	6
					4-9	7
					4-9	8
					4-9	9
					4-9	12
143	СТ РК ИСО 3826-2-2011 (ISO 3826-2:2008, IDT)	Folding plastic containers for human blood and its components. Part 2. Graphical symbols applying on labels and instructions	06.05.2017		4	9
					4	11
					4	58
144	СТ РК ИСО 3826-3-2011 (ISO 3826-3:2006, IDT)	Folding plastic containers for human blood and its components. Part 3. Blood packaging systems with built-in components	06.05.2017		5-9	3
					5-9	4
					5-9	5
					5-9	6
					8	9
					5, 6,9	12
					5, 6,9	14

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					5, 6,9	15
					5-7,9	16
					5-7,9	18
					5	27
					5	28
					8	58
145	СТБ EN 12470-1-2014 (EN 12470-1:2000, IDT)	Clinical thermometers. Part 1. Metallic liquid-in-glass thermometers with maximum device	06.05.2017		5-7	3
					5-7	4
					6,7	5
					6,7	6
					6,7	7
					8	9
					8.1, 8.2	11
					6.2,12-1A	12
					8.3	16
					6.1.2.7, 6.3.3, 7.8	28
					6.4-6.6, 7.9	31
					6.1	32
					4, 8.2	33
					8.2, 8.3	58
					8.2, 8.3	65
146	СТБ EN 12470-2-2014 (EN 12470-2:2000, IDT)	Clinical thermometers. Part 2. Phase change-type (dot matrix) thermometers	06.05.2017		5-7	3
					5-7	4
					6,7	5
					6,7	6
					6,7	7
					8	9
					8	11
					6.8	12
					6.7	18
					6.11	28
					6.2-6.6, 6.9,6.10,	31

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					7.2-7.7, 8.3	
					6.11	32
					4, 8.2.1	33
					8.2	58
					6.7	60
					8.3	65
147	СТБ EN 556-2-2008 (EN 556-2:2003, IDT)	Sterilization of medical products. Requirements for medical products to be designated “sterile”. Part 2. Requirements for aseptically processed medical products	06.05.2017	31.12.2019	4.1 "a", 4.1 "e", 4.1 "b"	3
					4.1 "a", 4.1 "e", 4.1 "b"	16
					4.2	19
148	СТБ IEC 60601-1-2012 (IEC 60601-1:2005, IDT)	Medical electrical equipment. Part 1. General safety requirements taking into account the main functional characteristics	06.05.2017		4-17	3
					4-17	4
					4-17	5
					4-17	6
					4-17	7
					4-17	8
					11	12
					11	14
					11	15
					15	26
					16	27
					9, 11-13, 15, 17	28
					11	29
					7	30
					12	31
					10	34
					10	35
					10	36
					10	37
					14	38
					13	39
					12	42

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					17	43
					17	44
					8	45
					9	46
					9	47
					9	48
					8, 15	49
					15	50
					11	51
					12, 15	52
					12,15	53
					12	54
					7, 12, 16	55
					7, 12, 16	56
					7, 12, 16	57
					7	58
					7	65
149	СТБ IEC 60601-2-43-2012 (IEC 60601-2-43:2010, IDT)	Medical electrical equipment. Part 2-43. Additional safety requirements and requirements to the main characteristics of X-ray equipment for interventional procedures	06.05.2017		201.4-201.17, 202, 203	3
					201.4-201.17, 202, 203	4
					201.4-201.17, 202, 203	5
					201.4-201.17, 202, 203	6
					201.4-201.17, 202, 203	7
					201.4-201.17, 202, 203	8
					201.11	12
					201.11	14
					201.11	15
					201.15	26
					201.16	27
					201.9, 201.11-201.13, 201.15, 201.17, 202	28
					201.11	29
					201.7	30

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.12	31
					201.10, 203	34
					201.10, 203	35
					201.10	36
					201.10, 203	37
					201.14	38
					201.13	39
					201.12	42
					201.17, 202	43
					201.17, 202	44
					201.8	45
					201.9	46
					201.9	47
					201.9	48
					201.8, 201.15	49
					201.15	50
					201.11	51
					201.12, 201.15	52
					201.12, 201.15	53
					201.12	54
					201.7	58
					201.7	65
150	СТБ IEC 60645-1-2014 (IEC 60645-1:2012, IDT)	Electroacoustics. Audiometric equipment. Part 1. Equipment for pure-tone audiometry	06.05.2017		4-14	3
					4-14	4
					4-14	6
					4-14	7
					4-14	8
					4-14	31
					4-14	32
					4-14	33
					15.1	58
					15.5	65

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
151	СТБ IEC 60645-2-2010 (IEC 60645-2:1993, IDT)	Audiometers. Part 2. Equipment for speech audiometry	06.05.2017		4-16	3
					4-16	4
					4-16	6
					4-16	7
					4-16	8
					4-16	31
					4-16	32
					4-16	33
					17.1	58
					17.2	65
152	СТБ ISO 3826-3-2014 (ISO 3826-3:2006, IDT)	Plastics collapsible containers for human blood and blood components. Part 3. Blood bag systems with integrated features	06.05.2017		5-9	3
					5-9	4
					5-9	5
					5-9	6
					8	9
					5,6,9	12
					5, 6,9	14
					5,6,9	15
					5-7,9	16
					5-7,9	18
					5	27
					5	28
					8	58
153	СТБ ISO 80601-2-56-2016 (ISO 80601-2-56:2009, IDT)	Medical electrical equipment. Part 2-56. Particular safety requirements taking into account the main functional characteristics to clinical thermometers for body temperature measurement	06.05.2017		201.7, 201.7.2.1, 201.7.2.1.101, 201.7.2.2, 201.7.9	9
					201.7, 201.7.2.1, 201.8, 201.9	11
					201.11	13
					201.11	14
					201.11	15
					201.11	16

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					201.11	19
					201.4, 201.4.2.101,201.7, 201.7.9.2.101 "e", 201.16, 201.101.1, 201.102.1,201.103, 201.103.2	27
					201.9, 201.12.1.101, 201.12.2, 201.15, 202	28
					201.11,201.13	29
					201.7.9.2.101 "d", 201.12, 201.101,	31
					201.102, 201.103	
					201.12.2	32
					201.7	33
					202	36
					201.14	38
					201.12	42
					202	43
					201.8	45
					201.9	46
					201.9	47
					201.9	48
					201.8, 201.11,201.15	49
					201.11,201.15	51
					201.7, 201.12.2,	54
					201.15,206	
					201.7	58
					201.7.2.1.101	60
					201.7, 201.16	65
154	СТБ ГОСТ Р 8.605-2012 (IEC/TR 61206:1993, MOD)	State system for ensuring the uniformity of measurements of the Republic of Belarus.	06.05.2017		4,5	3
					4,5	32

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
		Diagnostic medical ultrasonic equipment. General requirements for the continuous-wave doppler equipment parameters measurement techniques			4,5	38
					4,5	52
					4,5	53
					4,5	54
155	СТБ EN 1041-2006 (EN 1041:1998, IDT)	Medical products. Information supplied by the manufacturer	06.05.2017	31.12.2019	4.1.1-4.1.9	9
					4.1.1-4.1.9	11
					4.1.1-4.1.9	27
					4.1.1-4.1.9	33
					4.1.1-4.1.9	54
					4.1.1-4.1.9	58
					4.1.1-4.1.9	60
					4.1.1-4.1.9	65
II. Standards applicable tor medical products and in vitro diagnostics						
1	ГОСТ EN 556-1-2011 (EN 556-1:2001, IDT)	Sterilization of medical products. Requirements for medical products to be designated “sterile”. Part 1. Requirements for terminally sterilized medical products	06.05.2017		4.1	3
					4.1	11
					4.1	72
					4.2	74
2	ГОСТ IEC 60825-1-2013 (IEC 60825-1:2007, IDT)	Safety of laser products. Part 1. Equipment classification, requirements and user’s guide	06.05.2017	31.12.2019	4-6, 7.2, 8, 9	88
					4-6, 7.2, 8, 9	89
3	ГОСТ IEC 61010-1-2014 (IEC 61010-1:2010, IDT)	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 1. General requirements	06.05.2017		4-16	3
					4-16	4
					4-16	5
					4-16	6
					4-16	7
					4-16	8
					4-16	80
					4-16	82
					4-16	83
					4-16	84
					4-16	85

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					4-16	94
					4-16	95
					4-16	96
					4-16	99
					4-16	100
					4-16	101
4	ГОСТ IEC 61010-2-101-2013 (IEC 61010-2-101:2002, IDT)	Safety requirements for electrical equipment for measurement, control and laboratory use. Part 2-101. Particular requirements for in vitro diagnostic (IVD) medical equipment	06.05.2017	31.12.2019	4-16	3
					4-16	4
					4-16	5
					4-16	6
					4-16	7
					4-16	8
					4-16	80
					4-16	82
					4-16	83
					4-16	84
					4-16	85
					4-16	94
					4-16	95
					4-16	96
					4-16	99
					4-16	100
					4-16	101
5	ГОСТ ISO 11135-2012 (ISO 11135:1994, IDT)	Medical products. Validation and routine control of ethylene oxide sterilization	06.05.2017	31.12.2019	4-7	74
6	ГОСТ ISO 11137-1-2011 (ISO 11137-1:2006, IDT)	Sterilization of health care products. Radiation. Part 1. Requirements for development, validation and routine control of a sterilization process for medical products	06.05.2017		4-12	74
7	ГОСТ ISO 11137-2-2011 (ISO 11137-2:2006, IDT)	Sterilization of health care products. Radiation. Part 2. Establishing the	06.05.2017	31.12.2019	4-10	74

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
		sterilization dose				
8	ГОСТ ISO 11737-2-2011 (ISO 11737-2:1998, IDT)	Sterilization of medical products. Microbiological methods. Part 2. Tests of sterility performed in the validation of a sterilization process	06.05.2017	31.12.2019	4-7	74
9	ГОСТ ISO 13485-2011 (ISO 13485:2003, IDT)	Medical products. Quality management systems. System requirements for regulatory purposes	06.05.2017	31.12.2019	4.1, 4.2, 5.1, 5.3-5.6, 6.4, 7.1-7.6, 8.2.2, 8.2.3, 8.2.4, 8.3, 8.4, 8.5.1-8.5.3	3
					4.1,4.2, 5.1, 5.3-5.6, 6.4, 7.1-7.6, 8.2.2, 8.2.3, 8.2.4, 8.3, 8.4, 8.5.1-8.5.3	4
					4.1,4.2, 5.1, 5.3-5.6, 6.4, 7.1-7.6, 8.2.2, 8.2.3, 8.2.4, 8.3, 8.4, 8.5.1-8.5.3	5
					4.1,4.2,5.1,53-5.6, 6.4, 7.1-7.6, 8.2.2, 8.2.3, 8.2.4, 8.3, 8.4, 8.5.1-8.5.3	6
					4.1,4.2,5.1,53-5.6, 6.4, 7.1-7.6, 8.2.2, 8.2.3, 8.2.4, 8.3, 8.4, 8.5.1-8.53	7
					4.1,4.2,5.1,53-5.6, 6.4, 7.1-7.6, 8.2.2, 8.2.3, 8.2.4, 8.3, 8.4, 8.5.1-8.53	8
10	ГОСТ ISO 14971-2011 (ISO 14971:2007, IDT)	Medical products. Application of risk management to medical products	06.05.2017		1-9	3
					1-9	4
					1-9	5
					1-9	7

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					1-9	8
11	ГОСТ ISO 17511-2011 (ISO 17511:2003, IDT)	In vitro diagnostic medical products. Measurement of quantities in biological samples. Metrological traceability of values assigned to calibrators and control materials	06.05.2017		4-8	6
					8	106
12	ГОСТ ISO 18153-2011 (ISO 18153:2003, IDT)	In vitro diagnostic medical products. Measurement of quantities in biological samples. Metrological traceability of assigned values for catalytic concentration of enzymes in calibrators and control materials	06.05.2017		4,5	6
13	ГОСТ ISO 6710-2011 (ISO 6710:1995, IDT)	Single-use containers for venous blood specimen collection. Technical requirements and test methods	06.05.2017		5.1, 7.2	3
					5.1, 7.2	4
					5.1, 7.2	7
					4.2, 5.1, 5.2, 6.2, 7.1, 7.2	69
					4.2, 5.1, 6.2, 6.3, 7.1	71
					4.4, 6.2, 6.3, 7.1	72
					8.1, 8.2	73
					8.1, 8.2	74
					5.1	80
					5.1, 7.1, 7.2	82
14	ГОСТ ISO 14644-1-2002 (ISO 14644-1:1999, IDT)	Cleanrooms and associated controlled environments. Part 1. Classification of air cleanliness	06.05.2017	31.12.2019	3,4	75
15	ГОСТ ISO 14698-1-2005 (ISO 14698-1:2003, IDT)	Cleanrooms and associated controlled environments. Biocontamination control. Part 1. General principles and methods	06.05.2017		4-9	75
16	ГОСТ ISO 14698-2-2005 (ISO 14698-2:2003, IDT)	Cleanrooms and associated controlled environments. Biocontamination control. Part 2. Evaluation and interpretation of biocontamination data	06.05.2017		4	75

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
17	ГОСТ Р ЕН 12322-2010 (EN 12322:1999, IDT)	In vitro diagnostic medical products. Culture media for microbiology. Performance criteria for culture media	06.05.2017		4.1-4.4	6
					5	105
					5	106
18	ГОСТ Р ЕН 13532-2010 (EN 13532:2002, IDT)	General requirements for in vitro diagnostic medical products for self-testing	06.05.2017		4.11	3
					4.11	4
					4.11	5
					4.11	7
					4.8	71
					4.10	81
					4.1-4.4, 4.6, 4.7	82
					4.9	83
					4.2	92
					4.3	94
					4.4	IV.9
					4.5	97
					4.3	99
					4.1	IV. 10
					4.1	102
					4.1	103
19	ГОСТ Р ЕН 13612-2010 (EN 13612:2002, IDT)	Performance evaluation of in vitro diagnostic medical products	06.05.2017		4.2, 4.4, 4.5	6
					4.5	7
					4.5	72
					4.5	90
					4.3	IV. 10
20	ГОСТ Р ЕН 13641-2010 (EN 13641:2002, IDT)	Elimination or reduction of risk of infection related to in vitro diagnostic reagents	06.05.2017		4.1	3
					4.1	4
					4.1, 4.2, 4.3.2, 4.4	72
					5	105
21	ГОСТ Р ЕН 14254-2010 (EN 14254:2004, IDT)	In vitro diagnostic medical products. Single-use receptacles for the collection of specimens, other than blood, from humans	06.05.2017		11.1, 11,2, 11.4	9
					11.4	11
					4.1, 5.3, 7.1, 7.2, 8.1, 8.2, 8.3, 10	69

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
					4.1, 5.1, 5.2, 7.1, 7.2, 8.1, 8.2	71
					4.2, 4.3, 7.1, 7.2, 8.1, 8.2	72
					9	73
					9	74
					4.1, 5.1, 5.2	80
					5.1	81
					8.1, 8.2, 8.3, 5.1	82
					5.2	83
22	GOST R ISO 13408-1-2000 (ISO 13408-1:1998, IDT)	Aseptic processing of health care products. Part 1: General reguirements	06.05.2017	31.12.2019	3-21	74
23	GOST R ISO 13408-2-2007 (ISO 13408-2:2003, IDT)	Aseptic processing of health care products. Part 2. Filtration	06.05.2017		4-12	74
24	GOST R ISO 13408-3-2011 (ISO 13408-3:2006, IDT)	Aseptic processing of health care products. Part 3. Lyophilization	06.05.2017		4-9	74
25	GOST R ISO 13408-4-2011 (ISO 13408-4:2005, IDT)	Aseptic processing of health care products. Part 4. Clean-in-place technologies	06.05.2017		4-9	74
26	GOST R ISO 13408-5-2011 (ISO 13408-5:2006, IDT)	Aseptic processing of health care products. Part 5. Sterilization in place	06.05.2017		4-9	74
27	GOST R ISO 13408-6-2009 (ISO 13408-6:2005, IDT)	Aseptic processing of health care products. Part 6. Isolator systems	06.05.2017		4-9	74
28	GOST R ISO 14937-2012 (ISO 14937:2009, IDT)	Sterilization of health care products. General criteria for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical products	06.05.2017		4-12	74
29	GOST R ISO 15193-2015 (ISO 15193:2009, IDT)	In vitro medical products. Measurement of quantities in samples of biological origin. Requirements for content and presentation of reference measurement procedures	06.05.2017		4	85
					4	86
30	GOST R ISO 15194-2013 (ISO 15194:2009, IDT)	In vitro medical products. Measurement of quantities in samples of biological origin.	06.05.2017		4-6	85
					4-6	86

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
		Requirements for certified reference materials and the content of supporting documentation				
31	ГОСТ Р ИСО 15197-2015 (ISO 15197:2013, IDT)	In vitro diagnostic test systems. Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus	06.05.2017		4.3, 4.4, 6.5, 7	5
					4.2,6	6
					4.3, 4.4	7
					7	9
					5.1	11
					4.3, 5.2-5.6, 5.8, 5.10-5.12	82
					5.7	83
					6	90
					5.2	94
					5.3, 5.6	95
					5.2	99
					4.4, 7, 8	102
					4.4, 7, 8	103
					4.4, 7, 8	104
32	ГОСТ Р ИСО 15223-1-2014 (ISO 15223-1:2012, IDT)	Medical products. Symbols to be used with medical product labels, labelling and information to be supplied. Part 1. General requirements	06.05.2017		4	11
					5.1-5.5	105
33	ГОСТ Р ИСО 15882-2012 (ISO 15882:2008, IDT)	Sterilization of health care products. Chemical indicators. Guidance for selection, use and interpretation of results	06.05.2017		3-11	74
34	ГОСТ R ISO 17665-1-2016 (ISO 17665-1:2006, IDT)	Sterilization of health care products. Moist heat. Part 1. Requirements for development, validation and routine control of a sterilization process for medical product	01.03.2017		4-12	74
35	ГОСТ Р ИСО 20776-1-2010 (ISO 20776-1:2006, IDT)	Clinical laboratory testing and in vitro diagnostic test systems. Susceptibility	06.05.2017		3,4	6
					3,4	86

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
		testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices. Part 1. Reference method for testing the in vitro activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases				
36	ГОСТ Р ИСО 20857-2016 (ISO 20857:2010, IDT)	Sterilization of health care products. Dry heat. Requirements for the development, validation and routine control of a sterilization process for medical products	01.03.2017		4-12	74
37	ГОСТ Р ИСО 23640-2015 (ISO 23640:2011, IDT)	In vitro medical products. Evaluation of stability of in vitro diagnostic reagents	06.05.2017		4.1-4.3,5.1-53	7
38	ГОСТ Р ИСО 25424-2013 (ISO 25424:2009, IDT)	Sterilization of medical products. Low temperature steam and formaldehyde. Requirements for development, validation and routine control of a sterilization process for medical products	06.05.2017		4-12	74
39	ГОСТ Р МЭК 61326-1-2014 (IEC 61326-1:2012, IDT)	Electrical equipment for measurement, control and laboratory use. EMC requirements. Part 1. General requirements.	06.05.2017		4-8	82
					4-8	92
					4-8	93
40	ГОСТ Р МЭК 61326-2-6-2014 (IEC 61326-2-6:2012, IDT)	Electrical equipment for measurement, control and laboratory use. EMC requirements. Part 2-6. Particular requirements. In vitro diagnostic medical equipment	06.05.2017		4-9	82
					4-9	92
					4-9	93
41	ГОСТ Р МЭК 62304-2013 (IEC 62304:2006, IDT)	Medical products. Software. Lifecycle processes	06.05.2017		4-9	3
					4-9	4
					4-9	5
					4-9	8
					4-9	90
42	ГОСТ Р МЭК 62366-2013 (IEC	Medical products. Application of usability	06.05.2017	31.12.2019	4-7	8

Item No.	Standard designation	Standard name	Starting date of the standard application	Ending date of the standard application	Applicable structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
	62366:2007, IDT)	engineering to medical products			4-7	72
					4-7	87
					4-7	100
					4-7	102
					4-7	103
					4-7	104
43	СТБ EN 556-2-2008 (EN 556-2:2003, IDT)	Sterilization of medical products. Requirements for medical products to be designated “sterile”. Part 2. Requirements for aseptically processed medical products	06.05.2017	31.12.2019	4.1 “a”, 4.1 “e”, 4.1 “b”	3
					4.1 “a”, 4.1 “e”, 4.1 “b”	72
					4.2	74

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