

## On approval of the Rules for classification of medical devices depending on the degree of potential risk of use

### *Unofficial translation*

Order of the Minister of Healthcare of the Republic of Kazakhstan dated December 15, 2020 No. ҚР ДСМ-281/2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on December 20, 2020 No. 21808

#### Unofficial translation

In accordance with clause 2) of article 258 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On Public Health and Healthcare System" **I HEREBY ORDER:**

1. To approve the attached Rules for classification of medical devices depending on the degree of potential risk of use.

2. To recognize as invalid:

1) order of the Minister of Healthcare of the Republic of Kazakhstan dated November 24, 2009 No. 764 "On approval of the Rules for classification of medical devices depending on the degree of potential risk of use" (registered with the Ministry of Justice of the Republic of Kazakhstan dated November 26, 2009 No. 5936);

2) order of the Minister of Healthcare of the Republic of Kazakhstan dated September 30, 2019 No. ҚР ДСМ-129 "On amendments to the order of the Minister of Healthcare of the Republic of Kazakhstan dated November 24, 2009 No. 764 "On approval of the Rules for classification of medical devices and medical equipment" (registered with the Ministry of Justice of the Republic of Kazakhstan on October 1, 2019 No. 19422).

3. The Medical and Pharmaceutical Control Committee of the Ministry of Healthcare of the Republic of Kazakhstan in accordance with the procedure, established by the legislation of the Republic of Kazakhstan, shall ensure:

1) state registration of this order with the Ministry of Justice of the Republic of Kazakhstan;

2) placement of this order on the Internet resource of the Ministry of Healthcare of the Republic of Kazakhstan after its official publication;

3) within ten working days after the state registration of this order with the Ministry of Justice of the Republic of Kazakhstan submission to the Legal Department of the Ministry of Healthcare of the Republic of Kazakhstan of information about implementation of measures stipulated by subclauses 1) and 2) of this clause.

4. Control over execution of this order shall be entrusted to the supervising Vice-Minister of Healthcare of the Republic of Kazakhstan.

5. This order shall come into force upon expiry of ten calendar days after the date of its first official publication.

*Minister of Healthcare  
of the Republic of Kazakhstan*

*A. Tsoy*

Appendix  
to the order of the  
Minister of Healthcare of the  
Republic of Kazakhstan  
dated December 15, 2020  
No. ҚР ДСМ-281/2020

## **Rules for classification of medical devices depending on the degree of potential risk of use**

### **Chapter 1. General Provisions**

1. These rules for classification of medical devices depending on the degree of potential risk of use (hereinafter referred to as the Rules) have been developed in accordance with clause 2) of article 258 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On Public Health and Healthcare System" (hereinafter referred to as the Code) and shall determine the procedure for classification of medical devices depending on the degree of potential risk of use.

2. These rules shall apply to medical devices manufactured and imported into the territory of the Republic of Kazakhstan.

3. The following basic concepts are used in these Rules:

1) analyte – a sample component with a measurable quality;  
2) apheresis – method of obtaining individual blood components, subdivided into plasmapheresis and cytophoresis;

3) active diagnostic medical devices – active medical devices, intended for provision of information for the purposes of diagnostics, control of treatment or change in the physiological state, disease state or birth defects;

4) active therapeutic medical devices – active medical devices, intended for preservation, change, replacement or restoration of biological functions or structures, associated with treatment, relief from disease, injury, or disability;

5) active medical devices – medical devices, used separately or in combination with other medical devices, for which it is necessary to use energy, different from the one produced by human or gravity. Medical devices, intended for the transfer of energy or substances from an active medical device to a patient without their significant modification shall not be medical devices. Standalone software is considered as an active medical device;

6) a state expert organization in the field of circulation of pharmaceuticals and medical devices (hereinafter referred to as the Expert Organization) – state monopoly entity carrying out production and economic activities in the field of public health to ensure the safety, efficiency and quality of pharmaceuticals and medical devices;

- 7) a body hole – body opening - any natural orifice in the human body, as well as the outer surface of the eyeball or any permanent artificial hole (cavity);
- 8) harm – injury or damage to human health, equipment or the environment;
- 9) implanted medical devices – invasive medical devices, including partially or completely absorbable in the body, completely inserted into the human body or replacing the epithelial surface or the surface of the eye through surgery and remaining at the injection site after a surgical procedure, as well as medical devices partially inserted into the human body through surgery interventions and remaining at the injection site after a surgical procedure for more than 30 days;
- 10) invasive medical devices – medical devices, intended for full or partial introduction into the human body through its surface or through a body hole;
- 11) non-invasive medical devices - medical devices that are not intended for full or partial introduction into the human body through its surface or through a body hole;
- 12) potential risk of use - a combination of the probability of harm when using medical devices in accordance with the intended purpose specified by the manufacturer, and the severity of this harm;
- 13) medical devices for short-term use - medical devices intended for continuous use for no more than 60 minutes in accordance with the instructions for use or operating instructions;
- 14) medical device safety – absence of unacceptable risk when using a medical device associated with causing harm to life, human health, as well as the environment;
- 15) assessor to medical devices – an item which is not a medical device, intended by the manufacturer for combined use with one or more medical devices for use in accordance with their intended purpose;
- 16) medical device purpose – a documented decision of the manufacturer regarding the intended use of a medical device based on its properties as contained in the technical characteristics, instructions for use or instruction manual;
- 17) manufacturer of a medical device – an entity in the field of circulation of medicines and medical devices, responsible for the development and manufacture of a medical device, making it available for use on its own behalf, regardless of whether it is developed and (or) manufactured by this person or on his behalf by another person (persons), and carrying responsibility for its safety, quality and effectiveness;
- 18) nanomaterial – a material that contains particles in an unbound state, or particles in the form of aggregates or agglomerates, and in which at least 50 percent of the particles have sizes in the range of 1 ... 100 nm. In this case, aggregates are understood as particles consisting of fused or strongly-coupled particles, and agglomerates are associations of weakly-coupled particles. Nanomaterials also include graphene particles or carbon nanotubes with one or more external dimensions less than 1 nm.;

19) an applicant – manufacturer (maker) or their representative authorized to submit an application, documents and materials for the examination of medical devices for registration, re-registration, amendments to registration dossiers;

20) medical devices for temporary use – medical devices designed for continuous use from 60 minutes to 30 days in accordance with the instructions for use or instructions for use;

21) medical devices for long-term use – medical devices intended for continuous use for more than 30 days in accordance with the instructions for use or operations manual;

22) surgical invasive medical devices – invasive medical devices, completely or partially inserted into the human body through its surface or through a body hole by or in connection with surgery.

23) medical devices for in vitro diagnostics – any instruments, apparatus, units, equipment, materials, reagents, calibrators, control materials and other devices used for medical purposes separately or in combination with each other, as well as together with accessories necessary for the use of these devices for their intended purpose, including special software, and intended by the manufacturer of a medical device for use in in-vitro studies of samples of biological materials of a person to obtain information on the physiological or pathological state, congenital pathology, predisposition to a certain clinical condition or disease, tissue compatibility with a potential recipient, predicting responses to therapeutic influences, the choice of therapeutic agents and / or control of treatment.

## **Chapter 2. Procedure for classification of medical devices depending on the degree of potential risk of use**

8. Medical devices, depending on the degree of potential risk of use, are divided into 4 classes.

Classes are designated as 1, 2a, 2b and 3.

Each medical device belongs to only one class.

The assignment of medical devices to classes shall be carried out proceeding on the following:

- 1) class 1 includes medical devices with a low potential risk of use;
- 2) class 2a includes medical devices with an average degree of potential risk of use;
- 3) class 2b includes medical devices with an increased potential risk of use;
- 4) class 3 includes medical devices with a high potential risk of use.

9. When classifying a medical device, its functional purpose and conditions of use are taken into account, as well as the following criteria:

- 1) duration of use of a medical device;
- 2) invasiveness of a medical device;
- 3) the presence of contact of the medical device with the human body or interconnection with it;

4) method of administration of a medical device into the human body (through a body hole or by surgery);

5) the use of a medical device for the vital organs and systems (heart, central circulatory system, central nervous system);

6) the use of energy sources.

10. Determination of the class of a medical device, depending on the degree of potential risk of use, shall be carried out by the applicant in accordance with the Method for determining the class of medical devices (except for medical devices for in vitro diagnostics), depending on the potential risk of use according to Appendix 1 to these Rules.

#### **Paragraph 1. Classification of non-invasive medical devices**

11. Non- invasive medical devices belong to class 1, if clauses 11-13 of these Rules do not apply to them, with the exception of subclause 1 of clause 13 of these Rules.

12. Non-invasive medical devices, intended for storage of organs, parts of organs or storage or introduction into the human body of blood, other liquids, gases, vapors or tissues, belong to class 2a, including in the case of their use in conjunction with active medical devices of class 2a or higher class.

13. Non-invasive medical devices, intended to change the biological or physicochemical composition and properties of blood, tissues, cells, other physiological fluids or fluids that must enter the body, belong to class 2b. In the event that their action consists only of filtration from particles, processing in a centrifuge, gas or heat exchange, the indicated medical devices belong to class 2a.

14. Non-invasive medical devices, that come into contact with damaged skin include:

1) to class 1 - if they are used as mechanical barriers, for compression or absorption of exudates;

2) to class 2b - if they are used for wounds that can only be healed through secondary healing;

3) to class 2a - in other cases (including in the case when medical devices are designed primarily for influencing on the microenvironment of wounds).

#### **Paragraph 2. Classification of invasive medical devices**

15. Invasive medical devices (excluding surgical invasive), the use of which is associated with body holes and which are not intended to be attached to an active medical device or are intended to be attached to an active medical device of class 1, include:

1) to class 1 - if they are medical devices for short-term use;

2) to class 2a – if they are medical devices for temporary use. In the event that these medical devices are temporarily used in the oral cavity to the pharynx, in the ear canal to the tympanic membrane or in the nasal cavity, they are classified as class 1;

3) to class 2b - if these are medical devices for long-term use. In the event that these medical devices are used for a long time in the oral cavity to the pharynx, in the ear canal to the tympanic membrane or in the nasal cavity and are not absorbed by the mucous membrane, they belong to class 2a.

Invasive medical devices (excluding surgical invasive), the use of which is associated with body openings and which are intended to be attached to an active medical device of class 2a or higher, are classified as class 2a.

16. Surgical invasive medical devices for short-term use are classified as class 2a, except for the following cases:

1) if specified medical devices are intended for the diagnosis, observation, control or correction of pathologies of the heart, the central circulatory system or the central nervous system in direct contact with organs or parts of these systems, they belong to class 3;

2) if specified medical devices are reusable surgical instruments, they belong to class 1;

3) if specified medical devices designed to transfer energy in the form of ionizing radiation, they belong to class 2b;

4) if specified medical devices are designed to cause a biological effect or dissolve completely or to a large extent, they belong to class 2b;

5) if specified medical devices intended for the administration of medicinal products by non-professional users, they belong to class 2b.

17. Surgical invasive medical devices for temporary use belong to class 2a, except for the following cases:

1) if specified medical devices are intended for the diagnosis, observation, control or correction of pathologies of the heart or the central circulatory system in direct contact with organs or parts of these systems, they belong to class 3;

2) if specified medical devices are in direct contact with the central nervous system, they belong to class 3;

3) if specified medical devices designed to transfer energy in the form of ionizing radiation, they belong to class 2b;

4) if specified medical devices are designed to cause a biological effect or dissolve completely or to a large extent, they belong to class 3;

5) if specified medical devices undergo chemical changes in the human body, they belong to class 2b (with the exception of medical devices intended for implantation into teeth or for the administration of drugs).

18. Implantable medical devices, as well as surgical invasive medical devices for long-term use belong to class 2b, except for the following cases:

1) if specified medical devices designed for implantation into teeth, they belong to class 2a;

2) if specified medical devices are in direct contact with the heart, central circulatory system or central nervous system, they belong to class 3;

- 3) if specified medical devices are designed to cause a biological effect or dissolve completely or to a large extent, they belong to class 3;
- 4) if specified medical devices undergo chemical changes in the human body, they belong to class 3 (with the exception of medical devices intended for implantation into teeth or for the administration of drugs);
- 5) if specified medical devices are active implantable medical devices, including implantable accessories to active implantable medical devices, they belong to class 3;
- 6) if specified medical devices are breast implants, they belong to class 3;
- 7) if specified medical devices are total or partial hip, knee or shoulder prostheses, they belong to class 3;
- 8) if specified medical devices are intervertebral disc prostheses or implantable medical devices that come into contact with the spine, they belong to class 3.

### **Paragraph 3. Specific features of classification of active medical devices**

19. Active medical devices are classified taking into account the following specific features:

- 1) active therapeutic medical devices, intended for the transfer of energy or energy exchange, belong to class 2a. In the event that the transfer of energy to the human body or the exchange of energy with it poses a potential hazard due to the characteristic features of medical devices, taking into account the nature, density and place of energy exposure to body parts, these medical devices belong to class 2b (including active medical devices designed to create ionizing radiation, radiation therapy);

- 2) active medical devices, intended to control active therapeutic medical devices of class 2b or manage them, belong to class 2b. In case if the active medical devices are intended to control implantable medical devices or manage them, the specified medical devices belong to class 3.

20. Active diagnostic medical devices belong to class 2a, if they are intended for:

- 1) transfer of energy absorbed by a person. If the function of a medical device is to illuminate the patient's body in the visible range of the spectrum, such a medical device belongs to class 1;

- 2) presentation of the distribution of radiopharmaceutical drugs administered into the human body;

- 3) providing direct diagnostics or monitoring of vital body functions. In the case if specified medical devices are intended to control vital physiological parameters, changes in which could lead to an immediate danger to the patient (for example, changes in heart function, respiration or activity of the central nervous system), they belong to class 2b.

21. Active medical devices, generating ionizing radiation and intended for radiological diagnostics and therapy, including medical devices for the control or management of such devices, belong to class 2b.

22. Active medical devices, intended for the administration into the human body of drugs, physiological fluids or other substances and (or) removing them from the body, belong to class 2a. In the event that the method of administration (excretion) poses a potential hazard, taking into account the type of the relevant substances, the part of the body and the method of application indicated by the medical devices belong to class 2b.

23. Active medical devices to which clauses 18 - 21 of these Rules do not apply, belong to class 1.

#### **Paragraph 4. Specific features of classification of certain medical devices**

24. Medical devices, containing substances that, when used alone, are considered medicines, as well as products derived from human blood or plasma, and which affect the human body in addition to the effects of a medical device, belong to class 3.

25. Medical devices, designed to control conception or to protect against sexually transmitted diseases, belong to class 2b. If specified medical devices are implantable or invasive medical devices for long-term use, they belong to class 3.

26. Medical devices intended for the disinfection of invasive medical devices, as well as for cleaning, rinsing, disinfecting, hydrating contact lenses, belong to class 2b. Other medical devices designed to disinfect or sterilize medical devices, belong to class 2a.

27. Medical devices, designed for registration of images obtained from X-ray, magnetic resonance, ultrasound and other diagnostic devices, belong to class 2a.

28. Medical devices, which were made using necrotic tissue or animal cells or their derivatives, belong to class 3. In the case if specified medical devices are intended to come in contact only with intact skin, they belong to class 1.

29. Bags (polymer containers) for blood belong to class 2b.

30. Medical devices, which include nanomaterial, belong to class 3. In the event that the nanomaterial is in an isolated or bound state, excluding its entry into the patient's or user's body, such a medical device belongs to class 1.

31. Medical devices, intended for apheresis, including kits, connectors and solutions, belong to class 3.

32. If a medical device is intended to be used in combination with another medical device, then these Rules shall apply separately to each medical device.

33. For software (means), which is an independent product and used with a medical device, the same class is set as for the specified medical device.

34. In case if taking into account the information provided by the manufacturer with respect to the medical device, several clauses of these Rules are applicable, the clause, according to which the class of the medical device is established corresponding to the highest degree of potential risk of use, shall apply.

#### **Chapter 3. Classification of medical devices for in vitro diagnostics (in vitro)**



**Paragraph 1. Classes of medical devices for in vitro diagnostics (in vitro) depending on the degree of potential risk of use**

35. Medical devices for in vitro diagnostics (in vitro), depending on the degree of potential risk of use, are divided into 4 classes.

The classes are denominated as 1, 2a, 2b and 3.

Each in vitro diagnostic (in vitro) medical device can be assigned to one class only.

The assignment of medical devices for in vitro diagnostics (in vitro) to classes is based on the following:

- 1) medical devices for in vitro diagnostics (in vitro) with a low potential risk of use to an individual and a low level of potential risk of use to public health belong to class 1;
- 2) medical devices for in vitro diagnostics (in vitro) with a medium potential risk of use to an individual and a low level of potential risk of use to public health belong to class 2a;
- 3) class 2b – medical devices for in vitro diagnostics (in vitro) with a high degree of potential risk of use for an individual and / or an average degree of potential risk of use for public health;
- 4) class 3 – medical devices for in vitro diagnostics (in vitro) with a high potential risk of use for an individual and a high level of potential risk of use for public health.

36. Determination of the class of a medical device for in vitro diagnostics (in vitro), depending on the degree of potential risk of use, shall be carried out by the applicant in accordance with the Method for determining the class of medical devices for in vitro diagnostics, depending on the potential risk of use according to Appendix 2 to these Rules.

**Paragraph 2. Specific features of classification of medical devices for in vitro diagnostics (in vitro) depending on the degree of potential risk of use**

37. In the event that, taking into account the information provided by the manufacturer in relation to a medical device for in vitro diagnostics (in vitro), several clauses of these Rules apply, the clause, according to which the class of a medical device for in vitro diagnostics (in vitro) corresponding to the highest degree of potential risk of use, shall apply.

38. Calibration and control materials with quantitative and qualitative predetermined values belong to the same class as the medical devices for which they are intended to be controlled.

39. If the software is used as an independent medical device, it shall be classified as follows:

- 1) if the software controls or affects the performance of a medical device for in vitro diagnostics, it shall be classified in the same class as this medical device for in vitro diagnostics);
- 2) if the software is not associated with a medical device for in vitro diagnostics (in vitro), it shall be classified in accordance with paragraph 3 of this chapter.

### **Paragraph 3. Classification of medical devices for in vitro diagnostics (in vitro)**

40. Medical devices for in vitro diagnostics (in vitro), designed to detect infectious agents in blood, blood components, blood derivatives, cells, tissues or organs in order to assess the possibility of their transfusion or transplantation, as well as medical devices for in vitro diagnostics (in vitro), intended to identify infectious agents that cause life-threatening diseases with a high risk of spread, belong to class 3.

41. Medical devices for in vitro diagnostics (in vitro), which are used to determine blood groups or tissue types in order to guarantee the immunological compatibility of blood, blood components, cells, tissues or organs intended for transfusion or transplantation, belong to class 2b, with the exception of the AB0 system (A (AB01), B (AB02) , AB (AB03)), Rh systems (Rh1 (D), Rh2 (C), Rh3 (E), Rh4 (c), Rh5 (e)), Kell systems (Kell (K)), Kidd systems (JK1 (Jka), JK2 (Jkb)) and Duffy systems (FY1 (Fya), FY2 (Fyb)), which belong to class 3.

42. Medical devices for in vitro diagnostics (in vitro) belong to class 2b, if they are intended for:

- 1) identification of infectious agents of sexually transmitted diseases;
- 2) detection in cerebrospinal fluid or blood of infectious agents with a moderate risk of spread;
- 3) detecting the presence of infectious agents when there is a risk that an erroneous result is the cause of death or disability of the examined patient or fetus;
- 4) screening for pregnant women to determine their immune status against infections;
- 5) determining the status of an infectious disease or immune status where there is a risk that an erroneous result will lead to a therapeutic decision causing an imminent danger to the patient's life;
- 6) selective therapy, staging, screening or diagnostics of cancer;
- 7) genetic testing;
- 8) control of the levels of drugs, substances or biological components when there is a risk that an incorrect result will lead to a therapeutic decision causing a life-threatening situation for the patient;
- 9) therapy for patients suffering from a life-threatening infectious disease;
- 10) screening for congenital fetal diseases.

43. Medical devices for in vitro diagnostics (in vitro), designed for self-testing, belong to class 2b. If the test result obtained using the specified medical devices for in vitro diagnostics (in vitro) does not have a critical medical status or is preliminary and requires subsequent comparison with the corresponding laboratory tests, such medical devices belong to class 2a.

44. Medical devices for in vitro diagnostics (in vitro), which do not have a measuring function, by their objective properties are used as general laboratory ones, while they have special characteristics, in accordance with which they are intended by the manufacturer for

use in in vitro diagnostic procedures (in vitro) (without specifying specific types of laboratory tests (analytes)), and also containers for bioassay samples belong to class 1.

45. Medical devices for in vitro diagnostics (in vitro), to which clauses 38 - 42 of these Rules do not apply, including analytical instruments (analyzers) with a measuring function with an unfixed list of laboratory tests performed, which depends on the used reagent kits (test systems), belong to class 2a. The interdependence of the device and the reagents used does not allow the device to be evaluated separately, but this does not affect its assignment to class 2a.

Appendix 1  
to the Rules for classification of  
medical devices depending on the  
degree of potential risk of use

**Method for determining the class of medical devices (except for medical devices for in vitro diagnostics) depending on the potential risk of use**

Item No.	Question	Answer	Conclusion	
			class of a medical device	transition to the item
1	Is the medical device invasive?	yes no	— —	9 2
2	Is the medical device intended for storing organs, parts of organs, or storing or introducing blood, other liquids, gases, vapors or tissues into the human body?	yes no	— —	3 4
3	Is the medical device used in conjunction with a Class 2a or higher active medical device?	yes no	2 a 2a	3 2 32
4	Is the medical device intended to change the biological or physicochemical composition and properties of blood, tissues, cells, other physiological fluids or fluids that must enter the body?	yes no	— —	5 6
5	Does the medical device operate only in particle filtration, centrifugal processing, gas or heat exchange?	yes no	2 a 2b	3 2 32
6	Is the medical device in contact with damaged skin?	yes no	— 1	7 32
7	Is the medical device used as a mechanical barrier, for compression, or for the absorption of exudates?	yes no	1 —	3 2 8
8	Is the medical device used primarily for wounds that can only be healed through secondary healing (including medical devices that are primarily designed to target the microenvironment of wounds)?	yes no	2 b 2a	3 2 32
9	Is an invasive medical device surgical?	yes no	— —	1 5 10
10	Is the invasive medical device intended to be attached to a Class 2a or higher active medical device?	yes no	2 a —	3 2 11
11	Is the invasive medical device intended for short-term use?	yes no	1 —	3 2 12

12	Is the invasive medical device intended for temporary use?	yes no	— —	1 3 14
13	Is the medical device used in the oral cavity to the pharynx, in the ear canal to the eardrum, or in the nasal cavity?	yes no	1 2a	3 2 32
14	Is the medical device applied in the oral cavity to the pharynx, in the ear canal to the eardrum, or in the nasal cavity, and can the medical device be absorbed by the mucous membrane?	yes no	2 a 2b	3 2 32
15	Is the surgical invasive medical device intended for short-term use?	yes no	— —	1 6 21
16	Is a medical device intended to diagnose, monitor, control, or correct pathologies of the heart, central circulatory system, or central nervous system in direct contact with organs or parts of these systems?	yes no	3 —	3 2 17
17	Is a surgical invasive medical device a reusable surgical instrument?	yes no	1 —	3 2 18
18	Is a surgical invasive medical device designed to transmit energy in the form of ionizing radiation?	yes no	2 b —	3 2 19
19	Is the surgical invasive medical device intended to produce a biological effect or be completely or substantially absorbed?	yes no	2 b —	3 2 20
20	Is the surgical invasive medical device intended for non-professional drug administration?	yes no	2 b —	3 2 32
21	Is the surgical invasive medical device intended for temporary use?	yes no	— —	2 2 28
22	Is a surgical invasive medical device for temporary use intended for the diagnostics, observation, control or correction of pathologies of the heart or the central circulatory system in direct contact with organs and parts of these systems?	yes no	3 —	3 2 23
23	Does the surgical invasive medical device for temporary use come into contact with the central nervous system?	yes no	3 —	3 2 24
24	Is a surgical invasive medical device for temporary use intended to transfer energy in the form of ionizing radiation?	yes no	2 b —	3 2 25
25	Is a surgical invasive medical device for temporary use intended to produce a biological effect or be completely or significantly absorbed?	yes no	3 —	3 2 26
26	Does a surgical invasive medical device for temporary use undergo chemical changes in the human body (with the exception of medical devices implanted in teeth or intended for the administration of drugs)?	yes no	2 b 2a	2 7 32
27	Is a surgical invasive medical device for temporary use implanted in the teeth?	yes no	2 a 2b	3 2 32
28	Is the implantable medical device or surgical invasive medical device for long-term use intended for implantation in the teeth?	yes no	2 a —	3 2 29
29	Does the implantable medical device or surgical invasive medical device for long-term use directly contact the heart, central circulatory system, or central nervous system?	yes no	3 —	3 2 30
30	Is an implantable medical device or surgical invasive medical device intended for long-term use in order to induce a biological effect or be completely or substantially absorbed?	yes no	3 —	3 2 31
31	Does an implantable medical device or surgical invasive medical device for long-term use undergo chemical changes in the human body (with the exception			

	of medical devices implanted in teeth or intended for the administration of drugs)?	yes no	3 2b	3 2 32
32	Is the medical device active?	yes no	— —	3 3 46
33	Is an active medical device therapeutic?	yes no	— —	3 4 37
34	Is an active therapeutic medical device intended to transfer energy to the human body or exchange energy?	yes no	— —	3 5 36
35	Does the transfer of energy to the human body or the exchange of energy with it pose a potential hazard due to the characteristic features of an active therapeutic medical device, taking into account the nature, density and place of energy impact on body parts (including active medical devices designed to create ionizing radiation, radiation therapy)?	yes no	2 b —	4 4 36
36	Is an active medical device intended to control or manage a class 2b active therapeutic medical device?	yes no	2 b 2a	4 4 44
	Is the active medical device intended to monitor or control active implantable medical devices?	yes no	3 2b	e n d 44
37	Is an active medical device diagnostic?	yes no	— —	3 8 44
38	Is an active diagnostic medical device designed to transfer energy absorbed by a person?	yes no	— —	3 9 40
39	Is an active diagnostic medical device intended to illuminate the patient's body in the visible range of the spectrum?	yes no	1 2a	4 4 44
40	Is an active diagnostic medical device intended to represent the distribution of radiopharmaceutical drugs administered to a patient?	yes no	2 a —	4 4 41
41	Is an active diagnostic medical device intended to provide direct diagnosis or control of vital body functions?	yes no	— —	4 2 43
42	Is an active diagnostic medical device specifically designed to monitor vital physiological parameters, changes in which could lead to immediate danger to the patient (for example, changes in heart function, respiration, or central nervous system activity)?	yes no	2 b 2a	4 4 44
43	Is an active medical device that generates ionizing radiation intended for radiological diagnosis and therapy (including medical devices for monitoring or controlling such devices)?	yes no	2 b —	4 4 44
44	Is an active medical device intended for administration of drugs, physiological fluids or other substances into the patient's body and / or excretion them from the body?	yes no	— 1	4 5 46
45	Does the method of administration (excretion) (see item 44) represent a potential hazard, taking into account the type of substances involved, the part of the body and the method of administration?	yes no	2 b 2a	4 6 46
46	Does the medical device contain a substance that, if used alone, can be considered a drug, as well as a product derived from human blood or plasma, and which affects the human body in addition to the effects of the medical device?	yes no	3 —	4 7 47
47	Is the medical device used to control conception or to protect against sexually transmitted diseases?	yes no	— —	4 8 49
48	Is a conception control or sexually transmitted disease medical device an implantable or invasive medical device for long-term use?	yes no	3 2b	4 9 49

49	Is the medical device intended to disinfect or sterilize medical devices?	yes no	– –	5 0 51
50	Is the medical device intended to decontaminate invasive medical devices or to disinfect, clean, rinse, or hydrate contact lenses?	yes no	2 b 2a	5 1 51
51	Is a medical device used to record images from X-ray, magnetic resonance, ultrasound, and other diagnostic equipment?	yes no	2 a –	5 2 52
52	Is the medical device manufactured using dead tissue or animal cells or their derivatives?	yes no	– –	5 3 54
53	Is a medical device made using necrotic tissue or animal cells or their derivatives intended to come into contact only with intact skin?	yes no	1 3	5 4 54
54	Is a medical device a blood bag (polymer container)?	yes no	2 b –	e n d 55
55	Does a medical device contain nanomaterial?	yes no	– –	5 6 57
56	Is the nanomaterial that is part of a medical device in an isolated or bound state that prevents it from entering the patient's or user's body?	yes no	1 3	e n d end
57	Is the medical device intended for apheresis?	yes no	3 1	e n d end

Appendix 2  
to the Rules for classification of  
medical devices depending on the  
degree of potential risk of use

### **Method for determining the class of medical devices for in vitro diagnostics depending on the potential risk of use**

Item No.	Question	Answer	Conclusion	
			class of a medical device	transition to the item
1	Is the medical device for in vitro diagnostics intended for a fixed list of laboratory tests to be performed?	yes no	– –	2 3
2	Is the medical device for in vitro in vitro diagnostics intended to assess the possibility of blood transfusion or transplantation, to identify infectious agents that can cause life-threatening diseases with a high risk of spread?	yes no	3 –	e n d 5
3	Can the medical device for in vitro in vitro diagnostics be used as a general laboratory?	yes no	– 2a	4 end
4	Does the medical device for in vitro in vitro diagnostics have a measuring function?	yes no	2 a 1	e n d end
5	Is the medical device for in vitro in vitro diagnostics designed to identify infectious agents that can cause life-threatening diseases with a limited risk of spread, or to self-test?	yes no	2 b 2a	e n d end

