GOST R 51609-2000 Medical devices.
Classification according to the potential risk of using

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STATE STANDARD OF THE RUSSIAN FEDERATION

Medical devices. CLASSIFICATION ACCORDING
FROM POTENTIAL RISK OF

GENERAL REQUIREMENTS

MEDICAL PRODUCTS. CLASSIFICATION IN ACCORDANCE
WITH POTENTIAL RISK OF USING. GENERAL REQUIREMENTS

GOST R 51609-2000

Preface

1. Designed and made by the Technical Committee for Standardization TC 11 Medical devices and equipment, the Committee on New Medical Technology Russian Ministry of Health, Joint Stock Company "VNIIMP-Vita."
2. Adopted and put into effect by Decision of State Standard of Russia from May 17, 2000 N 140-st.
3. Section 5 of this standard is the authentic text of Annex 9 of the Directive 93/42/EEC of 14 June 1993 "Medical products".
4. First introduced.

1. Scope

This standard:

- **Applies to medical products (hereinafter - MI) domestic and foreign production, intended for use for medical purposes in the territory of the Russian Federation;**
- **Sets the rules and the classification of MI depending on the potential risk of their use;**

- **Used during the registration of MI Ministry of Health of Russia and the certification of MI in the GOST R certification system for determining the volume of work rules and procedures for monitoring the compliance of MI systems and their manufacturing quality regulatory requirements;**
- **Does not apply to medicines and disinfectants.**
- **The requirements of this standard are mandatory.**

2. Normative references

This standard references to the following standard: GOST R 15.013-94 system development and launch of new products. Medical products.

3. Definitions

For the purposes of this standard used by the following terms and definitions:

3.1. medical products (medical products and medical equipment): Instruments, apparatus, instruments, devices, kits, complexes, systems software, hardware, appliances, dressings and suture tools, dental materials, reagent kits, reference materials and standard samples, products of polymer, rubber and other materials which are used for medical purposes, alone or in combination with each other and are designed to:

- Prevention, diagnosis and treatment of diseases, rehabilitation, medical procedures, research, medical treatment, replacement or modification of parts of tissues, organs and the human body, restore or compensate for damaged or lost physiological functions, control of conception;
- The impact on the human body in such a way that their functionality can not be realized by means of chemical, pharmacological, immunological or metabolic interactions with the human body.

3.2. Accessories: The items themselves are not of MI and for the intended purpose used in conjunction with MI either in their composition to the MI could be used in accordance with the purpose.

3.3. MI brief application: MI, which in normal operation is designed for continuous use for not more than 60 minutes.

3.4. MI provisional application: MI, which when used in accordance with the instruction is intended for continuous use for up to 30 days.

3.5. MI long-term use: MI, which when used in accordance with the instruction is intended for continuous use for more than 30 days.

3.6. invasive MI: MI, which is completely or partially introduced into the body through its surface or through the anatomical cavity in the body, as well as through surgery, or in connection with it.

3.7. Noninvasive MI: MI, not intended for partial or full entry into the body through its surface and the anatomical cavity in the body or during surgery.

3.8. anatomical cavity: Natural cavity in the body, as well as the outer surface of the eyeball or permanent cavity created by surgery (ostomy).
3.9. surgically invasive MI: Invasive MI, which is injected into the tissues and organs of the patient through the surface of his body by surgery or in connection with it.

3.10. implantable MI: Invasive MI designed for partial or complete replacement of an organ or tissue and (or) for the partial or complete restoration of physiological functions.

3.11. active MI: MI, for an action which requires the use of energy, distinct from any person, or gravity.

3.12. active therapeutic MI: Active MI, which is intended to retain, modify, replace or restore biological functions or structures in connection with treatment or relief of illness, injury or disability.

3.13. active diagnostic MI: Active MI, which is intended to provide information for diagnosis, control or change the physiological state, state of disease or congenital defects.

3.14. Surgical Instruments: MI designed for surgery: the cutting, drilling, sawing, scratching, scraping, clamping, moving apart, cleaving or perforation, etc. Surgical instruments may be disposable and reusable. Disposable surgical instruments are used singly, reusable can be used following appropriate procedures.

3.15. central circulatory system (for this standard): A closed physiological system that includes the heart, departing from him and running into his blood vessels.

3.16. central nervous system: brain and spinal cord, including the meninges.

3.17. damage: Damage to the patient, personnel, equipment or the environment.

3.18. Hazards: Potential source of harm.

3.19. risk of MI: The probable frequency of occurrence of danger or probable increased the severity of the state from harm.

3.20. Safety MI: The set of normalized properties as provided for preventing harm in the application of MI.

3.21. Applicant: The person or entity that submits an application in the prescribed manner to the Russian Ministry of Health for registration of MI.

4. General Provisions

4.1. All MIs are divided depending on the degree of potential risk of their use for medical purposes into four classes. Classes are marked 1, 2a, 2b and 3. Degree of potential risk of MI increases in the order listed classes. Each of MI can be attributed (see Appendix B) only one class:

- Class 1 - MI, low-risk (some non-invasive electrodes, a number of surgical instruments, some medical equipment, etc etc);
- Class 2a - MI with an average risk (diagnostic ultrasound equipment, some bandages, some reagents blood, physiotherapy apparatus, etc.);
- Class 2b - MI at increased risk (for anesthesia machines, devices for administration of drugs, etc.);
- Class 3 - MI with a high degree of risk (implantable pacemakers, artificial heart valves, dialysis equipment, etc.).

A set of reagents can be classified in Class 2A, 2B or 3, depending on the potential risk of the results of their use.

4.2. In the classification of MI account for their functional purpose and conditions of use.

4.2.1. Criteria for classification of MI
In the classification of MI in this standard, consider the following:

- The duration of MI;

- Invasiveness MI;
- The presence of contact with the human body or the relationship with him;
- A method of introducing an MI in the body (through the anatomical cavity or surgically);
- Application for the vital organs (heart, central circulatory system, central nervous system);
- The use of energy sources.

4.3. The classification procedure

4.3.1. Class MI indicates the applicant when submitting an application to Ministry of Health, Russia and the documents for registration of MI (see GOST 15.013).

4.3.2. For newly developed MI class depending on the risk of their use indicate the project specifications (see GOST 15.013).

4.3.3. Class MI establishes the Ministry of Health of Russia on the results of examination of documents submitted by the applicant, taking into account procedures for medical application.

4.3.4. In case of disagreement with the results of examination, the applicant has the authority to defend their proposals and submit to the Ministry of Health Russia the necessary materials for further examination by the definition of the claimed MI.

4.3.5. The final decision on the establishment of an MI class takes MOH of Russia.

4.4. The applicant has the right to carry out procedures for reclassification of at least 2 years after the registration of MI or early, if it had reason. Reclassification procedure is similar to the classification procedure.

4.5. Classification of MI, registered by Ministry of Health of Russia until the introduction of this standard is carried out at their re-registration after the expiry of the relevant registration certificate, or earlier at the initiative of the applicant.

5. Rules for Classification of medical devices

5.1. Rules for classification of non-invasive medical devices.
5.1.1. Rule 1
Noninvasive MI is a Class 1, unless you use one of the following rules.

5.1.2. Rule 2
Noninvasive MI for the storage organs, parts of organs or storage or introduction into the patient blood and other fluids, gases, fumes or tissues, belong to the class 2A, including when used with an active MI class 2a, or a higher class.

5.1.3. Rule 3
Noninvasive MI for the biological or physico-chemical composition and properties of blood, other body fluids or liquids, which must be ingested, belong to 2b. However, if their action is only in the filtering process in a centrifuge or gas or heat transfer, the specified MI belong to the class 2a.

5.1.4. Rule 4
Noninvasive MI who come into contact with broken skin:

a) is a Class 1 if they are used as mechanical barriers or compression;
b) belong to the class 2b, when used for wounds that can heal only by means of secondary healing;

c) In all other cases refer to a class 2a, it also includes the MI, which are intended primarily to influence the microenvironment of wounds.

5.2. Rules for the classification of invasive medical devices.

5.2.1 Rule 5

5.2.1.1. Invasive MI, except for invasive surgery, the use of which is associated with cavities in the body and are not intended for connection to an active MI, belongs to the class:

a) 1, if it is short of MI;
b) 2a, if the provisional application of MI. If these MIs temporarily employed in the oral cavity to the pharynx, in the ear canal to the tympanic membrane or in the nose, then they are assigned to Class 1;
a) 2b, if prolonged use of MI. If these long-term use of MI in the mouth to the pharynx, in the ear canal to the tympanic membrane or in the nasal cavity and they can not be resorbable mucosa, they belong to the class 2a.

5.2.1.2. All invasive MI, except for invasive surgery, the use of which is associated with cavities in the body and are designed to attach to an active MI class 2a or higher class, belongs to the class 2a.

5.2.2. Rule 6

Surgically invasive MI brief application refers to a class 2a, however, if they:

a) are intended to diagnose, monitor, control or correction of abnormalities of the heart, the central circulatory system or central nervous system in direct contact with organs or parts of these systems, then they are assigned to Class 3;
b) are disposable surgical instruments, then they are assigned to Class 1;
a) are intended for transmission of energy in the form of ionizing radiation, they belong to the class 2b;
c) intended to cause a biological effect, dissolve completely or largely, they belong to the class 2b;
d) intended to administer medicines through dispensing system that uses a potentially dangerous method of introduction, then they are assigned to class 2b.

5.2.3. Rule 7

Surgically invasive MI provisional application belongs to the class 2a, however, if they:

a) are intended to diagnose, monitor, control or correction of abnormalities of the heart or central circulatory system in direct contact with organs or parts of these systems, then they are assigned to Class 3;
b) direct contact with the central nervous system, then they are assigned to Class 3;
a) are intended for transmission of energy in the form of ionizing radiation, they belong to the class 2b;
c) intended to cause a biological effect, dissolve completely or in large part, they belong to a class 3;
d) undergo chemical changes in the body or administered drugs, they belong to the class 2b, except implanted into the teeth of MI.

5.2.4. Rule 8

Implantable MI, as well as surgically invasive MI long-term use, refer to the class 2b, however, if they:

a) are intended for implantation in the teeth, then they are assigned to Class 2A;
b) direct contact with the heart of the central circulatory system or central nervous system, then they are assigned to Class 3;
a) are intended to cause a biological effect, or dissolve completely or largely, they belong to a class 3;
g) undergo chemical changes in the body or injected into the patient drugs, then they are assigned to Class 3 (except implanted in the teeth of MI).

5.3. Additional rules for active medical devices.

5.3.1. Rule 9

a) active therapeutic MI, which are designed for energy transfer or energy transfer, referred to as class 2a.However, if the energy transfer to the human body or an exchange of energy with it is potentially dangerous because of the characteristic features of MI in the light effects on body parts, attached to a power (including - active MI, intended to generate ionizing radiation, radiation therapy), their belong to the class 2b.
b) All active MI, designed to manage active therapeutic MI Class 2b belongs to the class 2b.

5.3.2. Rule 10

Active diagnostic of MI belong to the class 2a if they are intended for:

a) the transfer of energy absorbed by man, but if the function of MI is to highlight the patient's body in the visible range, then they are assigned to Class 1;
b) providing the distribution radiofarmakologicheskih assets put into the patient;
c) providing direct diagnostic or monitoring vital body functions, but if they are intended for monitoring of vital physiological parameters, which change could lead to an immediate danger to the patient, such as changing the function of the heart, respiratory or central nervous system activity, then they are referred Class 2b.
d) All active MI, designed to manage active diagnostic MI Class 2b belongs to the class 2b.

5.3.3. Rule 11

Active MI, intended for introduction into the patient medicines, body fluids or other substances and (or) their removal from the body, belongs to the class 2a. However, if the method of administration (elimination) is a potential risk for the type of substances, part of the body and methods of application, they are assigned to class 2b.

5.3.4. Rule 12

All other active MI is a Class 1.

5.4. Special rules.

5.4.1. Rule 13

All MI, in integral parts of which includes a substance which is able to represent a drug or other biologically active substance and the impact on the human body in addition to the effects of MI are classified in Class 3.

5.4.2. Rule 14

All MIs for controlling conception, or for protection against diseases, sexually transmitted infections, belong to the class 2b, but if they are implantable or invasive MI prolonged use, they belong to the class 3.

5.4.3. Rule 15

5.4.3.1. All MI, intended for the decontamination of MI is classified as 2a, but if they are used for cleaning, washing, disinfection of contact lenses, they belong to the class 2b.

5.4.4. Rule 16

Inactive MI used for diagnostic x-rays, belong to class 2a.

5.4.5. Rule 17

All of the MI, which were manufactured using animal tissue necrosis, or derivative products, referred to as Class 3, but if they are intended to come into contact only with intact skin, then they are assigned to Class 1.

5.4.6. Rule 18
Containers for blood, blood products and blood substitutes belong to the class 2b.
5.5. If MI is intended for use in combination with other MIs, the classification rules apply separately to each of the MI.

5.6. For a software tool that is a separate product and is used with MI, set the same class that also for the MI.

5.7. If taking into account the information submitted by the applicant to that of MI can apply multiple rules, the rules, which resulted in a class set of MI corresponding to the greatest degree of potential risk.

6. Methods of classification rules

6.1. In the classification of MI in this standard evaluate the applicability of all rules.

6.2. Class MI determined in accordance with sections 3-5. Applicability of each classification rules set by the response to a question, allowing a decision on referring the MI to the appropriate class under this rule. If the rule applies, then the record marked a possible class of MI and go to the specified next to the symbol class item. If several rules apply, then as a class MI set the highest grade. Possible algorithm for classification is presented in Appendix A. In the "Output Table A.1 indicates the class of MI on the above rule, and click the table to which to go forward.
Approximate classification of MI received the results of applying the algorithm, is presented in Appendix B.

- ALGORITHM FOR CLASSIFICATION AND TENTATIVE CLASSIFICATION OF CP TO RISK OF (RTF 124.817 kb)
  [Table omitted. Available from original source. Appears to be a decision chart for classification.]