THE EURASIAN ECONOMIC COMMISSION'S BOARD

RECOMMENDATION
dated November 12, 2018 No. 25

ABOUT CRITERIA
OF CLASSIFYING PRODUCTS AS MEDICAL DEVICES WITHIN THE FRAMEWORK
OF THE EURASIAN ECONOMIC UNION

List of amending documents
(as amended by Recommendation of the Eurasian Economic Commission's Board
No. 15 dated June 29, 2021)

The Eurasian Economic Commission's Board in accordance with Article 31 of the Treaty on the Eurasian Economic Union dated May 29, 2014, and Paragraph 2 of Article 3 of the Agreement on Common Principles and Rules for the Circulation of Medical Devices (Medical Devices and Medical Equipment) within the framework of the Eurasian Economic Union dated December 23, 2014,

in order to eliminate differences in the requirements for classifying products as Medical Devices,

recommends that the Member States of the Eurasian Economic Union, after 6 months from the date of publication of this Recommendation on the official website of the Eurasian Economic Union, apply the Criteria for Classifying Products as Medical Devices within the Framework of the Eurasian Economic Union as attached.

Chairman of the Board
of the Eurasian Economic Commission
T. SARGSYAN

Annex
to Recommendation of the Board
of the Eurasian Economic Commission
dated November 12, 2018 No. 25

CRITERIA
OF CLASSIFYING PRODUCTS AS MEDICAL DEVICES WITHIN THE FRAMEWORK
OF THE EURASIAN ECONOMIC UNION

List of amending documents
(as amended by Recommendation of the Eurasian Economic Commission's Board
No. 15 dated June 29, 2021)

I. General Provisions

1. This document has been developed in accordance with Article 31 of the Treaty on the Eurasian Economic Union dated May 29, 2014, and Paragraph 2 of Article 3 of the Agreement on Common Principles and Rules for the Circulation of Medical Devices (Medical Devices and Medical Equipment) within the framework the Eurasian Economic Union dated December 23, 2014, and defines the basic principles of classifying products as Medical Devices within the framework of the Eurasian Economic Union (hereinafter referred to as the Union) in cases where it cannot be done unambiguously, based on definitions established by acts constituting the Union's law.

2. This document may be used to draft documents for marketing authorization and expert examination of medical devices in accordance with the Rules for Marketing Authorization and Expert Examination of Safety, Quality and Efficiency of Medical Devices approved by Decision of the Eurasian Economic Commission's Council dated February 12, 2016 No. 46.

3. The provisions of this document may guide the manufacturers, authorized representatives of the manufacturer, as well as experts of authorized bodies (expert organizations) of the Union Member States.

II. Terms and definitions

4. For the purposes of applying this document, the concepts defined by the acts constituting the Union's law are used.

III. Borderline Medical Devices

5. The purpose of a Medical Device is one of the key criteria for classifying products as Medical Devices. The use of a Medical Device must be determined by its medical purpose. Such a medical purpose must be the only one or the main one.

1. Perfumes, cosmetics and personal hygiene products

6. If the products are intended for medical use by the manufacturer, then such products may be classified as Medical Devices. Examples of products classified as Medical Devices:

a) units and devices, breast pumps (milk pumps) intended by the manufacturer for the treatment and prevention of diseases and pathologies of the breast;

b) hot-water bottles and heating elements, the main purpose of which is temporary reduction and relief of pain;

c) products (diapers, napkins, pads, etc.) for people suffering from diseases of the genitourinary system or other diseases associated with impaired control of the excretory function;

d) lubrication gels, lubricants;

e) products for laser and photo epilation.
(Subparagraph “e” was introduced by the Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021)

7. If the manufacturer intends the products for the care of skin, hair, nails, lips, external genitals, teeth, and oral mucosa, including in cases where the additional purpose of these products is the prevention of diseases and/or age-related changes, then such products shall not be classified as Medical Devices. Examples of products not classified as Medical Devices:

a) napkins, diapers, pads, etc. (except for the products specified in Subparagraph “c” of Paragraph 6 hereof), as well as talcs, powders, wipes, wet wipes, and other products for children and newborns;

b) bottles, nipples, and rubber products for teething;

c) personal hygiene products for women: pads, tampons, napkins, towels, and other personal hygiene products for women;

d) personal hygiene products: antibacterial gels and liquids (sanitizers), paper tissues, wet wipes;

e) tools, materials and products intended by the manufacturer for cosmetic procedures (tattooing, manicure, pedicure, piercing, hair removal, etc.);

f) mattress pads;

g) heating tapes and elements, heated bottles for baby food;

h) slimming products (slimming underwear, clothing, etc.);

i) accessories for cleaning the oral cavity and oral hygiene products (toothbrushes and tongue cleaning, dental floss, toothpicks, toothpastes, tooth powders, teeth whitening products, mouthwash products, oral sprays, etc.);
(as amended by the Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021)

j) general hygiene products: razors, shaving accessories;

k) beautifying products: wigs for women and men;

l) products for the care of skin, hair, nails, lips, external genitals, teeth, and oral mucosa, slowing down and/or correcting the manifestations of aging (creams, wipes, masks, body and hair washing products, decorative cosmetics, etc.);

m) antibacterial soap, gel, mousse, etc.;

n) products for intimate hygiene and skin care of the external genitals: gels, foams, soaps, creams, deodorants, etc.;

o) cosmetic patches, cosmetic eye patches;

p) products to reduce the manifestations of cellulitis: creams, gels, oils, scrubs, etc.

2. Disinfectants and disinfecting equipment

8. If the products are intended for medical use by the manufacturer, then such products may be classified as Medical Devices. Examples of products classified as Medical Devices:

a) air recirculators intended by the manufacturer for air purification in medical organizations (with the exception of administrative and utility premises);

b) equipment intended by the manufacturer for air disinfection in medical organizations (bactericidal lamps, etc.);
(as amended by the Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021)

c) equipment intended by the manufacturer for sterilization and disinfection of Medical Devices in medical organizations;

d) antiseptic wipes for the treatment of surgeon’s hands, surgical and injection fields;
(Subparagraph “d” was introduced by the Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021)

e) sterilization quality control indicators.
(Subparagraph “e” was introduced by the Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021)

9. If the products are used for the treatment of premises, clothing, and equipment for the purpose of disinfection, disinection, as well as purification and maintaining a certain microclimate, including in the case of its use in medical organizations, then such products shall not be classified as Medical Devices. Examples of products not classified as Medical Devices:

a) disinfecting solutions, and cleaning agents (with the exception of products intended by the manufacturer for special treatment of Medical Devices);
(as amended by the Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021)

b) insecticidal agents for the treatment of premises against insects;

c) insect repellent agents (repellents) and acarorepellent agents for the purpose of protection against insects;

d) agents to combat pediculosis (shampoos, lotions, emulsion concentrates, caps or towels, and napkins soaked with a special agent);

e) recirculators, air ionizers, and other air modification equipment intended by the manufacturer for household use.

3. General-purpose products

10. If the products are used in medical organizations for general purposes and if the intended use of

these products does not include medical purposes, then such products shall not be classified as Medical Devices. Examples of products not classified as Medical Devices:

a) monitors, printers, scanners, telephones, facsimile machines, system units, and other organizational equipment, including accessories thereto;

b) TV sets;

c) refrigerators for storing products (with the exception of the equipment specified in Paragraph 26 hereof).

4. Products for adaptation and rehabilitation of people with disabilities

11. If the products are used for the adaptation and rehabilitation of people with disabilities, then such products may be classified as both Medical Devices and general-purpose products. The determining criteria are the presence of a direct relationship between the corrective action of the product and the personal needs of the patient, as well as an indication that the product is intended for medical purposes. Examples of products classified as Medical Devices:

a) accessories and prosthetic devices for limbs;

b) hearing aids and devices for sound amplification;

c) orthopedic shoes;

d) orthoses for the back and limbs;

e) walking devices for people with disabilities;

f) crutches and canes;

g) wheelchairs;

h) lifting devices to facilitate the movement of patients (with the exception of lifting devices specified in Subparagraphs “c” and “e” of Paragraph 12 hereof);

i) speech-generating devices.
(Subparagraph “i” was introduced by the Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021)

12. If there is no direct relationship between the corrective action of the product and the personal needs of the patient and/or if the intended use of the product does not provide for its use for medical purposes, such products shall not be classified as Medical Devices, but rather shall be defined as a general-purpose product. Examples of products not classified as Medical Devices:

a) sound equipment for people suffering from various types of dementia, for people with impaired vision, sound signals of transitions, and sound signals of orientation (the equipment can be used both at home and in public places);

b) special equipment for baths and showers for people with disabilities (chairs, seats, and other devices);

c) stair lifts and lift cars for lifting wheelchairs;

d) portable ramps and devices for rehabilitation;

e) special ladders and lifts for baths and swimming pools for people with disabilities;

f) devices for doors and walls for the disabled;

g) tactile transition signals and yellow circles.

5. Products for sports and physical therapy

13. If the main purpose of products for sports and physical therapy is use for medical purposes in accordance with the manufacturer's designation, then such products may be classified as Medical Devices. Examples of products classified as Medical Devices:

a) cooling (heating) bags, plasters, bandages to reduce pain;

b) cryotherapy equipment;

c) bandages, roll gauze, dressings, elastic bandages, and tapes intended by the manufacturer for recovery and treatment after sprain of muscles or ligaments;

d) equipment, exercise machines designed by the manufacturer for stress tests, the main indication for the use of which is to measure the physiological functions of the human body (with the function of blood pressure and pulse measuring, as well as breathing tests) (if the information obtained during the use of these products is intended for the diagnostics and decision-making on the disease treatment).

14. Products for sports and physical therapy in most cases shall not be classified as Medical Devices, including if their functional characteristics suggest their use for medical purposes. Examples of products not classified as Medical Devices:

a) treadmills, exercise machines with a pulse measurement function used in gyms and fitness clubs;

b) wristbands and bracelets measuring the number of steps taken and/or pulse;

c) bands and expanders designed by the manufacturer for training and stretching muscles.

6. Personal protective equipment

15. If personal protective equipment is intended by the manufacturer to protect patients or medical personnel and is used for medical purposes, then such personal protective equipment may be classified as Medical Devices. Examples of personal protective equipment classified as Medical Devices:

a) medical masks and medical respirators designed to limit the transmission of infectious agents;
(as amended by the Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021)

b) surgical and examination gloves;

c) shoe covers designed by the manufacturer to prevent cross-contamination in a medical organization;
(Subparagraph "b" as amended by the Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021)

d) products for the protection of patients or medical personnel from radiation, used in medical organizations during radiation diagnostics or radiation therapy;
(as amended by the Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021)

e) mouth pieces used in dental practice or for the treatment of sleep apnea;

f) protective glasses used during medical procedures;

g) clothing for medical personnel and patients used during medical procedures;
(as amended by the Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021)

h) surgical underwear (including sheets, diapers, and covers used in surgical rooms);
(Subparagraph "h" as amended by the Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021)

i) soft contact lenses with zero refraction.

16. Examples of personal protective equipment not classified as Medical Devices:

a) masks and respirators for respiratory protection from aerosols, vapors, and gases of dangerous

and harmful substances that are not intended by the manufacturer for medical use, including those designed to work in harmful production conditions and emergency situations;
(as amended by the Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021)

b) gloves and other products used, in particular, for household purposes (cleaning) (for example, shoe covers and caps used in administrative and household premises);

c) products for protection against chemical and physical factors, including radiation, intended by the manufacturer for use at production facilities or at home;
(as amended by the Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021)

d) mouth pieces designed by the manufacturer to protect teeth during sports;

e) products to protect the eyes from dust, computer radiation, and the sun (safety glasses, sunglasses);
(as amended by the Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021)

f) special clothing and special shoes that are not intended by the manufacturer for medical use.

17. Deleted. — Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021.

7. Software

18. The software is a Medical Device provided that it meets all of the following criteria:

a) the software is a computer program or software modules, regardless of the hardware platform used, as well as the ways of placing the software and providing access to it;

b) the software is not an integral part of another Medical Device;

c) the software is intended by the manufacturer to provide medical care;

d) the result of the software is the interpretation of data in automatic mode, including using artificial intelligence technologies, or according to parameters set by a medical professional affecting the clinical decision-making, a data set.
(Paragraph 18 as amended by the Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021)

19. Examples of methods and technologies used in software functions that do not constitute data interpretation:

a) display of data received from a Medical Device, including in a predefined format;

b) calculation according to the predefined formulas;

c) conversion between the units of measurement;

d) generation of statistical reports and graphs;

e) raster or vector image editor;

f) signaling of deviations in the data if it is possible to display the source data and provided that the deviation signaling parameters are set by the user;

g) the functions of creating screen forms, business processes, reporting, and other representations used to automate the business processes of a medical organization during the software operation.
(Paragraph 19 as amended by the Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021)

20. Examples of software (including the examples of functions, data set sources, purposes, platforms, ways of granting access, etc.) classified as Medical Devices:

a) software for viewing an individual anatomical 3D model by a doctor based on computed tomography images meeting the following criteria:

interpretation function is the calculation of the distance between two points of an anatomical 3D model;

the source of the data set is a CT scanner;

the purpose is the use by radiologists, including during the provision of emergency care;

hardware platform is a smartphone or a tablet;

the method of granting access is the app store;

b) software to support medical decision-making in the case of a stroke, meeting the following criteria:

interpretation function is a differentiation between ischemic and hemorrhagic stroke based on diagnostic images;

the source of the data set is a computer or magnetic resonance tomographic scanner;

the purpose is the use by resuscitators, neurosurgeons, and neurologists in neuro-intensive care and vascular centers, including during the provision of emergency care;

the hardware platform is any with web browser support;

the method of providing access is an Internet site based on the SaaS licensing model;

c) software to assist a doctor in the diagnostics of malignant neoplasms meeting the following criteria:

the function of interpretation is to build a map of pathological changes in the skin surface, calculating their fractal dimension to assess the degree of probability of their malignancy;

the source of the data set is medical workers taking photos with a built-in smartphone camera;

the purpose is the use by dermatovenerologists during the first visit;

the hardware platform is a smartphone;

the method of granting access is the developer’s website;

d) software to help a doctor diagnose tuberculosis or viral meningitis in children, meeting the following criteria:

interpretation function is an analysis of cerebrospinal fluid spectroscopy data in order to diagnose tuberculosis or viral meningitis in children;

the source of the data set is a spectrograph;

the purpose is the use by a laboratory technician;

the hardware platform is a personal computer;

the method of granting access is the purchase of a license and an electronic medium;

e) software to support medical decision-making when determining the risk of colorectal cancer meeting the following criteria:

the interpretation function is to assess the risk of developing colorectal cancer based on available data on a high-risk patient when developing a custom preventive action plan;

the source of the data set is medical workers and diagnostic equipment;

the purpose is the use by doctors of various specialties during the first or a follow-up visit;

the hardware platform is a personal computer;

the method of granting access is the purchase of a license and an electronic medium;

f) software to assist a doctor in the diagnostics of arrhythmia meeting the following criteria:

interpretation function is the analysis of heart rate data for the diagnostics of arrhythmia;

the source of the data set is pulse oximeters with wireless data transmission interface;

the purpose is the use by doctors of any specialty, including during the provision of emergency care;

the hardware platform is a smartphone;

the method of granting access is the app store;

g) software to assist the doctor in planning the surgery procedure meeting the following criteria:

interpretation function is the construction and visualization of an individual anatomical 3D model based on computed tomography images used to determine the placement of catheters on the inside of the bronchial tree and in the lung tissue or to place markers in the soft lung tissue;

the source of the data set is a CT scanner;

the purpose is the use by surgeons (in thoracic surgery, radiosurgery);

the hardware platform is a personal computer;

the method of granting access is the acquisition of the right to use the program with the ability to download the distribution kit from the developer’s website;

h) software to assist the doctor in performing morphometric measurements meeting the following criteria:

interpretation function is the image recognition and morphometry of cytological and histological preparations;

the source of the data set is digital microscopes;

the purpose is the use by laboratory assistants;

the hardware platform is a personal computer;

the method of granting access is the acquisition of the right to use the program for an unlimited period with the ability to download the distribution kit from the developer’s website;

i) software for remote monitoring of the health status of elderly patients with comorbid chronic diseases meeting the following criteria:

interpretation function is the automatic detection of pathological changes in blood pressure, heart rate, and signs of rhythm disturbance, followed by notification of persons who monitor and/or care for the patient, according to the data collected and received on the central server in automatic mode;

the source of the data set is blood pressure monitors with wireless data transmission interface;

the purpose is the use by a medical professional;

the hardware platform is a personal computer;

the method of granting access is the acquisition of the right to use the program with the ability to download the distribution kit from the developer’s website;

j) software for the development of an individual rehabilitation program meeting the following criteria:

interpretation function is the prediction and evaluation of the degree of the expected result based on the available data about the patient;

the source of the data set is medical workers and diagnostic equipment;

the purpose is the use by rehabilitation doctors;

the hardware platform is a personal computer;

the method of granting access is the purchase of a license and an electronic medium from the developer;

k) software used as prescribed by a doctor for the diabetic patient with a high risk of hypoglycemia to calculate a bolus dose of insulin based on data on carbohydrate intake, expected physical activity, and blood glucose levels before meals, meeting the following criteria:

interpretation function is the selection of the prandial insulin dose;

the source of the data set is the patient and diagnostic equipment;

the purpose is use by the patient as prescribed by the attending physician;

the hardware platform is any with web browser support;

the method of providing access is an Internet site based on the SaaS licensing model;

l) software of the radiological system of archiving and transmission of images for receiving, storing, transmitting, processing (image quality changes, compression), and viewing images by a doctor meeting the following criteria:

interpretation function is the determination of the image morphometric indicators;

the source of the data set is various types of radiation diagnostics equipment;

the purpose is use by doctors to provide medical care;

the hardware platform is a personal computer;

the method of granting access is the purchase of a license and an electronic medium from the developer.
(Paragraph 20 as amended by the Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021)

21. Examples of software not classified as Medical Devices:

a) software designed to automate the administrative and economic activities of a medical organization;

b) software, including mobile applications, designed by the manufacturer for the purposes of promoting a healthy lifestyle and for developing a responsible attitude to preserving and promoting health, as well as maintaining active longevity among people, which, among other things, measures (calculates) the number of steps, walking (running) speed, pulse, the amount spent and/or consumed calories (fluid), weight, body mass index, etc.;

c) medical information systems of a medical organization, laboratory information systems, software for maintaining electronic medical records, and image archiving and transmission systems, if such software does not contain data interpretation functions;

d) software, including its updates, used to manage a Medical Device and monitor its operability;

e) software using the data obtained from one or more Medical Devices but not intended to provide medical care. For example, it is software that encrypts and/or combines data (including the patient data) received from one or more Medical Devices for their further transmission;

f) software for the exchange of text and/or voice messages, electronic documents, photographic images, video and audio recordings (streams), and other data between a medical professional and a patient, their registration, storage, and granting access to them when providing medical care, including with the use of telemedicine technologies, or for making appointments;

g) software for accounting, planning, and monitoring of routine maintenance and scheduled repair of Medical Devices;

h) software intended for use by an unlimited number of users for educational, popular science, reference, and informational purposes, including for choosing a medical specialist, reminding (monitoring) about the need to take a drug, providing information from the summary of product characteristics and basic prescribing information.
(Paragraph 21 as amended by the Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021)

22 - 25. Deleted. — Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021.

8. Packaging and storage equipment for medical devices and other products

26. If the equipment is intended by the manufacturer for the storage of Medical Devices and other medical items (medicines, etc.) requiring special storage conditions, then such products may be classified as Medical Devices. Examples of products classified as Medical Devices:

a) equipment for storage and transportation of biological fluids and materials having a regime for maintenance of temperature and other special storage conditions;

b) equipment intended by the manufacturer for the storage of medical products, having a regime for maintenance of temperature and other special storage conditions;

c) packaging for sterilization of Medical Devices used in medical institutions;
(Subparagraph “c” was introduced by the Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021)

d) devices (injectors) for the administration of medicinal products produced in replaceable cartridges.
(Subparagraph “d” was introduced by the Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021)

27. Packaging and storage equipment for medical and other products (medicines, etc.) not requiring special storage conditions shall not be classified as Medical Devices. Examples of products not classified as Medical Devices:

a) bags for first aid kits (first aid kits, bags, and cases for emergency medical care, cases for storing and transporting drugs, medicines, and products not requiring special storage conditions, etc.);

b) eyeglass cases, lens cases;

c) cases for devices (injectors) for the administration of medicinal products produced in replaceable cartridges.

28. The following shall not be classified as Medical Devices:

a) primary, intermediate and secondary (consumer) packaging of medicinal products, including the primary packaging of a medicinal product, which is a means of administration (for example, a multi-dose syringe pen with a fixed cartridge mounted, a pre-filled syringe);

b) dosing device (dispenser) and/or device for dissolving (diluting) the medicinal product (for example, adapter, dosing syringe, dosing cap, dosing spoon), enclosed in the secondary (consumer) packaging of the medicinal product;

c) sachets or tablets with a desiccant enclosed in the primary or secondary (consumer) packaging of the medicinal product.
(Paragraph 28 as amended by the Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021)

9. Physiotherapy equipment and products for household use

29. If the main purpose of the product is physiotherapy, it is not a natural resource and at the same time is intended by the manufacturer for use only in a medical organization or as prescribed by a doctor, then such products may be classified as Medical Devices. An example of products classified as Medical Devices is physiotherapy equipment designed by the manufacturer for the prevention and treatment of

various diseases.

30. Examples of products not classified as Medical Devices:

a) peloids, mineral waters, stones for stone therapy, and other natural resources;

b) cedar barrels, infrared saunas, and other general tonic products.

10. Furniture

31. If the furniture is used in a special medical room (treatment room, operating room, etc.) and/or is subjected to a certain type of treatment, then such products may be classified as Medical Devices. Examples of products classified as Medical Devices:

a) medical couches;

b) special furniture, including anesthesiologist's tables, treatment tables, tripods (racks) for infusions, etc.;
(Subparagraph "b" as amended by the Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021)

c) massage tables;

d) operating tables;

e) functional medical beds;

f) medical chairs (dental, gynecological, dialysis, for a donor, etc.).
(Subparagraph "f" was introduced by the Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021)

32. If the furniture is not used in a special medical room (treatment room, operating room, etc.) and is not used for medical purposes in accordance with its main purpose, then such products shall not be classified as Medical Devices. Examples of products not classified as Medical Devices:

a) desk;

b) office chairs;

c) sofa, chairs, banquettes, and other furniture used in the waiting room for patients;

d) a cabinet for storing medical products that do not require special storage conditions;

e) furniture for dining rooms in medical organizations.

11. Medical Devices containing medicines

33. If the product contains medicines and its main effect is not due to the pharmacological, immunological, genetic, or metabolic effects, but due to the physical or mechanical effects, then such products may be classified as Medical Devices. Examples of products classified as Medical Devices:

a) highly elastic materials with viscoelastic properties containing hyaluronic acid and its salts, as well as other components;

b) deleted. — Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021;

c) stents and other implantable drug-coated products in which the antiproliferative or other pharmacological effects of the medicine are secondary to the mechanical recovery of the lumen of a vessel or another part of the body, achieved with the help of a stent or another implantable product;

d) means for irrigation of the nose and throat, including those containing substances, the main purpose of which is not due to the pharmacological, immunological, genetic, or metabolic effects;

e) Medical Devices in various dosage forms (for example, solutions, drops, sprays, powders, pastes, gels, etc.), including those containing medicines, the main purpose of which is not achieved by pharmacological, immunological, genetic, or metabolic effects on the human body;

f) dressings (including napkins), bandages, wound dressings, including those containing medicinal or antiseptic agents (including alcohols) and/or other substances, the main purpose of which is not achieved by pharmacological, immunological, or metabolic effects;

g) media and solutions for the transportation of organs and tissues not having a metabolic effect;

h) eye drops, moisturizing solutions for irrigation of the eye, including those containing substances, the main purpose of which is not achieved by pharmacological, immunological, or metabolic effects;

i) hemostatic sponges not containing substances involved in thrombosis and having a hemostatic effect due to the mechanical obstruction of bleeding;

j) concentrates and solutions for hemodialysis;

k) deleted. — Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021;

l) hyaluronic acid products (for example, for intra-articular, intradermal administration, etc.);

m) deleted. — Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021.

12. Products for in vitro diagnostics

34. The products intended by the manufacturer for laboratory use as Medical Devices for in vitro diagnostics shall be classified in accordance with the definition of a Medical Device for in vitro diagnostics established by the acts of the Eurasian Economic Commission. Examples of products classified as Medical Devices for in vitro diagnostics:

a) hematocrit centrifuge, a centrifuge for cytological studies;
(as amended by the Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021)

b) deleted. — Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021;

c) test tubes and containers for collecting human biological material;

d) tablets sorbed with antigens or antibodies to detect various diseases or pathological conditions, blood groups, and Rh factor;
(as amended by the Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021)

e) genetic tests designed by the manufacturer to diagnose genetic disorders and human diseases, as well as to identify predisposition to them;

f) nutrient media designed and intended specifically to provide information concerning a physiological or pathological condition using the biological material collected from a human;
(Subparagraph “f” was introduced by the Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021)

g) reagent kits designed for the isolation of nucleic acids (DNA and/or RNA) from biological material obtained from humans and subsequent use in combination with a Medical Device for in vitro diagnostics in order to detect a specific analyte.
(Subparagraph “g” was introduced by the Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021)

35. If the products do not have specific characteristics allowing to use the same for a special purpose to conduct medical diagnostic tests in vitro, then such products cannot be considered Medical Devices for in vitro diagnostics and are general laboratory products. Examples of products that shall not be classified as Medical Devices for in vitro diagnostics:

a) reagent kits intended by the manufacturer for sanitary and hygienic and sanitary-epidemiological studies, quantitative and qualitative studies in environmental objects, cosmetic, chemical, food products, and food raw materials (for example, to identify pathogens of infectious diseases, heavy metals, etc.);

b) standard samples, international reference materials, and materials intended by the manufacturer for external quality control;

c) reagent kits intended by the manufacturer for forensic or law enforcement activities;

d) products, including equipment, measuring instruments, and reagents intended by the manufacturer for research purposes;
(Subparagraph “d” as amended by the Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021)

e) centrifuges, pumps, agitators, scales, dispensers, incubators, microtomes, sterilizers for laboratory equipment, devices for wrapping tissue in paraffin, microscopes, shakers, laminar cabinets, etc., unless their intended purpose indicates that the products are intended specifically for medical use;

f) pipettes, filters, and other consumables for general purposes (disposable and reusable pipettes, plastic pipettes, Pasteur pipettes, etc.);

g) plastic and glass test tubes and vials;

h) empty tablets for enzyme immunoassay, empty Petri dishes, etc.;

i) general laboratory, non-specialized washing solutions for laboratory equipment, cell culture medium, various common buffer solutions, coloring agents, chemical reagents, etc.;
(as amended by the Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021)

j) DNA and RNA isolation kits provide only for the isolation of a nucleic acid sample without its mandatory intended use in combination with a Medical Device for in vitro diagnostics intended by the manufacturer for the detection of a specific analyte;

k) blood, plasma, serum of rabbit, veal, sheep, horse, and other animals, nutrient media without specific medical use, and other nutritional supplements or auxiliary tests (for example, indole formation test, oxidase test, hydrogen sulfide formation test, Voges-Proskauer test).
(Subparagraph “k” was introduced by the Recommendation No. 15 of the Eurasian Economic Commission's Board dated June 29, 2021)