

**THE EURASIAN ECONOMIC COMMISSION**

**THE BOARD**

**RECOMMENDATION**

|  |  |  |
| --- | --- | --- |
| June 27, 2023 | **No. 15** | Moscow |

**On amending the List of Standards Applying which on Voluntary Basis Will Result in Compliance of Medical Devices, in Whole or in Part, with the General Requirements for Medical Device Safety and Efficiency, Requirements for their Marking and Operational Documentation.**

The Eurasian Economic Commission's Board, based on paragraph 2 of Article 3, paragraph 4 of Article 4 and paragraph 4 of Article 7 of the Agreement on Unified Principles and Rules for the Circulation of Medical Devices (Medical Accessories and Medical Equipment) within the Eurasian Economic Union dated December 23, 2014, and in accordance with paragraph 110 of General Requirements for Medical Device Safety and Efficiency, Requirements for their Marking and Operational Documentation approved by Decision No. 27 of the Eurasian Economic Commission's Council dated February 12, 2016

recommends to the Member States of the Eurasian Economic Union to apply the List of Standards Applying which on Voluntary Basis Will Result in Compliance of Medical Devices, in Whole or in Part, with the General Requirements for Medical Device Safety and Efficiency, Requirements for their Marking and Operational Documentation at the lapse of 6 months from the date of publication of this Recommendation on the website of the Eurasian Economic Union considering the amendments according to the Annex (Annex to Recommendation No. 17 of the Eurasian Economic Commission's Board dated September 4, 2017).

|  |  |
| --- | --- |
| Chairman of the Board  of the Eurasian Economic Commission | M. Myasnikovich |

ANNEX

to Recommendation of the Board

of the Eurasian Economic Commission

No. 15 dated June 27, 2023

**AMENDMENTS**

**to be made to the List of Standards Applying which on Voluntary Basis**

**Will Result in Compliance of Medical Devices, in Whole or in Part,**

**with the General Requirements for Medical Device Safety and Efficiency,**

**Requirements for their Marking and Operational Documentation**

1. Section I:

a) items 2, 15 – 18, 25, 29, 31, 47, 68, 83, 91, 129, 138, 139, 150 and 153 shall be read as follows:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 2 | GOST 21643-2022 | Medical suture devices. General specifications | December 1, 2023 |  | 3.2, 3.6 – 3.21,  5.6 – 5.19 | 3 |
| 3.26, 5.24 | 5 |
| 3.2, 3.6 – 3.21,  5.6 – 5.19 | 6 |
|  |  |  |  |  | 3.27, 3.28 | 7 |
|  |  |  |  |  | 3.4, 3.5, 5.4, 5.5 | 12 |
| 15 | GOST ISO 10555-1-2021,  (ISO 10555-1:2013+ Amd.1:2017, IDT) | Intravascular sterile and single-use catheters. Part 1. General requirements | December 1, 2023 |  | 4, 5 | 3 |
| 4, 5 | 4 |
| 4, 5 | 5 |
| 4, 5 | 6 |
| 4, 5 | 7 |
| 4, 5 | 12 |
| 4, 5 | 13 |
| 5, 6 | 27 |
| 4, 5 | 28 |
| 16 | GOST ISO 10555-5-2021 (ISO 10555-5:2013, IDT) | Intravascular sterile and single-use catheters.  Part 5. Over-needle peripheral catheters | December 1, 2023 |  | 4, Annexes A – D | 3 |
| 4, Annexes A – D | 4 |
| 4, Annexes A – D | 5 |
| 4, Annexes A – D | 6 |
| 4, Annexes A – D | 7 |
| 4, Annexes A – D | 12 |
| 4, Annexes A – D | 13 |
| 4, Annexes A – D | 27 |
| 4, Annexes A – D | 28 |
| 17 | GOST ISO 10993-11-2021 (ISO 10993-11:2017, IDT) | Medical devices. Biological evaluation of medical devices.  Part 11. Tests for systemic toxicity | December 1, 2023 |  | 4 – 6 | 12 |
| 4 – 6 | 13 |
| 4 – 6 | 15 |
| 18 | GOST ISO 10993-1-2021 (ISO 10993-1:2018, IDT) | Medical devices. Biological evaluation of medical devices.  Part 1. Evaluation and testing within a risk management process | December 1, 2023 |  | 5 – 7 | 12 |
| 4 – 7 | 13 |
| 4 – 7 | 15 |
| 25 | GOST ISO 10993-16-2021 (ISO 10993-16:2017, IDT) | Medical devices. Biological evaluation of medical devices.  Part 16. Toxicokinetic study design for degradation products and leachables | December 1, 2023 |  | 4, 5, Annex A | 12 |
| 4, 5, Annex A | 13 |
| 4, 5, Annex A | 15 |
| 29 | GOST ISO 10993-4-2020 (ISO 10993-4:2017, IDT) | Medical devices. Biological evaluation of medical devices.  Part 4. Toxicokinetic study design for degradation products and leachables | December 1, 2023 |  | 6 | 12 |
| 6 | 13 |
| 6 | 15 |
| 31 | GOST ISO 10993-6-2021 (ISO 10993-6:2016, IDT) | Medical devices. Biological evaluation of medical devices.  Part 6. Tests for local effects after implantation | December 1, 2023 |  | 4, 5, Annexes A, B, C, D | 12 |
| 4, 5, Annexes A, B, C, D | 13 |
| 4, 5, Annexes A, B, C, D | 15 |
| 47 | GOST ISO 14971-2021 (ISO 14971:2019, IDT) | Medical devices. Application of risk management to medical devices | December 1, 2023 |  | 4 – 10 | 3 |
| 4 – 10 | 4 |
| 4 – 10 | 5 |
| 4 – 10 | 7 |
| 4 – 10 | 8 |
| 68 | GOST R ISO 10328-2021 (ISO 10328:2016, IDT) | Prostheses. Structural testing of lower-limb prostheses. Requirements and test methods | December 1, 2023 |  | 4 – 16 | 3 |
| 4 – 16 | 4 |
| 4 – 16 | 5 |
| 4 – 16 | 6 |
| 4 – 16 | 7 |
| 83 | GOST R ISO 15223-1-2020 (ISO 15223-1:2016, IDT) | Medical devices. Symbols to be used with medical device labels, labelling, and information to be supplied. Part 1. General requirements | December 1, 2023 |  | 4 | 11 |
| 5.1 – 5.4 | 58 |
| 5.2.7 | 60 |
| 91 | GOST R ISO 21535-2020 (ISO 21535:2007 + Amd.1:2016, IDT) | Non-active surgical implants. Joint replacement implants. Specific requirements for hip-joint replacement implants | December 1, 2023 |  | 4 – 8 | 3 |
| 4 – 8 | 4 |
| 4, 5, 7, 8, 10 | 5 |
| 4 – 10 | 6 |
| 4 – 8 | 7 |
| 5, 7 | 8 |
| 4 – 8 | 12 |
| 4, 6 – 8, 10 | 13 |
| 6 – 8 | 14 |
| 9, 10 | 16 |
| 9, 10 | 18 |
|  |  |  |  |  | 9, 10 | 19 |
|  |  |  |  |  | 9, 10 | 20 |
|  |  |  |  |  | 9, 10 | 21 |
|  |  |  |  |  | 6 | 22 |
|  |  |  |  |  | 6 | 23 |
|  |  |  |  |  | 5, 6, 11 | 27 |
|  |  |  |  |  | 4, 5, 6 | 28 |
|  |  |  |  |  | 9 | 58 |
|  |  |  |  |  | 9, 10 | 60 |
|  |  |  |  |  | 9 | 65 |
| 129 | GOST R IEC 60601-2-47-2017 (IEC 60601-2-47:2012, IDT) | Medical electrical equipment.  Part 2-47. Particular requirements for basic safety and essential performance of ambulatory electrocardiographic systems | May 6, 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 |
| 138 | GOST IEC 62304-2022  (IEC 62304:2006 +  Amd. 1:2015, IDT) | Medical devices. Software. Life cycle processes | December 1, 2023 |  | 4 – 9 | 3 |
| 4 – 9 | 4 |
| 4 – 9 | 5 |
| 4 – 9 | 8 |
| 4 – 9 | 28 |
| 4 – 9 | 38 |
| 139 | GOST R IEC 62366-1-2021 (IEC 62366-1:2015, IDT) | Medical devices.  Part 1. Application of usability engineering to medical devices | December 1, 2023 |  | 4 – 5 | 3 |
| 4 – 5 | 4 |
| 4 – 5 | 6 |
| 4 – 5 | 8 |
| 4 – 5 | 28 |
| 4 – 5 | 32 |
| 4 – 5 | 33 |
| 4 – 5 | 50 |
| 4 – 5 | 52 |
| 4 – 5 | 53 |
| 4 – 5 | 54 |
| 4 – 5 | 55 |
| 4 – 5 | 56 |
| 4 – 5 | 57 |
| 150 | STB IEC 60645-1-2020 (IEC 60645-1:2017, IDT) | Electroacoustics. Audiometric testing equipment.  Part 1. Tone audiometry and voice-ear measurement equipment. | December 1, 2023 |  | 4 – 14 | 3 |
| 4 – 14 | 4 |
| 4 – 14 | 6 |
| 4 – 14 | 7 |
| 4 – 14 | 8 |
| 4 – 14 | 31 |
| 4 – 14 | 32 |
| 4 – 14 | 33 |
| 15.1 | 58 |
| 15.2 | 65 |
| 153 | STB ISO 80601-2-56-2021 (ISO 80601-2-56:2017, IDT) | Medical electrical equipment.  Part 2-56. Particular safety requirements and requirements for main characteristics of medical thermometers for measuring body temperature | December 1, 2023 |  | 201.7, 201.7.2.1, 201.7.2.1.101, 201.7.2.2, 201.7.9 | 9 |
| 201.7, 201.7.2.1, 201.8, 201.9 | 11 |
| 201.11 | 13 |
| 201.11 | 14 |
| 201.11 | 15 |
| 201.11 | 16 |
| 201.11 | 19 |
|  |  |  |  |  | 201.4, 201.4.2.101, 201.7, 201.7.9.2.101 "f", 201.16, 201.101.1, 201.102.1, 201.103.2 | 27 |
|  |  |  |  |  | 201.9, 201.12.1.101, 201.12.2, 201.15, 202 | 28 |
|  |  |  |  |  | 201.11, 201.13 | 29 |
|  |  |  |  |  | 201.7.9.2.101 "e", 201.12, 201.101, 201.102, 201.103 | 31 |
|  |  |  |  |  | 201.12.2 | 32 |
|  |  |  |  |  | 201.7 | 33 |
|  |  |  |  |  | 202 | 36 |
|  |  |  |  |  | 201.14 | 38 |
|  |  |  |  |  | 201.12 | 42 |
|  |  |  |  |  | 202 | 43 |
|  |  |  |  |  | 201.8 | 45 |
|  |  |  |  |  | 201.9 | 46 |
|  |  |  |  |  | 201.9 | 47 |
|  |  |  |  |  | 201.9 | 48 |
|  |  |  |  |  | 201.8, 201.11, 201.15 | 49 |
|  |  |  |  |  | 201.11, 201.15 | 51 |
|  |  |  |  |  | 201.6, 201.7, 201.12.2, 201.15 | 54 |
|  |  |  |  |  | 201.7 | 58 |
|  |  |  |  |  | 201.7.2.1.101 | 60 |
|  |  |  |  |  | 201.7, 201.16 | 65 |

b) delete "December 31, 2019" in the fifth column in items 6, 8, 9, 14, 30, 37 – 44, 46, 48, 52, 53, 65, 70, 73, 85, 93, 94, 100, 101, 106, 134, 141, 147 and 155;

c) delete item 151.

2. In Section II:

a) items 10, 32, 41 and 42 shall be read as follows:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 10 | GOST ISO 14971-2021 (ISO 14971:2019, IDT) | Medical devices. Application of risk management to medical devices | December 1, 2023 |  | 4 – 10 | 3 |
| 4 – 10 | 4 |
| 4 – 10 | 5 |
| 4 – 10 | 7 |
| 4 – 10 | 8 |
| 32 | GOST R ISO 15223-1-2020 (ISO 15223-1:2016, IDT) | Medical devices.  Symbols to be used with medical device labels, labelling, and information to be supplied. Part 1. General requirements | December 1, 2023 |  | 4 | 11 |
| 5.1 – 5.5 | 105 |
| 41 | GOST IEC 62304-2022  (IEC 62304:2006 +  Amd. 1:2015, IDT) | Medical devices. Software. Life cycle processes | December 1, 2023 |  | 4 – 9 | 3 |
| 4 – 9 | 4 |
| 4 – 9 | 5 |
| 4 – 9 | 8 |
| 4 – 9 | 82 |
| 4 – 9 | 90 |
| 42 | GOST R IEC 62366-1-2021 (IEC 62366-1:2015, IDT) | Medical devices.  Part 1. Application of usability engineering to medical devices | December 1, 2023 |  | 4 – 5 | 3 |
| 4 – 5 | 4 |
| 4 – 5 | 6 |
| 4 – 5 | 8 |
| 4 – 5 | 69 |
| 4 – 5 | 70 |
| 4 – 5 | 71 |
| 4 – 5 | 72 |
| 4 – 5 | 82 |
| 4 – 5 | 87 |
| 4 – 5 | 100 |
| 4 – 5 | 102 |
| 4 – 5 | 103 |
| 4 – 5 | 104 |

b) delete "December 31, 2019" in the fifth column in items 2, 4, 7, 8, 22 and 43

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_