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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.

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| 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

**LIST**

**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 |
| 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 |
|  |  |  |  | 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 |
| 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 |
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|  |  |  |  |  | 201.15 | 26 |
|  |  |  |  |  | 201.16 | 27 |
|  |  |  |  |  | 201.9, 201.11-201.13, 201.15, 201.17 | 28 |
|  |  |  |  |  | 201.11 | 29 |
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|  |  |  |  |  | 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 | | |
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|  | |  | | |  | |  | |  | | | 4,5 | | 12 | | |
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|  | |  | | |  | |  | |  | | | 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 testing | | 06.05.2017 | | 31.12.2019 | | | 4-7 | | 12 | | |
| 4-7 | | 13 | | |
| 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 and quantification of degradation products from metals and alloys | | 06.05.2017 | |  | | | 4-9 | | 12 | | |
| 4-9 | | 13 | | |
| 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 | | |
| 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 В, С, D | | 12 | | |
| 4-6, Annexes В, С, D | | 13 | | |
| 4-6, Annexes В, С, 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 10993-7:2008, IDT) | | | Medical products. Biological evaluation of medical products. Part 7. Ethylene oxide sterilization residuals | | 01.01.2018 | |  | | | 4,5 | | 13 | | |
| 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 | | |
| 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 | | |
| 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 | | |
| 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 | | |
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| 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 | | |
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| 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 | | |
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| 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 | | |
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| 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 | |
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| 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 | | |
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| 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 | | |
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| 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 | | |
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| 56 | | ГОСТ OIML R 76-1-2011 (OIML R76-1:2006, IDT) | | | State system for ensuring the uniformity of measurements. Non-automatic weighing instruments. Part 1. Metrological and technical requirements. Tests | | 06.05.2017 | |  | | | Annex A | | 31 | | |
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| 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 | | |
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| 61 | | ГОСТ Р 52459.27-2009 (EN 301 489-27:2004, MOD) | | | Еlectromagnetic 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 | | |
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| 62 | | ГОСТ Р 52459.31-2009 (EN 301 489-31:2005, MOD) | | | Еlectromagnetic compatibility of technical equipment. Radio communication 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 | | 06.05.2017 | |  | | | 4-7 | | 28 | | |
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| 63 | | ГОСТ Р 52770-2007 | | | Medical products. Safety requirements. Methods of sanitation-chemical and toxicolоgical tests | | 06.05.2017 | | 30.09.2017 | | | 4.3, 5, Annexes A, B | | 13 | | |
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| 64 | | ГОСТ Р 52770-2016 | | | Medical products. Safety requirements. Methods of sanitation-chemical and toxicolоgical tests | | 01.10.2017 | |  | | | 4.1-4.5, 5, 6, Annexes A, B, C | | 13 | | |
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| 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 | | |
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| 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 | | |
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| 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 | | |
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| 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 | | |
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| 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 | | |
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| 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 "а", "c", "с", "d1", "d2", "d8" | | 3 | | |
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| 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 | | |
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| 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 | | |
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| 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 | | |
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| 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 | | |
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| 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 | | |
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| 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 | | |
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| 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 | | |
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| 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 | | |
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| 79 | | ГОСТ Р ИСО 14155-2014 (ISO 14155:2011, IDT) | | | Clinical investigations. Good clinical practice | | 06.05.2017 | |  | | | 4-9, Annex A | | 3 | | |
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| 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 | | |
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| 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 | | |
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| 82 | | ГОСТ Р ИСО 15032-2001 (ISO 15032:2000, IDT) | | | Prostheses. Structural testing of hip units | | 06.05.2017 | |  | | | 4-9 | | 3 | | |
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| 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 | | |
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| 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 | | |
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| 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 | | |
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| 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 | | |
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| 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 | | |
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| 88 | | ГОСТ Р ИСО 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 | | 18 | | |
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| 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 | | |
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| 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 | | |
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| 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 | | |
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| 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 | |
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| 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 С | | 12 | | |
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| 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 | | |
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| 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 | | |
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| 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 | | |
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| 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 | | |
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| 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 | | |
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| 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 | | |
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| 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 | | |
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| 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 | | |
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| 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 | | |
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|  | |  | | |  | |  | |  | | | 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 account the main functional characteristics | | 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 | | |
|  | | |  | |  | | |  | |  | | 201.11.6.6, 201.11.6.7, 201.105 | | | 16 | |
| 201.11.6.7 | | | 19 | |
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| 201.14 | | | 38 | |
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|  | |  | | |  | |  | |  | | | 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 account the main functional characteristics | | 06.05.2017 | |  | | | 4-17 | | 3 | | |
|  | |  | |  | | | 4-17 | | 4 | | |
|  | |  | |  | | | 4-17 | | 5 | | |
|  | |  | | |  | |  | | | 4-17 | | 6 | | |
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|  | |  | | |  | |  | |  | | | 11 | | 14 | | |
|  | |  | | |  | |  | |  | | | 11 | | 15 | | |
|  | |  | | |  | |  | |  | | | 15 | | 26 | | |
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|  | |  | | |  | |  | |  | | | 11 | | 29 | | |
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|  | |  | | |  | |  | |  | | | 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 | | |
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|  | |  | | |  | |  | |  | | | 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 | | | 4-6 (not applicable unchanged to implantable products) | | 28 | | |
|  | |  | |  | | |  | | |
|  | |  | | |  | |  | | |  | | |
|  | |  | | |  | |  | |  | | | 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 account the main functional characteristics to electron accelerators operating within the range from 1 to 50 MeV | | 06.05.2017 | |  | | | 201.4-201.17, 206 | | 3 | | |
| 201.4-201.17, 206 | | 4 | | |
|  | |  | | |  | |  | |  | | | 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 | | |
| 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 | | |
|  | |  | | |  | |  | |  | | | 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 | | |
|  | |  | | |  | |  | |  | | | 201.12 | | 31 | | |
|  | |  | | |  | |  | |  | | | 201.10 | | 34 | | |
|  | |  | | |  | |  | |  | | | 201.10 | | 35 | | |
|  | |  | | |  | |  | |  | | | 201.10 | | 36 | | |
|  | |  | | |  | |  | |  | | | 201.10 | | 37 | | |
|  | |  | | |  | |  | |  | | | 201.14 | | 38 | | |
|  | |  | | |  | |  | |  | | | 201.13 | | 39 | | |
|  | | |  | |  | | |  | |  | | 201.12 | | | 42 | |
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| 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 | |
| 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 | | |
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|  | |  | | |  | |  | |  | | | 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 | | |
| 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 | | |
|  | |  | | |  | |  | |  | | | 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 | | |
|  | |  | | |  | |  | |  | | | 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, | | 3 | | |
|  | |  | |  | | | 208 | |  | | |
|  | |  | | |  | |  | | | 201.4-201.17, 202, | | 4 | | |
|  | |  | | |  | |  | | | 208 | |  | | |
|  | |  | | |  | |  | | | 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 | | |
|  | |  | | |  | |  | |  | | | 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 | | |
|  | |  | | |  | |  | |  | | | 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 | |
|  | | |  | |  | | |  | |  | | 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 | | |
|  | |  | | |  | |  | |  | | | 201.12, 201.15 | | 52 | | |
|  | |  | | |  | |  | |  | | | 201.12, 201.15 | | 53 | | |
|  | |  | | |  | |  | |  | | | 201.12 | | 54 | | |
|  | |  | | |  | |  | |  | | | 201.7 | | 58 | | |
|  | |  | | |  | |  | |  | | | 201.7 | | 65 | | |
| 117 | | ГОСТ Р МЭК EC 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 | | |
|  | |  | | |  | |  | |  | | | 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 | | |
|  | |  | | |  | |  | |  | | | 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 | | |
|  | |  | | |  | |  | |  | | | 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 | | |
|  | |  | | |  | |  | |  | | | 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 to equipment for extracorporeally induced lithotripsy | | 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 | | |
| 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 | | |
|  | |  | | |  | |  | |  | | | 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 | | |
|  | |  | | |  | |  | |  | | | 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 | | |
|  | |  | | |  | |  | |  | | | 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 | | |
|  | |  | | |  | |  | |  | | | 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 | | |
| 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 to X-ray equipment for computed tomography | | 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, 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 | |
|  | | |  | |  | | |  | |  | | 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 | | |
|  | |  | | |  | |  | |  | | | 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 | | |
|  | |  | | |  | |  | |  | | | 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 | |
|  | | |  | |  | | |  | |  | | 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 | | |
|  | |  | | |  | |  | |  | | | 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 | | |
|  | |  | | |  | |  | |  | | | 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 | | |
|  | |  | | |  | |  | |  | | | 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, 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 | |
| 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, 202.101,203 | | | 6 | |
| 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 | | |
|  | |  | | |  | |  | |  | | | 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 Х-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 | | |
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| 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 | | |
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| 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 | | |
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| 142 | | СТ РК ГОСТ Р ИСО 15032-2008 (ISO 15032:2000, IDT) | | | Prostheses. Structural testing of hip units | | 06.05.2017 | |  | | | 4-9 | | 3 | | |
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| 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 | | |
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| 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 | | |
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| 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 | | |
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| 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 | | |
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| 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 "а", 4.1 "е", 4.1 "b" | | 3 | | |
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| 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 | | |
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| 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 | |
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| 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 | | |
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| 151 | | СТБ IEC 60645-2-2010 (IEC 60645-2:1993, IDT) | | | Audiometers. Part 2. Equipment for speech audiometry | | 06.05.2017 | |  | | | 4-16 | | 3 | | |
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| 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 | | |
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| 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 | |
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| 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. Diagnostic medical ultrasonic equipment. General requirements for the continuous-wave doppler equipment parameters measurement techniques | | 06.05.2017 | |  | | | 4,5 | | 3 | | |
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| 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 | | |
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| 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 | | |
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| 2 | | ГОСТ IEC 60825-1-2013 (IEC 60825-1:2007, IDT) | | | Safety of laser products. Part 1. Equipment clаssification, 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 | | |
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| 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 | | |
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| 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 sterilization dose | | 06.05.2017 | | 31.12.2019 | | | 4-10 | | 74 | | |
| 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 | | |
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