DATA ON REGULATORY DOCUMENTATION

Biofeedback Treadmills of the Reaterra series

2024

1. Introduction

Biofeedback Treadmills of the Reaterra series within medical and preventive treatment facilities (MPTF) as follows:

- the activation of the neuromuscular apparatus of the body, strengthening muscles, and relieving pain

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MEDICAL ITEM MANUFACTURING ADDRESS

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TYPE OF MEDICAL ITEM AS PER NOMENCLATURE CLASSIFICATION OF MEDICAL DEVICES

285040

CLASS OF POTENTIAL RISK OF MEDICAL ITEM APPLICATION AS PER NOMENCLATURE CLASSIFICATION OF MEDICAL DEVICES

2a

CODE AS PER ALL-RUSSIAN CLASSIFIER OF MEDICAL DEVICES

ОКПД-2 32.50.22.120

CLASSIFICATION RULES MDR 2017/745

2A (Rule 9)

2. Data on regulatory documentation

Technical Specification (Russian: TU)

TU 32.50.50-021-68709709-2022

Medical item corresponds to the following standards:

GOST 15150-69, GOST R 50444-92, GOST ISO 14971-2011, GOST 14254-2015, GOST R 51260-2017, GOST R IEC 60601-1-2010, GOST R IEC 62304-2013, GOST R IEC 60601-1-2-2014, GOST R 27.001-2009, GOST 27.003-2016, GOST 9.303-84, GOST R ISO/ IEC 9126-93, GOST R ISO 9127-94, GOST R ISO/ IEC 12119-2000, GOST 28195-89, MU 287-113, GOST R IEC 60601-1-6-2014, GOST R 51632-2014.

Control methods:

GOST 9.302-88, GOST 8.051-81, GOST 15150-69, GOST R 50444-92, GOST 14254-2015, GOST R 51260-2017, GOST R IEC 60601-1-2010, GOST R IEC 60601-1-2-2014, GOST R ISO/ IEC 9126-93, GOST R ISO 9127-94, GOST R ISO/ IEC 12119-2000, GOST 28195-89, МУ 287-113, GOST R IEC 60601-1-6-2014, GOST R 51632-2014.

3. List of main EC standards, which are applicable to the medical device Biofeedback Treadmills of the Reaterra series:

3.1 Regulation (EU) 2017/745 is a regulation of the European Union on the clinical investigation and sale of medical devices for human use, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

3.2 Commission Delegated Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances.

3.3 EN ISO 13485:2016/AC:2016 Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016).

3.4 EN ISO 14971:2019 Medical devices – Application of risk management to medical devices.

3.5 EN ISO 15223-1:2016 Medical devices. Symbols to be used with medical device labels, labelling, and information to be supplied. Part 1. General requirements (ISO 15223-1:2016, Corrected version 2017-03).

3.6 EN 1041:2008+A1:2013 Information supplied by the manufacturer of medical devices.

3.7 EN ISO 14155:2011/AC:2011 Clinical investigation of medical devices for human subjects – Good clinical practice (ISO 14155:2011).

3.8 EN 60601-1:2006+A12:2014 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

3.9 EN 60601-1-2:2015 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.

3.10 EN 60601-1-6:2010+A1:2015 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability (IEC 60601-1-6:2010).

3.11 EN 60601-1-8:2007/A11:2017 Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (IEC 60601-1-8:2006).

3.12 EN 60601-1-11:2015 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC 60601-1-11:2015).

3.13 EN 60601-2-10:2015+A1:2016 Medical electrical equipment – Part 2-10: Particular requirements for the safety of nerve and muscle stimulators (IEC 60601-2-10(2012)).

3.14 EN 62366:2008+A1:2015 Medical devices – Application of usability engineering to medical devices (IEC 62366:2007).

3.15 EN 62304:2006+A1:2015 Medical device software – Software life-cycle processes (IEC 62304:2006).

3.16 EN 12182:2005 - Assistive products for persons with disability - General requirements and test method.

3.17 DS/ EN 55011-2020 Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement.

4 Compliance to standards

Russian state technical standards	International standard, Harmonized European standards
GOST 15150-69 Machines, instruments and other industrial products. Modifications for different climatic regions. Categories, operating, storage and transportation conditions as to environment climatic aspects influence.	IEC 60721-2-1 Classification of environmental conditions – Part 2-1: Environmental conditions appearing in nature – Temperature and humidity IEC 60068-1 Environmental testing – Part 1: General and guidance.
GOST ISO 14971-2011 Medical devices. Application of risk management to medical devices.	ISO 14971:2019 Medical devices — Application of risk management to medical devices.
GOST 14254-2015 Degrees of protection provided by enclosures (IP Code).	IEC 60529:2013 Degrees of protection provided by enclosures (IP Code).

GOST R IEC 60601-1-2010 Medical electrical equipment. Part 1. General requirements for basic safety and essential performance.	IEC 60601-1:2005 Medical electrical equipment – Part 1. General requirements for basic safety and essential performance, technical amendment Corr. 1-2006, Corr. 2-2007, I-SH 01-2008, I-SH 02-2009.
GOST R IEC 62304-2013 Medical devices. Software. Life cycle processes.	IEC 62304:2006 Medical device software – Software life cycle processes.
GOST R IEC 60601-1-2-2014 «Medical electrical equipment. Part 1-2. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests.	IEC 60601-1-2:2007 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests, technical amendment I-SH 01-2010.
GOST R ISO/ IEC 9126-93 Information technology. Software product evaluation. Quality characteristics and guidelines for their use.	ISO/ IEC 25010:2011 Systems and software engineering – Systems and software Quality Requirements and Evaluation (SquaRE) – system and software quality models.
GOST 17187-2010 Sound level meters. Part 1. Technical requirements.	IEC 61672-1:2002 Electroacoustics – Sound level meters – Part 1: Specifications.
GOST 28195-89 Quality control of software systems. General principles.	ISO/IEC 25010:2011 Systems and software engineering – Systems and software Quality Requirements and Evaluation (SquaRE) – System and software quality models, IDT).
GOST R ISO 15223-1-2014 Medical devices. Symbols to be used with medical device labels, labeling, and information to be supplied. Part 1. General requirements.	ISO 15223-1:2012 Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied - Part 1: General requirements.
GOST R 51632-2014 Technical aids for disabled persons. General technical requirements and test methods.	EN 12182:2005 Assistive products for persons with disability - General requirements and test method.
GOST R ISO/ IEC 12119 Information technology. Software packages. Quality requirements and testing.	ISO/IEC 12119:1994 Information technology — Software packages — Quality requirements and testing.
GOST R ISO/ IEC 9126 Information technology. Software product evaluation. Quality characteristics and guidelines for their use.	ISO/IEC 9126:1991 Information technology; software product evaluation; Quality characteristics and guidelines for their use.
GOST R ISO 9127 Information processing systems. User documentation and cover information for consumer software packages.	ISO 9127:1988 Information processing systems — User documentation and cover information for consumer software packages.
GOST 33571-2015 Resources saving. Packaging. Requirements for the use of European Standards in the field of packaging and packaging waste.	EN 13427:2004 Packaging - Requirements for the use of European Standards in the field of packaging and packaging waste, MOD.
GOST R ISO 9127 Information processing systems. User documentation and cover information for consumer software packages.	ISO 9127:1988 Information processing systems — User documentation and cover information for consumer software packages.

Russian state technical standards	International standard, Harmonized European standards
GOST 28195 QUALITY CONTROL OF SOFTWARE SYSTEM. General principles.	ISO/IEC 25010:2011 Systems and software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — System and software quality models.
GOST R 50444 Medical instruments, apparatus and equipment. General specifications.	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.
GOST R 51318.11-2006 (SICPR 11:2004) Electromagnetic compatibility of technical equipment. Industrial, scientific, medical and domestic (ISMD) high-frequency equipment. Radio disturbance. Limits and methods of measurement.	CISPR 11:2004 Industrial, scientific and medical (ISM) radio-frequency equipment - Electromagnetic disturbance characteristics - Limits and methods of measurement.

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