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**EURASIAN ECONOMIC COMMISSION
BOARD**

DECISION

December 22, 2015

No. 173

city of Moscow

**On Approval of Rules for Classification of Medical Products
Depending on the Potential Risk of Their Use**

In accordance with paragraph 2 of Article 31 of the Treaty on the Eurasian Economic Union dated May 29, 2014, paragraph 4 of Article 4 of the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Medical Equipment) within the Eurasian Economic Union dated December 23, 2014, paragraph 23 of Annex No. 2 to the Rules of Procedure of the Eurasian Economic Commission approved by Decision No. 98 of the Supreme Eurasian Economic Council dated December 23, 2014, and in order to implement Decision No. 109 of the Supreme Eurasian Economic Council dated December 23, 2014 “On Implementation of the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Medical Equipment) within the Eurasian Economic Union”, the Board of the Eurasian Economic Commission **decided:**

1. To approve the attached Rules for Classification of Medical Products Depending on the Potential Risk of Their Use.

2. This Decision shall enter into force after 30 calendar days have elapsed from the effective date of the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Medical Equipment) within the Eurasian Economic Union dated December 23, 2014 or of the Protocol signed on December 2, 2015 on the accession of the Republic of Armenia to the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Medical Equipment) within the Eurasian Economic Union dated December 23, 2014, whichever comes later, but not earlier than after 30 calendar days have elapsed from the date of the official publication of this Decision.

Chairman of the Board
of the Eurasian Economic Commission

V. Khristenko

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APPROVED
by Decision No. 173 of the Board of
the Eurasian Economic Commission
dated December 22, 2015

RULES
for classification of medical products
depending on the potential risk of their use

I. General provisions

1. These Rules are developed in order to implement the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Medical Equipment) within the Eurasian Economic Union dated December 23, 2014 and establish a procedure for classification of medical products depending on potential risk of infliction of harm to health and life of patients, personnel, operating the medical product and other persons.

2. These Rules are applied to medical products released into circulation within the Eurasian Economic Union.

3. For the purposes of these Rules the concepts are used having the following meanings:

“active diagnostic medical products” – active medical products, designed for provision of information for the purposes of diagnostics, control of treatment of physiological state change, disease condition and congenital defects;

“active medical products” - medical products used separately or in combination with other medical products for the action of which the use of energy other than that produced by man or gravity is necessary.

Medical products intended for the transfer of energy or substances from an active medical product to a patient without their substantial change are not active medical products. Self-contained software is considered an active medical product;

“active therapeutic medical products” - active medical products intended to preserve, modify, replace or restore biological functions or structures associated with treatment, disease relief, injury or disability;

“analyte” - a component of a specimen with a measurable property;

“apheresis” - a method of obtainment of individual blood components, divided into plasmapheresis and cytophoresis;

“harm” - injury or damage to human health, equipment or the environment;

“implantable medical products” - invasive medical products, including those partially or completely degradable in the body, fully introduced into the human body or replacing the epithelial surface or ocular surface through surgical intervention and remaining at the site of administration after a surgical procedure, as well as medical products, partially introduced into the human body through surgical intervention and remaining at the site of administration after the surgical procedure for more than 30 days;

“invasive medical products” - medical products intended for full or partial introduction into the human body through its surface or through the body orifice;

“medical products for temporary use” - medical products intended for continuous use from 60 minutes to 30 days in accordance with the instruction for use or operation manual;

“medical products for in vitro diagnostics” - any instruments, apparatus, devices, equipment, materials, reagents, calibrators, control materials and other products used for medical purposes separately or in combination with each other, as well as with accessories necessary for use of the specified products (including special software) and designed by the manufacturer for use in in vitro studies of human biological material samples to obtain information on physiological or pathological state, congenital pathology, predisposition to certain clinical condition or disease,

compatibility of tissues with a potential recipient, prediction of responses to therapeutic effects, selection of therapeutic agents and (or) treatment control;

“medical products for long-term use” - medical products intended for continuous use for more than 30 days in accordance with the instruction for use or the operation manual;

“medical products for short-term use” - medical products intended for continuous use for not more than 60 minutes in accordance with the instruction for use or operation manual;

“medical product designation” - a documented manufacturer’s decision regarding the intended use of the medical product based on its properties, as reflected in the technical specifications, instructions for use or operation manual;

“nanomaterial” - a material that contains particles that are in an unbound state, or particles in the form of aggregates or agglomerates, and in which at least 50 percent of the particles have dimensions in range of 1 ... 100 nm. In this case, aggregates are understood to be particles consisting of fused or tightly bound particles, under agglomerates - a combination of loosely bound particles. Nanomaterials also include graphene particles or carbon nanotubes with one or more external dimensions of less than 1 nm;

“non-invasive medical products” - medical products not intended for full or partial introduction into the human body through its surface or through the body orifice;

“body orifice” - any natural opening in the human body, as well as the outer surface of the eyeball or any permanent artificial opening (cavity);

“potential risk of use” - a combination of possibility of harm when using medical products in accordance with the designation determined by the manufacturer and the severity of this harm;

“accessories” - items that are not medical products and according to the intended purpose used in combination with medical products or in their composition so that the medical product can be used in accordance with the designation;

“manufacturer” – a juridical or natural person registered as an individual entrepreneur responsible for the development and manufacture of the medical product and ensuring its availability for use on its own behalf, regardless of whether the medical product has been designed and (or) manufactured by that person or on his behalf by another person (persons);

“surgical invasive medical products” - invasive medical products that are introduced into the human body in whole or in part through its surface or through the body orifice by surgical intervention or in connection with it.

II. Classification of medical products, except for medical products for in vitro diagnostics

1. Classes of medical products depending on the degree of the potential risk of use

4. Medical products depending on the degree of the potential risk of use are divided into 4 classes.

Classes have designations 1, 2a, 2b and 3.

Each medical product can be assigned only to one class.

Medical products are assigned to classes based on the following:

class 1 includes medical products with a low degree of the potential risk of use;

class 2a includes medical products with a medium degree of the potential risk of use;

class 2b includes medical products with an increased degree of the potential risk of use;

class 3 includes medical products with a high degree of the potential risk of use.

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

a) duration of medical product use;

b) medical product invasiveness;

c) contact of the medical product with a human body or interrelation with it;

- d) route of introduction of the medical product into the human body (through the body orifice or surgically);
- e) use of the medical product for vital organs or systems (heart, central blood circulatory system, central nervous system);
- f) use of energy sources.

2. Classification of non-invasive medical products

6. Non-invasive medical products belong to class 1, if paragraphs 7-9 of these Rules are not applied to them, except for subparagraph “a” of paragraph 9 of these Rules.

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

8. Non-invasive medical products designed to modify a biological or physical and chemical composition and properties of blood, tissues, cells, other body fluids or liquids that should enter the body belong to class 2b. However, if their effect is only a filtration from particles, centrifuge treatment, gas or heat exchange, the mentioned medical products belong to class 2a.

9. Non-invasive medical products which are in contact with the damaged skin belong:

- a) to class 1 if they are used as mechanical barriers for compression or absorption of exudates;
- b) to class 2b if they are used for wounds, that can be cured only by secondary adhesion;
- c) to class 2a – in other cases (in particular if the medical product is designed primary for effect on wound microenvironment).

3. Classification of invasive medical products

10. Invasive medical products (except for surgical invasive ones), the use of which relates to the body orifices and which are not designed for connection to the active medical product of class 1, belong:

- a) to class 1 if these are medical products for short-term use;
- b) to class 2a if these are medical products for temporary use. However if the specified medical products are temporary used in the mouth cavity to the pharynx, in acoustic meatus to the eardrum or in the nasal cavity they belong to class 1;
- c) to class 2b if these are medical products for long-term use. However if these medical products are used in the mouth cavity to the pharynx, in acoustic meatus to the eardrum or in the nasal cavity for a long time and cannot be absorbed by the mucous membrane they belong to class 2a.

Invasive medical products (except for surgical invasive ones), the use of which relates to the body orifices and which are designed to connection with the active medical products of class 2a or higher class belong to class 2a.

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

- a) if the specified medical products are designed to diagnostics, supervision, control and correction of pathologies of the heart, central blood circulatory system or central nervous system in direct contact with organs or part of these systems, they belong to class 3;
- b) if the specified medical products are reusable surgical instruments, they belong to class 1;
- c) if the specified medical products are designed to transfer energy in the form of ionization radiation they belong to class 2b;
- d) if the specified medical products are designed to cause biological effect or reabsorb in full or in large part, they belong to class 2b;

e) if the specified medical products are designed for introduction of drug products by amateur users they belong to class 2b.

12. Surgical invasive medical products for temporary use belong to class 2a except for the following cases:

a) if the specified medical products for diagnostics, supervision, control and correction of pathologies of the heart or central blood circulatory system in direct contact with organs and parts of these systems they belong to class 3;

b) if the specified medical products come into direct contact with the central nervous system, they belong to class 3;

c) if the specified medical products are designed to transfer energy in the form of ionization radiation they belong to class 2b;

d) if the specified medical products are designed to cause biological effects or reabsorb in full or in large part they belong to class 3;

e) if the specified medical products undergo chemical changes in the human body they belong to class 2b (except for medical products designed for implantation between teeth or administration of drug products).

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

a) if the specified medical products are designed for implantation between teeth they belong to class 2a;

b) if the specified medical products come into direct contact with the heart, central blood circulatory system or central nervous system, they belong to class 3;

c) if the specified medical products are designed to cause biological effect or reabsorb in full or in large part they belong to class 3;

d) if the specified medical products undergo chemical changes in the human body they belong to class 3 (except for medical products designed for implantation between teeth or administration of drug products));

e) if the specified medical products are active implantable medical products including implantable accessories to active implantable medical products, they belong to class 3;

f) if the specified medical products are breast implants they belong to class 3;

g) if the specified medical products are to total or partial prostheses of pelvis, knee or shoulder joints they belong to class 3;

h) if the specified medical products are intervertebral disc prostheses or implantable medical products coming into contact with the spinal column they belong to class 3.

4. Peculiarities of classification of active medical products

14. Active medical products are classified taking into account the following properties:

a) active therapeutic medical products designed for energy transfer or energy exchange belong to class 2a. However, if the energy transfer to the human body or energy exchange with it is a potential hazard due to the characteristic features of medical products, taking into account the nature, density and place of impact of energy on parts of the body, the specified medical products belong to class 2b (including active medical products designed to create ionization radiation, radiation therapy);

b) active medical products designed to control active therapeutic medical products of class 2b or manage them belong to class 2b. However, if active medical products are designed to control active implantable medical products or manage them, the specified medical products belong to class 3.

15. Active diagnostic medical products belong to class 2a if they are designed to:

a) transfer energy, absorbed by a human. However if the function of the medical product is lightning of the patient's body in the visible spectrum range, such medical product belong to class 1;

b) distribute radiopharmaceutical drug products administered into the human body;

c) provide a direct diagnostics or control of vital body functions. However if the specified medical products are designed to control vital physiological parameters, changes of which might lead to immediate danger for the patient (e.g. change of the function of the heart, breath or activity of the central nervous system), they belong to class 2b.

16. Active medical products, generating ionization radiation for radiological diagnostics and therapy, in particular medical products for control of such products or their management, belong to class 2b.

17. Active medical products, designed for administration of drug products, body fluids or other substances into the human body and (or) their clearance from the body, belong to class 2a. However if the method of administration (clearance) pose a potential danger taking into account appropriate substances, part of the body and methods of use, the specified medical products belong to class 2b.

18. Active medical products in respect of which paragraphs 14-17 of these Rules are not applied belong to class 1.

5. Peculiarities of classification of certain medical products

19. Medical products containing substances which when used alone can be considered as drug products, as well as products, obtained from human blood or plasma and which affect the human body in addition to the effect of the medical product, belong to class 3.

20. Medical products designed to control conception or to protect against sexually transmitted diseases belong to class 2b. However, if the specified medical products are implantable or invasive medical products for long-term use, they belong to class 3.

21. Medical products designed for disinfection of invasive medical products, as well as for cleaning, washing, decontamination, hydration of contact lenses, belong to class 2b. Other medical products designed for disinfection or sterilization of medical products belong to class 2a.

22. Medical products designed for recording of images obtained from X-ray, magnetic resonance, ultrasound and other diagnostic apparatus belong to class 2a.

23. Medical products that were manufactured using dead tissue or animal cells or their derivatives belong to class 3. However, if the specified medical products are designed to come into contact only with intact skin, they belong to class 1.

24. Packages (polymer containers) for blood belong to class 2b.

25. Medical products containing a nanomaterial belong to class 3. However, if the nanomaterial is in isolated or bound state preventing it from entering the patient's or user's body, such medical product belongs to class 1.

26. Medical products designed for apheresis, including kits, connectors and solutions, belong to class 3.

27. If the medical product is designed for use in combination with another medical product, these Rules apply separately to each medical product.

28. For software (tool), which is an independent product and used with a medical product, the same class as for the specified medical product is established.

29. If, in the light of the information regarding the medical product provided by the manufacturer, several paragraphs of these Rules apply, the paragraph is applied according to which the class of the medical product corresponding to the greatest degree of the potential risk of use is established.

6. Algorithm for classification
of medical products
depending on the potential risk of their use

30. When classifying medical products applicability of these Rules regarding classification of medical products is evaluated.

31. Classification of medical product (except for medical products for in vitro diagnostics) depending on the potential risk of their use is performed in accordance with Annex No. 1.

III. Classification of medical products
for in vitro diagnostics

1. Classes of medical products for in vitro diagnostics
depending on the potential risk of their use

32. Medical products for in vitro diagnostics are divided into 4 classes depending on the degree of the potential risk of use.

Classes have designations 1, 2a, 2b and 3.

Each medical product for in vitro diagnostics can be assigned to one class.

Medical products for in vitro diagnostics are assigned to classes based on the following:

class 1 includes medical products for in vitro diagnostics with a low degree of the potential risk of use for an individual and low degree of the potential risk of use for public health;

class 2a includes medical products for in vitro diagnostics with a medium degree of the potential risk of use for an individual and low degree of the potential risk of use for public health;

class 2b includes medical products for in vitro diagnostics with a high degree of the potential risk of use for an individual and (or) middle degree of the potential risk of use for public health;

class 3 includes medical products for in vitro diagnostics with a high degree of the potential risk of use for an individual and high degree of the potential risk of use for public health.

2. Peculiarities of classification
of medical products for in vitro diagnostics
depending on the degree of the potential risk of use

33. If, light of the information regarding the medical product for in vitro diagnostics provided by the manufacturer, several paragraphs of these Rules apply, the paragraph according to which the class of the medical product for in vitro diagnostics corresponding to the greatest degree of the potential risk of use is established.

34. Calibration and control materials with quantitatively and qualitatively set values belong to the same class as the medical products for the control of which they are designed.

35. If the software is used as an independent medical product, it is classified as follows:

a) if the software controls the work or affects the result of the work of the medical product for in vitro diagnostics, it is classified in the same class as this medical product for in vitro diagnostics;

b) if the software is not associated with a medical product for in vitro diagnostics, it is classified in accordance with subsection 3 of this section.

3. Classification of medical products
for in vitro diagnostics

36. Medical products for in vitro diagnostics, designed to detect infectious agents in the blood, blood components, blood derivatives, cells, tissues or organs in order to evaluate

possibility of their transfusion or transplantation, as well as medical products for in vitro diagnostics designed to detect infectious agents which can become a cause of life threatening diseases with a high risk of spread, belong to class 3.

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

38. Medical products for in vitro diagnostics belong to class 2b if they are designed for:

- a) detection of infectious agents of sexually transmitted diseases;
- b) detection of infectious agents with moderate risk of spread in cerebrospinal fluid or blood;
- c) detection of infectious agents if there is a risk that an erroneous result can be a cause of death or disabling of the observed patient or fetus;
- d) screening of pregnant women in order to determine their immune status against infections;
- e) determination of infectious disease status or immune status if there is a risk that an erroneous result leads to therapeutic decision, causing inevitable danger to the patient life;
- f) selecting therapy, determination of disease stage, screening or cancer diagnostics;
- g) genetic testing;
- h) control of levels of drugs, substances or biological components if there is a risk that an erroneous result leads to therapeutic decision causing life threatening situation for the patient;
- i) therapy of patients, suffering from life threatening infectious disease;
- j) screening of congenital fetus diseases.

39. Medical products for in vitro diagnostics designed for self-testing belong to class 2b. However if the result of the analysis obtained when using the specified medical products for in vitro diagnostics does not have a critical medical status or is preliminary one and requires subsequent comparison with appropriate laboratory tests, such medical products belong to class 2a.

40. Medical products for in vitro diagnostics which do not have measuring function can be used as general laboratory in their objective properties, however they have special characteristics in accordance with which they are designed by the manufacturer for the use in procedures for in vitro diagnostics (without indication of certain types of laboratory tests (analytes)), as well as receptacle for bio-test samples belong to class 1.

41. Medical products for in vitro diagnostics to which paragraphs 36-40 of these Rules are not applied, including analytical instruments (analyzers) with a measuring function with unfixed lists of the performed laboratory trials, which depends on the used reagent kits (test-systems), belong to class 2a. Interdependence of the analytical instrument and used reagents, generally, does not allow to evaluate the instrument separately however this does not affect its assignment to class 2a.

4. Algorithm for classification
of medical products for in vitro diagnostics
depending on the potential risk of their use

42. Medical products for in vitro diagnostics depending on the potential risk of their use are classified in accordance with the algorithm according to Annex No. 2.

43. Examples of classification of medical products for in vitro diagnostics depending on the potential risk of their use are provided in Annex No. 3.

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ANNEX No. 1
to the Rules for classification of
medical products depending on
the potential risk of their use

ALGORITHM
for classification of medical products
(except for medical products for in vitro diagnostics)
depending on the potential risk of their use

Position number	Paragraph of the Rules	Question	Answer	Conclusion	
				medical product class	transition to the position
1	2	3	4	5	6
1	6	is a medical product invasive?	yes	-	9
			no	-	2
2	7	is a medical product designed for storage of organs, parts of organs or storage or introduction of blood, other fluids, gases, vapors or tissues into the human body?	yes	-	3
			no	-	4
3	7	is a medical product used with active medical products of class 2a or a higher class?	yes	2a	32
			no	2a	32
4	8	is a medical product designed to change a biological or physicochemical composition and properties of blood, tissues, cells, other body fluids or liquids that should enter the body?	yes	-	5
			no	-	6
5	8	does the action of the medical product involve only filtration of particles, treatment in a centrifuge, gas or heat exchange?	yes	2a	32
			no	2b	32
6	9	is a medical product in contact with damaged skin?	yes	-	7
			no	1	32
7	subparagraph "a" of paragraph 9	is a medical product used as a mechanical barrier, for compression or for the absorption of exudates?	yes	1	32
			no	-	8
8	subparagraphs "b" and "c" of paragraph 9	is a medical product used primarily for wounds that can only be cured by secondary adhesion (including medical products that are designed primarily to affect the microenvironment of wounds)?	yes	2b	32
			no	2a	32
9	10	is an invasive medical product surgical?	yes	-	15
			no	-	10

Position number	Paragraph of the Rules	Question	Answer	Conclusion	
				medical product class	transition to the position
1	2	3	4	5	6
10	10	is an invasive medical product designed for connection to an active medical product of class 2a or a higher class?	yes	2a	32
			no	-	11
11	subparagraph "a" of paragraph 10	is an invasive medical product intended for short-term use?	yes	1	32
			no	-	12
12	subparagraph "b" of paragraph 10	is an invasive medical product intended for temporary use?	yes	-	13
			no	-	14
13	subparagraph "b" of paragraph 10	is a medical product used in the mouth cavity to pharynx, in acoustic meatus to the eardrum or in the nasal cavity?	yes	1	32
			no	2a	32
14	subparagraph "c" of paragraph 10	is a medical product used in the mouth cavity to pharynx, in acoustic meatus to the eardrum or in the nasal cavity and can the medical product be absorbed by mucous membrane?	yes	2a	32
			no	2b	32
15	11	is a surgical medical product designed for short-term use?	yes	-	16
			no	-	21
16	subparagraph "a" of paragraph 11	is a medical product designed for diagnostics, supervision, control or correction of pathologies of the heart, central blood circulatory system or central nervous system in direct contact with organs or parts?	yes	3	32
			no	-	17
17	subparagraph "b" of paragraph 11	is an invasive surgical medical product a reusable surgical instrument?	yes	1	32
			no	-	18
18	subparagraph "c" of paragraph 11	is an invasive surgical medical product designed to transfer energy in the form of ionization radiation?	yes	2b	32
			no	-	19
19	subparagraph "d" of paragraph 11	is a surgical invasive medical product intended to cause a biological effect or reabsorb in full or in large part?	yes	2b	32
			no	-	20
20	subparagraph "e" of paragraph 11	is a surgical invasive medical product designed to administer drug product by amateur users?	yes	2b	32
			no	-	32
21	12	is a surgical invasive medical	yes	-	22

Position number	Paragraph of the Rules	Question	Answer	Conclusion	
				medical product class	transition to the position
1	2	3	4	5	6
		product designed for temporary use?	no	-	28
22	subparagraph "a" of paragraph 12	is a surgical invasive medical product designed for temporary use for diagnostics, supervision, control and correction of pathologies of the heart or central blood circulatory system in direct contact with organs or parts of these systems?	yes no	3 -	32 23
23	subparagraph "b" of paragraph 12	is a surgical invasive medical product in contact with the central nervous system for temporary use?	yes no	3 -	32 24
24	subparagraph "c" of paragraph 12	is a surgical invasive medical product intended for temporary use to transfer energy in the form of ionization radiation?	yes no	2b -	32 25
25	subparagraph "d" of paragraph 12	is a surgical invasive medical product intended for temporary use in order to cause a biological effect or to reabsorb in full or in large part?	yes no	3 -3	2 26
26	subparagraph "e" of paragraph 12	does a medical product for temporary use undergo chemical changes in the human body (except for medical products implantable between teeth or designed for administration of drug products?)	yes no	2b 2a	27 32
27	subparagraph "e" of paragraph 12	is a surgical invasive medical product for temporary use implantable between teeth?	yes no	2a 2b	32 32
28	subparagraph "a" of paragraph 13	is an implantable medical product or surgical invasive medical product for long-term use designed for implantation between teeth?	yes no	2a -	32 29
29	subparagraph "b" of paragraph 13	is an implantable medical product or surgical invasive medical product for long-term	yes no	3 -	32 30

Position number	Paragraph of the Rules	Question	Answer	Conclusion	
				medical product class	transition to the position
1	2	3	4	5	6
		use in direct contact with the heart, central blood circulatory system or central nervous system?			
30	subparagraph "c" of paragraph 13	is an implantable medical product or surgical invasive medical product for long-term use designed to cause biological effect or reabsorb in full or in large part?	yes no	3 -	32 31
31	subparagraph "d" of paragraph 13	does an implantable medical product or surgical invasive medical product undergo chemical changes in the human body (except for medical products, implantable between teeth or designed for administration of drug products)?	yes no	3 2b	32 32
32	14	is a medical product active?	yes no	- -	33 46
33	14	is an active medical product therapeutic?	yes no	- -	34 37
34	subparagraph "a" of paragraph 14	is an active therapeutic medical product designed to transfer energy to the human body or energy exchange?	yes no	- -	35 36
35	subparagraph "a" of paragraph 14	does the transfer of energy to the human body or energy exchange with it pose potential danger due to characteristic features of the active therapeutic medical product, taking into account the nature, density and location of the impact of energy on parts of the body (including active medical products intended to create ionization radiation, radiation therapy)?	yes no	2b -	44 36
36	subparagraph "b" of paragraph 14	is an active medical product intended to control active therapeutic medical products of class 2b or to manage them?	yes no	2b 2a	44 44
		is an active medical product intended to control active	yes no	3 2b	end 44

Position number	Paragraph of the Rules	Question	Answer	Conclusion	
				medical product class	transition to the position
1	2	3	4	5	6
	subparagraph "b" of paragraph 14	implantable medical product or to manage them?			
37	15	is an active medical product diagnostic?	yes	-	38
			no	-	44
38	subparagraph "a" of paragraph 15	is an active diagnostic medical product designed to transfer energy absorbed by the human?	yes	-	39
			no	-	40
39	subparagraph "a" of paragraph 15	is an active diagnostic medical product designed for lightning of the patient's body in the visible spectrum range?	yes	1	44
			no	2a	44
40	subparagraph "b" of paragraph 15	is an active diagnostic medical product intended to represent distribution of radiopharmaceutical drug products administered into the patient's body?	yes	2a	44
			no	-	41
41	subparagraph "c" of paragraph 15	is an active diagnostic medical product intended to provide direct diagnostics or control of vital body functions?	yes	-	42
			no	-	43
42	subparagraph "c" of paragraph 15	is an active diagnostic medical product specifically designed to monitor vital physiological parameters, changes of which might lead to immediate danger to the patient (e.g., changes in heart function, breath or central nervous system activity)?	yes	2b	44
			no	2a	44
43	16	is an active medical product that generates ionization radiation intended for radiological diagnostics and therapy (including medical products for control of such products and management of them)?	yes	2b	44
			no	-	44
44	17	is an active medical product intended for administration of drug products, body fluids or other substances into the patient's body and (or) their clearance from the body?	yes	-	45
	18		no	1	46
45	17	does the introduction (elimination) method (see item	yes	2b	46
			no	2a	46

Position number	Paragraph of the Rules	Question	Answer	Conclusion	
				medical product class	transition to the position
1	2	3	4	5	6
		44) pose a potential danger, taking into account a type of the relevant substances, organism part and method of application?			
46	19	does a medical product contain a substance that, when applied alone, can be considered as a drug product, and also as a product derived from human blood or plasma and which affects the human body in addition to the effects of the medical product?	yes no	3 -	47 47
47	19	is a medical product used for control of conception or protection against sexually transmitted diseases?	yes no	- -	48 49
48	20	is a medical product for control of conception or for protection against sexually transmitted diseases, an implantable or invasive medical product for long-term use?	yes no	3 2b	49 49
49	21	is a medical product intended for disinfection or sterilization of medical products?	yes no	- -	50 51
50	21	is a medical product intended for disinfection of invasive medical products or for disinfection, cleaning, washing or hydration of contact lenses?	yes no	2b 2a	51 51
51	22	is a medical product used to register images obtained from X-ray, magnetic resonance, ultrasound and other diagnostic apparatus?	yes no	2a -	52 52
52	23	is a medical product manufactured using dead tissues or animal cells or their derivatives?	yes no	- -	53 54
53	23	is a medical product manufactured with the use of dead tissues or animal cells or their derivatives intended to be in contact only with intact skin?	yes no	1 3	54 54

Position number	Paragraph of the Rules	Question	Answer	Conclusion	
				medical product class	transition to the position
1	2	3	4	5	6
54	24	is a medical product a blood package (polymeric container)?	yes no	2b -	end 55
55	25	does a medical product contain a nanomaterial?	yes no	- -	56 57
56	25	is a nanomaterial that is contained in the medical product in an isolated or bound state, excluding its entry into the patient's or user's body?	yes no	1 3	end end
57	26	is a medical product intended for apheresis?	yes no	3 1	end end

Note. The applicability of paragraphs of these Rules for the purposes of classification of a medical product is assessed by answering a question that allows assigning the medical product to the appropriate class. If the paragraph of these Rules is applicable, it is necessary to mark a possible class of the medical product and go to the position indicated next to the class designation. In case several provisions are applicable, the class of the medical product is the class corresponding to the highest degree of the potential risk of use.

ANNEX No. 2
to the Rules for classification of
medical products depending on
the potential risk of their use

ALGORITHM
for classification of medical products
for in vitro diagnostics depending on the potential risk of their use

Position number	Paragraph of the Rules	Question	Answer	Conclusion	
				medical product class	transition to the position
1	2	3	4	5	6
1	41	is a medical product for in vitro diagnostics for a fixed list of laboratory tests performed?	yes no	- -	2 3
2	36 37	is a medical product for 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 -	end 5
3	40	can a medical product for in vitro diagnostics be used as a general laboratory?	yes no	- 2a	4 end
4	40	does a medical product for in vitro diagnostics have a measurement function?	yes no	2a 1	end end
5	38 39	is a medical product for in vitro diagnostics intended for detection of infectious agents that can cause life-threatening diseases with a limited risk of spread or for self-testing?	yes no	2b 2a	end end

ANNEX No. 3
to the Rules for classification of
medical products depending on
the potential risk of their use

EXAMPLES
of classification of medical products for in vitro diagnostics
depending on the potential risk of their use

Class	Medical products for in vitro diagnostics
1	washing and buffer solutions specialized microscopes tanks for samples of bio-tests mixing devices
2a	selective biochemical analyzers hematological analyzers specialized photometers test-systems, reagent kits for routine biochemical and hematological studies dispensers pregnancy tests for self-testing ovulation tests for self-testing test strips for urinalysis
2b	test systems, reagent kits, calibrators and control materials for detection of pathologic antibodies against erythrocytes test systems, reagent kits, calibrators and control materials for detection of the following intrauterine infections: rubella, toxoplasmosis test systems, reagent kits, calibrators and control materials for the diagnostics of phenylketonuria test systems, reagent kits, calibrators and control materials for detection of cytomegalovirus, chlamydia test systems, reagent kits, calibrators and control materials for detection of the following tissue HLA-groups: DR, A, B blood glucose analyzers for self-diagnostics, including appropriate calibrators and control materials
3	test systems, reagent kits, calibrators and control materials for determination of the following blood groups: ABO systems, Rh system (C, c, D, E, e), Kell system test systems, reagent kits, calibrators and control materials for detection and confirmation of HIV markers (HIV-1 and HIV-2, HTLV-I and HTLV-II, hepatitis B, C and D) tests to determine the bacterial contamination of blood components especially dangerous infections with a high risk of spread