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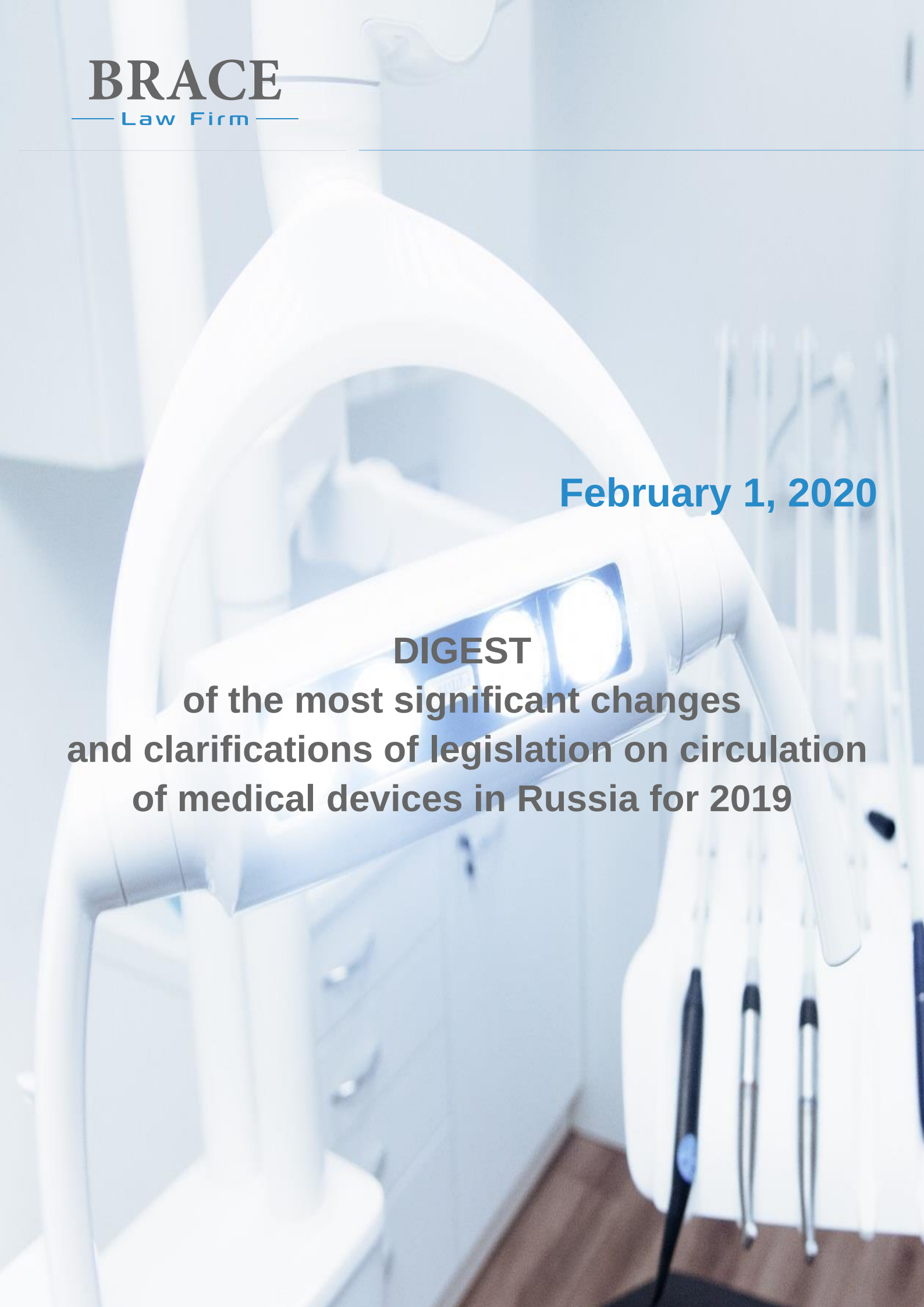

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DIGEST
of the most significant changes and clarifications of legislation on circulation of medical devices in Russia for 2019

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Dear colleagues!

We bring to your attention the Digest of the most significant changes and clarifications of the legislation on the circulation of medical devices for 2019.

It should be noted that in 2019 a large number of regulatory acts were adopted in the field of the circulation of medical devices both at the level of the Russian Federation and at the level of the Eurasian Economic Union.

When forming the digest, we were guided by the influence of various changes on the industry and the difficulties that medical device market participants may encounter.

The above and other significant changes can be found in this digest.

Sincerely yours,

BRACE Law Firm

1. A list of medical devices for the re-equipment of medical organizations subordinate to the executive authorities of the constituent entities of the Russian Federation that provide medical care to patients with cancer has been approved.

Order of the Ministry of Health of the Russian Federation dated February 12, 2019 N 56н "On approval of the list of medical devices for the re-equipment of medical organizations subordinate to the executive authorities of the constituent entities of the Russian Federation providing medical care to patients with cancer"

According to the Rules for the provision and distribution of other inter-budget transfers from the federal budget to the budgets of the constituent entities of the Russian Federation for the re-equipment of medical organizations providing medical care to patients with cancer, approved by Decree of the Government of the Russian Federation dated December 30, 2018 N 1772, other inter-budget transfers are provided to co-finance expenditure obligations of the constituent entities of the Russian Federation Federations arising in connection with the creation within the powers granted by law Of the Russian Federation, conditions for the development of medical care and ensuring its accessibility for citizens in the part providing for the re-equipment of medical organizations with medical devices according to the list approved by the Ministry of Health of the Russian Federation.

According to this legal norm, the List of medical devices was approved, which included 147 units of medical devices (including anesthesia-breathing apparatus for mechanical ventilation, equipment for radiotherapy, endovideoscopic complexes, etc.).

2. The Russian Ministry of Health has given recommendations on providing medical products for patients with diabetes.

Recommendations on the organization of providing citizens with diabetes who have insulin pumps with consumables approved by the Ministry of Health of the Russian Federation

On March 28, 2019, recommendations were published on the official website of the Ministry of Health explaining that, following the Nomenclature of Medical Services, approved by order of the Ministry of Health of the Russian Federation N 804n of October 13, 2017, there is no provision for consumables for an insulin pump.

Thus, the monthly provision of supplies for the insulin pump at the expense of compulsory medical insurance, including in the framework of medical care in the conditions of round-the-clock and day hospitals, is not carried out.

However, certain categories of citizens, including people with disabilities and children with disabilities, have the right to apply for a set of social services, including providing necessary medical devices with prescriptions for medical devices at the expense of the federal budget.

The list of medical devices dispensed for medical devices for the provision of a set of social services was approved by order of the Government of the Russian Federation dated December 31, 2018 N 3053-r, which includes supplies for the insulin pump.

Besides, attention is drawn to the fact that the state authorities of the constituent entities of the Russian Federation, in the framework of the requirements for the territorial program of state guarantees of free medical care for citizens for 2019 and the planning period 2020 and 2021, have the right to include supplies for the insulin pump in the list of medical devices dispensed the population following the list of population groups and categories of diseases for which outpatient treatment of drugs and medical devices are dispensed prescription free, and following the list of groups in outpatient treatment which medicines available on prescription from a 50-percent discount.

3. From May 2019, mobile medical teams should be equipped according to the standards

of the Ministry of Health of Russia.

Order of the Ministry of Health of Russia dated March 27, 2019 N 164n "On Amendments to the Regulation on the Organization of Primary Health Care for Adults, Approved by Order N 543n of the Ministry of Health and Social Development of the Russian Federation dated May 15, 2012" (Registered in the Ministry of Justice of Russia on April 22, 2012 .2019 N 54470)

The Regulation on the organization of primary health care for adults has introduced a standard for equipping mobile medical teams. Previously, there were no specific requirements for their equipment.

Now there are 5 standards for equipping mobile medical teams: for providing primary health care, conducting preventive medical examinations, the first stage of medical examination, fluorography and mammography.

Each mobile medical team is provided with a mobile medical complex. The composition of devices and devices in it depends on what manipulations are supposed to be carried out.

To provide primary medical care, there should be 32 types of equipment in the mobile complex according to the standard. For example, this:

- portable three- or six-channel electrocardiograph, a system for remote transmission of an electrocardiogram to a remote cardiopulmon;
- portable blood glucose analyzer with test strips;
- automatic defibrillator;
- disposable conicotomy kit;
- oxygen inhaler;
- bactericidal air irradiator;
- manual breathing apparatus (Ambu bag).

It is possible to conduct a preventive medical examination in a mobile complex if there is equipment according to the standard for the provision of primary medical care and three more devices. This is an express analyzer of blood cholesterol with test strips, a transpalpebral tonometer for measuring intraocular pressure, and a fluorograph.

For the first stage of the clinical examination, test strips are required to study feces for occult blood and a mammograph. They will be needed in addition to the equipment that is required by the standards for primary medical care and preventive medical examination.

The mobile medical team for fluorography should have a mobile medical complex with a fluorograph, and for mammography - a mobile medical complex with a mammograph.

All mobile complexes are equipped with radio communications and a mobile subscriber set of an automated navigation and dispatch control system with the ability to use GLONASS and GPS and the ability to send an alarm.

4. The rules governing the volume of turnover of medical alcohol, alcohol-containing drugs and medical devices came into force.

Decree of the Government of the Russian Federation of April 20, 2019 N 472 "On the procedure for recording and declaring the volume of production, turnover and (or) use of the pharmaceutical substance ethyl alcohol (ethanol), as well as the production, manufacture and (or) turnover (except for retail sale) of alcohol-containing medicines preparations and (or) alcohol-containing medical devices and on amendments to the Decree of the Government of the Russian Federation of June 19, 2006 N 380" (together with the "Rules for accounting the volume of production, turnover and (or) use of the pharmaceutical of the substance of ethyl alcohol (ethanol), as well as the production, manufacture

and (or) turnover (except for retail sale) of alcohol-containing drugs and (or) alcohol-containing medical devices"

Now, drug manufacturers, pharmaceutical distributors, medical organizations, pharmacies will be able to fulfill the duties that have appeared with them since January 2018.

On May 8, 2019, two documents entered into force.

One of the documents determines how to keep track of the volume:

- production, turnover and (or) use of the pharmaceutical substance of ethyl alcohol;
- production, manufacture and (or) turnover (except for retail sale) of alcohol-containing drugs, alcohol-containing medical devices.

To account for the volume of turnover of the pharmaceutical substance of ethyl alcohol, technical means of recording and transmitting information to the Unified State Automated Information System should be used.

There are exceptions. So, pharmacies and medical organizations that purchase the pharmaceutical substance of ethanol as a raw material or auxiliary material for the manufacture of medicines and medical devices (including alcohol-containing ones) should keep records of the volume of purchase and use of such a substance:

- using automatic means and technical means - if the volume exceeds 200 decalitres per year;
- without using these funds – if the volume is 200 decalitres per year or less.

Manufacturers of the pharmaceutical substance of ethanol must take into account and declare the volume of production, supply and (or) use of such a substance for their own needs. Currently, this should be done according to the new accounting and declaration rules.

Another document describes how to submit declarations on volumes of production, turnover, use, manufacture in these cases. Later, the Government will determine which alcohol-containing medicines and medical devices are not affected by innovations. For this, special lists will be approved.

5. The criteria of the Eurasian Economic Commission have begun to apply to assist manufacturers in classifying manufactured products as medical devices.

Recommendation of the Board of the Eurasian Economic Commission of November 12, 2018 N 25 "On Criteria for the classification of products as medical devices within the framework of the Eurasian Economic Union"

The Board of the Eurasian Economic Commission recommended the application of criteria from May 16, 2019. They will be useful to those manufacturers of medical devices who prepare documents for their registration and examination according to the rules of the EAEU.

The document identifies 12 groups of goods:

- perfumes and cosmetics and personal care products;
- disinfectants and equipment;
- general purpose products;
- products for the adaptation and rehabilitation of people with disabilities;
- products for sports and physiotherapy exercises;
- personal protective equipment;
- software;
- packaging and equipment for storage of medical devices and other products;
- physiotherapeutic equipment and household products;
- furniture;
- medical devices containing medicines;

- in vitro diagnostic products.

For each group, signs are identified that allow you to attribute the product to medical devices.

6. Federal Service for Surveillance in Healthcare will inspect the production of medical devices.

Decree of the Government of the Russian Federation of May 29, 2019 N 685 "On Amending Certain Acts of the Government of the Russian Federation"

The Government of the Russian Federation empowered Federal Service for Surveillance in Healthcare with the authority to organize inspections of the production of medical devices, as well as to inspect inspection organizations following the Requirements for the implementation, maintenance and evaluation of a quality management system for medical devices, depending on the potential risk of their use, approved by the decision of the Council of the Eurasian Economic Commission of November 10 2017 N 106.

7. The Board of the Eurasian Economic Commission has prepared guidelines for the examination of the safety, quality and effectiveness of medical devices.

Recommendation of the Board of the Eurasian Economic Commission of May 21, 2019 N 14

The safety, quality and effectiveness of the medical device are confirmed by evaluating:

- registration dossier documents;
- production inspection reports;
- the manufacturer's plan to collect and analyze data on the safety and effectiveness of the medical device at the post-sale stage (for products claimed for registration) and information on the identified side effects of the medical device during operation (for products that have a circulation history);
- information about adverse events and recalls of medical devices from the market (for products with a circulation history) or notifications on the safety of medical devices, as well as information on corrective actions taken in these cases;
- reports on post-registration clinical monitoring.

When examining the safety, quality and effectiveness of medical devices, a risk-based approach is used. Expert requirements for the volume and level of detail of evidence from the registration dossier should be proportional to the class of potential risk of using medical devices.

8. The Board of the Eurasian Economic Commission approved the classifier of areas of medical use of medical devices.

Decision of the Board of the Eurasian Economic Commission of April 16, 2019 N 62

The classifier is used in the preparation of documents (including registration dossiers) submitted by participants in the circulation of medical devices to government agencies of the EAEU countries. The decision entered into force on May 19, 2019 and is currently in force.

9. The Board of the Eurasian Economic Commission made recommendations on the content and structure of documents for the registration dossier of a medical device.

Recommendation of the Board of the Eurasian Economic Commission of October 08, 2019 N 29 "On Methodological Recommendations on the content and structure of documents for the registration dossier of a medical device"

For the examination and registration of a medical device, the applicant provides: a registration dossier on electronic media, as well as copies of documents confirming payment of the examination and registration of the medical device in the reference state.

The recommendations contain requirements for the content of the registration dossier. So, as part of the registration dossier, the applicant must submit:

- application for examination and registration of a medical device;
- power of attorney from the manufacturer for the right to represent interests during registration;
- a copy of the permit document for the right to manufacture in the country of origin with the attachment (if any);
- copies of certificates for the quality management system of the manufacturer of medical devices;
- a declaration of conformity with the safety and efficacy requirements of medical devices or an equivalent document (if any);
- a copy of registration certificate (free sale certificate, export certificate);
- a copy of a document certifying registration in other countries (if any);
- a certificate for a medical device with a description of the scope, purpose, brief description of the medical device (data on labeling and packaging);
- information on the development and production (schemes of production processes, the main stages of production, packaging, testing and the final product release procedure);
- information about the manufacturer (name, type of activity, legal address, form of ownership, composition of the manual);
- information about marketing (history provided that the product has been circulated on the market for more than 2 years);
- reports of accidents and reviews (a list of undesirable events or accidents related to the use of the product, and an indication of the time over which these cases occurred);
- a list of standards that a medical device complies with;
- guidelines on the compliance of the medical device with the general requirements for the safety and effectiveness of medical devices;
- a document establishing the requirements for the technical characteristics of a medical device;
- protocols of technical tests and protocols of studies (tests) for assessing the biological effect of a medical device;
- a report on clinical evidence of the effectiveness and safety of a medical device and a report on risk analysis, etc.

It is established that clinical data on a medical device obtained during clinical trials (studies) or when using a medical device in non-EAEU member states may be presented in a clinical evidence report on the effectiveness and safety of a medical device to prove the effectiveness and safety of a medical device if such data confirm the effectiveness and safety of the medical device according to indications for medical use following and with the appointment of a medical device.

10. The EAEU has made recommendations regarding the procedure for interaction between the operator of the nomenclature of medical products of the Eurasian Economic Union and legal entities and individuals registered as individual entrepreneurs, as well as authorized bodies of the EAEU member states.

The recommended procedure for interaction between the operator of the nomenclature of medical products of the Eurasian Economic Union and legal entities and individuals registered as individual entrepreneurs, as well as the authorized bodies of the Member States of the Eurasian Economic Union (Appendix N 2 to the protocol of the seventh meeting of the working group on coordination of work on the creation and maintenance of the nomenclature medical devices of the Eurasian Economic Union of July 17, 2019 N1-NMI)

To determine the type of medical device and (or) confirm the absence in the nomenclature of the type corresponding to the claimed medical device, the applicant is entitled to send the operator an application to determine the type of medical device following the nomenclature. The application processing time is 20 days. Based on the results of the review, the operator sends the applicant a conclusion on the presence or absence in the nomenclature of a species corresponding to the claimed medical device.

After confirming the absence in the nomenclature of a type corresponding to the claimed medical device, the applicant may submit to the operator an application for the creation of a new type of medical device in the nomenclature.

The following documents must be attached to the application:

- a copy of the application for determining the type of medical device following the nomenclature;
- name of the medical device (model of the medical device) of the device in English;
- technical description of the medical device, including a detailed description of new properties and characteristics that required the creation of a new type in Russian and English;
- instructions for the use of a medical device in Russian and English.

The operator sends the application and relevant documents to the Federal State Budgetary Institution. Consideration of the application is carried out on the basis of an agreement concluded by the applicant with the Federal State Budget Institution in accordance with the legislation of the Member State of the Union in whose territory the operator is registered.

11. Wheelchairs take part in the experiment on the labeling of medical devices.

Decree of the Government of the Russian Federation of August 07, 2019 N 1028 "On experimenting on the territory of the Russian Federation with a means of identifying wheelchairs related to medical devices and monitoring their circulation" (together with the "Regulations on conducting a labeling experiment on the territory of the Russian Federation" means of identification of wheelchairs related to medical devices and monitoring of their turnover")

The government established that from September 1, 2019 to June 1, 2021, an experiment will be conducted on the territory of the Russian Federation to mark wheelchairs related to medical devices using identification.

It is recommended that the information system operator, in agreement with the Ministry of Industry and Trade of the Russian Federation, develop requirements for the information system, as well as requirements for ensuring the protection of information contained in the information system and ensuring information security when using information and communication technologies as part of the experiment.

The Ministry of Industry and Trade of the Russian Federation has been instructed to ensure by December 1, 2019, in agreement with the federal executive authorities and state extra-budgetary funds, the approval of methodological recommendations for the experiment and the schedule of the experiment, as well as approval of the requirements for the information system and requirements to ensure the protection of information contained in the information system, and to ensure information security when using information on-communication technology as part of the experiment.

The experiment is planned to be carried out in 2 stages: the first stage about wheelchairs with a manual drive (without mechanical devices for movement); the second stage about electric wheelchairs (others equipped with an engine or other mechanical devices for movement).

12. The Rules for the provision of subsidies for the implementation of projects for the development of modern technologies and the implementation of competitive medical devices on their basis have been approved.

Decree of the Government of the Russian Federation of November 16, 2019 N 1463 "On the approval of the Rules for the provision of subsidies from the federal budget to Russian organizations for the financial provision of part of the costs of implementing projects to develop modern technologies, organizing the production and implementation of competitive medical devices on their basis and recognizing invalid some of the acts Government of the Russian Federation"

Subsidies are provided to support Russian organizations - manufacturers of industrial products registered in the Russian Federation and engaged in the development of modern technologies, organization of production and sale of competitive medical products on their basis.

The subsidy is supposed to compensate for the following costs:

- remuneration of employees, as well as deductions for insurance contributions for compulsory health insurance, deductions for insurance contributions for compulsory social insurance, deductions for insurance contributions for compulsory pension insurance;
- material costs (excluding capital investments in fixed assets of the manufacturing organization) (without value added tax);
- overhead costs (except for hospitality expenses, travel to the place of recreation, organization and participation in exhibitions) - in the amount of not more than 60 percent of the amount of expenses;
- payment for work (services) provided by third-party organizations involved in the implementation of the project on the territory of the Russian Federation, as well as on the territories of foreign states in the case of conducting clinical trials of medical devices on their territory and registration of medical devices (without value added tax) - in the amount of no more than 80 percent of the amount of the subsidy.

It is forbidden to use the funds of subsidies for the purchase of foreign currency, except operations carried out following the currency legislation of the Russian Federation when purchasing (supplying) high-tech imported equipment, raw materials, consumables and components related to the achievement of the objectives of the grant.

The Ministry of Industry and Trade of the Russian Federation presents subsidies on a competitive basis

13. The Ministry of Health provided additional information on weighted average prices for medical devices, for which access restrictions are imposed for public procurement.

Letter of the Ministry of Health of Russia dated November 29, 2019 N 25-3 / I / 2-11362 "On weighted average prices for medical devices, in respect of which access restrictions are established for procurement to meet state and municipal needs"

To calculate the initial (maximum) price of a contract for the supply of medical devices included in the list of disposable medical devices made of polyvinylchloride plastics originating from foreign countries, for which access restrictions are set for procurement to meet state and municipal needs, approved Decree of the Government of the Russian Federation of February 5, 2015 N 102 in the specified document provides additional information on the coefficient localization factor.

The formula for calculating the localization coefficients is given, as well as the localization coefficients for the names of medical devices for 2019 (for example, the localization coefficient for blood transfusion devices, blood substitutes and infusion solutions - 1; the localization coefficient for leukocyte filters with containers - 0.99; localization coefficient for urinals - 0.98, etc.).

14. The List of medical devices implanted into the human body when providing medical care as part of the state guarantee program for the free provision of medical care to citizens has been supplemented.

Order of the Government of the Russian Federation of October 08, 2019 N 2333-r "On Amending the Order of the Government of the Russian Federation of December 31, 2018 N 3053-r"

The list is supplemented with such medical products as:

- clip for ligation, made of synthetic polymer, absorbable;
- endoscopic ligation loop;
- two-chamber implantable pacemaker, frequency adaptive, compatible with magnetic resonance imager;
- Endocardial pacemaker lead compatible with magnetic resonance imaging.

15. The Ministry of Finance is now authorized to agree on lists of medical devices.

Decree of the Government of the Russian Federation of October 10, 2019 N 1306 "On Amending Clause 20 of the Rules for the Formation of Lists of Medical Devices"

Draft lists of medical devices implanted into the human body when providing medical care under the state guarantees program for the free provision of medical care to citizens (hereinafter referred to as the state guarantees program), as well as medical devices dispensed with medical devices for the provision of a set of social services, are subject to approval Ministry of Finance of the Russian Federation.

16. The standards for the cost of preferential provision of medical devices are established.

Decree of the Government of the Russian Federation of November 30, 2019 N 1554 "On Amending the Decree of the Government of the Russian Federation of December 29, 2004 N 864"

As of January 1, 2020, the standard financial costs per month for one citizen receiving state social assistance in the form of an appropriate set of social services (including services for providing medical products) is 860.6 rubles - in terms of security following medical care standards prescribed by a doctor (paramedic) with medicines for medical use, medical products, as well as specialized medical nutrition products for children with disabilities.

17. Federal Service for Surveillance in Healthcare gave explanations regarding licensing requirements for the provision of medical care in oncology.

Letter of Federal Service for Surveillance in Healthcare dated September 10, 2019 N 01i-2204/19 "On compliance with license requirements for the provision of medical care in oncology"

It is reported that in the framework of the implementation of regional projects that are part of the Federal project "Fight against oncological diseases" and the implementation of regional programs to improve the organization of medical care for patients with cancer in medical organizations licensed to carry out medical activities on the profile of "oncology" It is planned to re-equip more than 160 medical organizations, including pathological and anatomical departments. Purchased and installed medical devices in these medical organizations must comply with the List of medical devices approved by order of the Ministry of Health of Russia dated February 12, 2019 N 56n "On approving the list of medical devices for re-equipping medical organizations, subordinate to the executive authorities of the constituent entities of the Russian Federation providing medical care to patients with oncological diseases".

18. The Ministry of Health has approved a program for the development of a palliative care system, a list of medical devices designed to support the functions of organs and systems of the human body provided for use at home, and the procedure for transferring such medical devices to palliative patients.

Order of the Ministry of Health of the Russian Federation of October 3, 2019 N 831 "On approval of the departmental target program "Development of the palliative care system"

Order of the Ministry of Health of Russia dated May 31, 2019 N 348n "On approval of the list of medical devices intended to maintain the functions of organs and systems of the human body provided for use at home"

Order of the Ministry of Health of the Russian Federation of July 10, 2019 N 505n "On approval of the Procedure for the transfer from a medical organization to a patient (his legal representative) of medical devices intended to maintain the functions of organs and systems of the human body, for use at home in the provision of palliative medical care"

Within the framework of the program, it is planned to allocate subsidies from the federal budget to the budgets of the constituent entities of the Russian Federation to co-finance the implementation of state programs of the constituent entities of the Russian Federation containing measures to develop a palliative care system for equipping medical organizations providing palliative care, including medical devices for use on housework.

It is assumed that the goal of improving the availability and quality of palliative care in the constituent entities of the Russian Federation will be achieved by improving the material and technical base of medical organizations providing palliative care in outpatient settings, including at home, in day care and inpatient settings.

The list of medical devices designed to maintain the functions of organs and systems of the human body provided for use at home includes such medical devices as: anesthesiology systems, inhalers, ventilation systems, infusion pumps, etc.

The decision to transfer the medical device to the patient (his legal representative) is made by the medical commission of the medical organization within three working days from the date of receipt of such documents as: informed consent of the patient (his legal representative) for medical intervention, as well as a questionnaire about the patient's home conditions. When transferring to a patient in need of long-term respiratory support (his legal representative) a ventilator, the second

ventilator can be transferred if the patient (his legal representative) fails to maintain spontaneous ventilation of the patient for 2 – 4 hours.

19. The Federal Biomedical Agency of Russia has given recommendations on the implementation of donor blood and its components by the subjects of the necessary measures aimed at introducing and ensuring compliance with the Rules for the collection, storage, transportation and clinical use of donated blood.

Recommendations on the implementation by donors of blood donor blood and its components of the necessary measures aimed at implementing and ensuring compliance with the Rules for the collection, storage, transportation and clinical use of donor blood and its components, approved by the Federal Biomedical Agency of Russia of Russia

Recommendations include such Measures to comply with the mandatory requirements for storage and transportation of donated blood and (or) its components as:

- use of medical devices that provide established storage and transportation conditions;
- availability of temperature measuring instruments during storage and transportation for more than 30 minutes.

20. Federal Service for Surveillance in Healthcare approved a program for the prevention of violations of mandatory requirements in the implementation of state supervision in the field of circulation of medical devices.

The order of Federal Service for Surveillance in Healthcare dated July 08, 2019 N 507 "On approval of the departmental program for the prevention of violations of mandatory requirements in the implementation of state control of the quality and safety of medical activity, federal state supervision in the field of circulation of medicines and state control over the circulation of medical devices"

Among the main detected violations are: violation of restrictions on the reception of representatives of organizations (or individuals) engaged in activities related to the circulation of medicines and medical devices; receipt of gifts (cash) from organizations (or individuals) engaged in activities related to the circulation of medicines and medical products; conclusion of an agreement with the company edera(company representative) on the appointment and/or recommendation of a specific drug and / or medical device, as well as receipt from the companies of samples of drugs, medical devices for delivery to patients, etc.

The program is designed to ensure the creation of conditions for reducing cases of violation in the implementation of medical activities, increasing the effectiveness of state control over the quality and safety of medical activities, federal state supervision in the field of circulation of medicines, state control over the circulation of medical devices, improving the working conditions of the inspectorial staff of the Federal Service for Surveillance in Healthcare and forming the interest of controlled objects in compliance with applicable law state control of the quality and safety of medical activity, state control over the circulation of medical devices.

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About us

BRACE Law Firm renders legal services to manufacturers and distributors of drugs, medical products, dietary supplements, and other healthcare organizations on issues of Russian and international law.

Our main industrial practice is “Health care and pharmaceutics”.

We provide legal assistance in the field of legal support of commercial activities, dispute resolution and litigation, antitrust law, public and corporate procurement, international trade law and some other areas.