BRACE
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DIGEST
of the most significant changes and clarifications of legislation on circulation of medical devices in Russia for 2018

1. Amendments to the Rules of state registration of medical devices.

Resolution of the Government of the Russian Federation of May 31, 2018 No. 633 "On Amendments to the Rules for the State Registration of Medical Products"

This resolution expanded the list of documents are to be submitted for state registration of a medical product. In an application for state registration of a medical device, it became necessary to indicate information on a trademark and other means of individualization in case of their application to packaging and the All-Russian classifier of products by type of economic activity.

Registration of medical devices of the 1 class of potential risk of use and medical devices for in vitro diagnostics is carried out in one stage without obtaining permission to conduct clinical trials.

As regards correction of the procedure for making changes this resolution introduced a distinction between changes that require and do not require an examination of the quality, effectiveness and safety of the medical device, identifies possible reasons for changes and lists the documents and information necessary for making the appropriate changes. For approval of (1) changes to registration documents requiring examination of the quality of efficiency and safety of medical device, a period of 35 working days is specified, (2) for changes that do not require such examination - 15 business days.

The document came into force on June 13, 2018.

2. The board of the Eurasian Economic Commission of the Eurasian Economic Union established criteria determining the procedure for classifying products as medical devices.

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

This recommendation clarifies that for attributing a product to the category of medical device should be guided by its purpose, while it "*should be the only or main*".

The document identified signs, in accordance with which the product should be attributed to medical devices in the following groups of products:

- perfumery and cosmetic products and personal care products;
- disinfectants and equipment;
- general purpose products;
- products for adaptation and rehabilitation of people with disabilities;
- products for sports and physical therapy;
- personal protective equipment;
- software;
- packaging and equipment for storage of medical products and other products;
- physiotherapy equipment and household products;
- furniture;
- medical products containing medicines;
- products for in vitro diagnostics.

Also in these groups of products the Eurasian Economic Commission identified types of destinations and examples of products that do not apply to medical devices.

The commencement date of the document is May 16, 2019.

3. The general process "Formation, maintenance and use of a single register of authorized organizations of the Eurasian Economic Union, conducting research (testing) of medical devices for the purpose of their registration" was put into effect.

The Order of the Board of the Eurasian Economic Commission on November 12, 2018 No. 176

From November 26, 2018, the EAEU Act came into force, defining the overall process "Formation, maintenance and use of a single register of authorized organizations of the Eurasian Economic Union, conducting research (testing) of medical products for the purpose of their registration."

The accession of new participants to the general process is carried out by performing the procedure of accession in accordance with the Procedure for joining the general process "Formation, maintenance and use of a single register of authorized organizations of the Eurasian Economic Union, conducting research (testing) of medical products for their registration", approved by the Decision of the Board of the Eurasian Economic Commission of August 30, 2016 No. 93.

4. The general process "Formation, maintenance and use of a unified information database of monitoring the safety, quality and effectiveness of medical devices" was launched.

Order of the Board of the Eurasian Economic Commission dated November 12, 2018 No. 177 "On the implementation of the general process" Formation, maintenance and use of a single information database monitoring the safety, quality and effectiveness of medical devices"

From November 26, 2018, the general process "Formation, maintenance and use of a single information database of monitoring the safety, quality and effectiveness of medical devices" was launched.

The accession of new participants to the general process, entered into action in accordance with this order, is carried out by performing the procedure of accession in accordance with the Procedure for joining the general process "Formation, maintenance and use of a single information database monitoring the safety, quality and effectiveness of medical devices", approved by the Decision of the Board Eurasian Economic Commission of August 30, 2016 No. 94.

5. Within the EAEU, a classifier has been adopted for the types of documents drawn up when reviewing the registration dossier of a medical product.

Decision of the Board of the Eurasian Economic Commission No. 135 dated August 21, 2018 "On the Classifier of the Types of Documents Issued When Considering the Registration Dossier of a Medical Product"

A classifier has been approved for the types of documents drawn up when reviewing the registration dossier of a medical product.

When forming documents submitted by participants in the circulation of medical devices to state bodies of the Eurasian Economic Union member states, including in electronic form, when reviewing the registration file of a medical product in order to register it and related procedures, documents are assigned designations according to this classifier.

The use of classifier code marks is mandatory for the implementation of common processes within the framework of the EAEU in the area of circulation of medical devices.

The commencement of the document is September 23, 2018.

6. Within the framework of the EAEU, the types of changes made to the registration dossier of a medical product have been approved.

Decision of the Board of the Eurasian Economic Commission No. 134 dd. August 21, 2018 "On the directory of the types of changes made to the registration dossier of a medical product"

When making changes according to the rules of the EAEU, it will be necessary to focus on the Handbook, which is part of the resources of the unified regulatory reference information system of the Eurasian Economic Union.

The procedure provides for the following changes:

- changing the name of the medical device;
- changing the composition of accessories, and (or) components, and (or) consumables;
- changing information about the indications for use, scope, contraindications, side effects;
- changing information about the manufacturer of the medical device;
- change of information contained in the technical and (or) operational documentation for a medical device;
- change of information about the applicant.

The commencement of the document is September 23, 2018.

7. Differentiated criteria for elements of a medical product, which are components of a medical product, for the purpose of its state registration.

Decision of the Board of the Eurasian Economic Commission No. 116 dated July 24, 2017 "On the Criteria for Differentiating the Elements of a Medical Device that Are Part of the Medical Device for Registration"

The decision of the Board of the Eurasian Economic Commission provides a definition and criteria for referring to the above definitions of the following concepts:

- the main unit (part) of a medical device;
- accessories for a medical device;
- medical device accessories;
- consumables to a medical device.

Also in the appendix to the Decision of the Board of the Eurasian Economic Commission, a typical algorithm for attributing to the component of a medical device is given. Discrepancies with the recommendations of the algorithm for identification should be justified by the applicant in the submitted registration dossier and confirmed during the examination as part of the procedure for registering a medical product and making changes to the registration dossier.

The commencement of the document is August 25, 2018.

8. At the level of the EAEU, the criteria for inclusion in one registration certificate of several modifications of a medical product relating to one type of medical product in accordance with the nomenclature of medical products used in the Eurasian Economic Union have been adopted.

Decision of the Board of the Eurasian Economic Commission dated July 24, 2018 No. 123 "On the criteria for inclusion in one registration certificate of several modifications of a medical product related to one type of medical product in accordance with the nomenclature of medical products used in the Eurasian Economic Union"

According to this decision, several modifications of a medical device can be made in one registration certificate, forming a standard series or being a performance group, having the following uniform data:

- type of medical device (in accordance with the nomenclature classification of the Eurasian Economic Union);
- manufacturer;
- technical documentation on which the product is manufactured;
- risk class;
- the presence and / or quantitative content of the same clinically (diagnostically) significant analyte (s) in a biological sample (for medical devices for in vitro diagnostics).

Differences of modifications can be presented in the form of the following differences that do not affect the principle of operation and functional purpose:

- configuration;
- various technical parameters.

The commencement of the document is August 25, 2018.

9. Within the EAEU, a classifier has been adopted for the types of adverse events associated with the use of medical devices.

Decision of the Board of the Eurasian Economic Commission No. 47 of April 3, 2018 "On the classifier of types of adverse events related to the use of medical devices"

This classifier is necessary to systematize information about the types of adverse events associated with the use of medical devices provided during the monitoring of the safety quality and effectiveness of a medical product that are in circulation in the Eurasian Economic Union.

The use of classifier code marks is mandatory for the implementation of common processes within the framework of the EAEU in the area of circulation of medical devices.

The document came into force on May 06, 2018.

10. The EAEU classifier of the types of documents for the registration form of a medical product has been adopted.

Decision of the Board of the Eurasian Economic Commission No. 48 of April 3, 2018 "On the Classification of the Types of Documents of the Registration File of a Medical Device"

A classifier has been developed for the types of documents of the medical product registration dossier (hereinafter the classifier). The use of classifier code marks is mandatory in the framework of the Eurasian Economic Union in the field of circulation of medical devices.

Provides codes for the following types of documents:

- Applications;
- Power of Attorney;
- Declarations;
- Certificates of quality management system compliance;

- Permits (licenses);
- A document confirming the registration of a medical product in third countries;
- Certificates for export, free sale;
- Description of the medical device;
- Packaging and labeling models;
- Instructions, manuals;
- Reviews;
- Reports;
- Lists;
- Plans;
- Protocols;
- Letters of manufacturers of medical devices;
- Other documents and information.
- Provides codes for the following types of documents:

The beginning of the document is May 06, 2018.

11. The nomenclature of medical products of the Eurasian Economic Union has been adopted.

The decision of the Board of the Eurasian Economic Commission dated April 03, 2018 No. 46 "On the nomenclature of medical products of the Eurasian Economic Union"

The nomenclature of medical devices has been developed to systematize information about the types of medical devices, including taking into account the classification signs of medical devices. This nomenclature is supposed to be used when forming registration dossiers for medical devices, controlling the circulation of medical devices and for ensuring information interaction.

The use of code nomenclature is mandatory for the implementation of common processes within the framework of the Eurasian Economic Union in the field of circulation of medical devices.

The beginning of the document is May 6, 2018.

12. Exemption from VAT on the sale of accessories to medical devices separately from these products is applied if there are registration certificates for these accessories, as well as the inclusion of such accessories in the list approved by the Government of the Russian Federation.

Letter of the Ministry of Finance of Russia dated November 29, 2018 No. 03-07-14 / 86270

The Ministry of Finance of Russia clarified the issue of exemption from VAT on the sale of accessories to medical devices separately from these products.

In accordance with subsection 1 of clause 2 of Article 149 of the Tax Code of the Russian Federation, exemption from value added tax in respect of sold medical devices (medical equipment) is applied when submitting to the tax authority a registration certificate of a medical product issued in accordance with the law of the Eurasian Economic Union, or until December 31, 2021 of the registration certificate for a medical device (a registration certificate for a medical device (medical equipment)) issued in accordance with Russian legislation.

The list of the above-mentioned medical products, in accordance with the All-Russian Classifier of Products by Economic Activity (All-Russian classifier of products by type of economic activity) and

the Common Commodity Nomenclature for Foreign Economic Activity of the Eurasian Economic Union (Commodity nomenclature of foreign economic activity EAEU), was approved by Government Decree of September 30, 2015 No. 1042.

Thus, exemption from value added tax on the sale of accessories to medical devices separately from these products is applied if there are registration certificates for these accessories, as well as the inclusion of such accessories in the list approved by the above-mentioned decree of the Government of the Russian Federation.

Similar positions are enshrined in the letters of the Ministry of Finance of Russia dated November 29, 2018 No. 03-07-07 / 86263, dated November 02, 2018 No. 03-07-07 / 78832, dated September 07, 2018 No. 03-07-07 / 64096, dated September 03, 2018 № 03-07-07 / 62696, dated April 03, 2018 № 03-07-07 / 21278.

13. The Ministry of Finance of Russia clarified that when a participant proposes a state procurement of medical products of the same type, but from different manufacturers, in the second part of the application, such a participant must submit registration certificates for each item offered for delivery.

In response to a request for a bid by the participant in an electronic auction of medical products of two manufacturers that meet the requirements of the customer, taking into account the availability of registration certificates, he explained the following.

According to sub-clause “b” of clause 1 of part 3 of article 66 of Federal Law No. 44-FZ of April 5, 2013, the first part of an application for participation in an electronic auction when concluding a contract for the supply of goods must contain specific indicators corresponding to the values established by the documentation of such auction, and indication of the trademark (its verbal designation) (if available), service mark (if available), company name (if available), patents (if available), utility models (if available), industrial designs (if available), name of the country origin of goods.

The auction commission checks the first parts of applications for participation in an electronic auction, containing information on compliance with the requirements established by the documentation on such an auction in relation to the purchased goods, works, services. Based on the results of consideration of the first parts of applications for participation in an electronic auction, containing information provided for by part 3 of article 66 of the Federal Law No. 44-FZ of April 5, 2013, the auction commission makes a decision on the admission of a procurement participant who submitted an application for participation in such an auction to participate in it and the recognition of this participant in the procurement of such an auction or the refusal to admit to participate in such an auction.

An electronic auction participant is not allowed to participate in the auction if the information provided by part 3 of article 66 of the Federal Law No. 44-FZ of April 5, 2013, or the provision of inaccurate information is not provided, as well as in the case of non-compliance of this information with the documentation of such auction.

On the basis of the above, the auction commission checks the first parts of applications for participation in an electronic auction for compliance with the requirements established by the documentation of such an auction in relation to the procured goods, works and services.

The circulation of medical devices registered in the manner established by the Government of the Russian Federation and authorized by the federal executive authority is permitted on the territory of the Russian Federation.

Thus, according to the Ministry of Finance of Russia, when a participant proposes the purchase of medical products of the same type but from different manufacturers (provided that such products meet the requirements set by the customer in the documentation for the electronic auction), in the second part of the application, such a participant must submit registration certificates for each item offered for delivery.

14. The Ministry of Finance of Russia clarified the issue of applying the 10% VAT rate for medical devices as of January 1, 2017, in connection with the replacement of All-Russian classifier of products codes with All-Russian classifier of products by type of economic activity codes.

Letter of the Ministry of Finance of the Russian Federation No. 03-07-07 / 78235 of October 31, 2018

By the Decree of the Government of the Russian Federation of January 23, 2018 No. 50, the Decree amended the parts of the replacement of All-Russian classifier of products codes with All-Russian classifier of products by type of economic activity codes. At the same time, in accordance with clause 3 of Resolution No. 50 of the Government of the Russian Federation of January 23, 2018, these changes apply to legal relations arising from January 1, 2017.

Thus, starting from January 1, 2017, when considering the issue of applying a value added tax rate of 10 percent in relation to medical devices, one should be guided by the Resolution (as amended by Government Resolution No. 50 of January 23, 2018).

As for the All-Russian classifier of products by type of economic activity codes of types of medical devices that are not included in this resolution, the Ministry of Finance of Russia recommended addressing this issue to the Ministry of Industry and Trade of Russia.

Similar positions are fixed in the letters of the Ministry of Finance of Russia dated September 6, 2018 No. 03-07-07 / 63701, dated September 04, 2018 No. 03-07-07 / 63078, dated June 28, 2017 No. 03-07-07 / 44705.

15. VAT exemption for medical devices remains.

Letter of the Ministry of Finance of Russia dated July 03, 2018 No. 03-07-14 / 45961

VAT benefits in the form of VAT exemption, as well as a reduced VAT rate of 10%, remain.

Thus, on the basis of clause 2 of Article 164 of the Tax Code of the Russian Federation, a reduced VAT rate of 10 percent for medicines and medical devices is established and is in effect.

The list of products to which the reduced VAT rate applies is approved by the Decree of the Government of the Russian Federation of September 15, 2008 No. 688.

16. Exemption from value added tax with respect to medical products sold in Russia is applied if there are registration certificates for these products and are in the list approved by Government Decree 1042.

Letter of the Ministry of Finance of Russia of June 28, 2018 No. 03-07-07 / 44696

In accordance with subsection 1 of clause 2 of Article 149 of the Russian Tax Code, exemption from value added tax is carried out for medical devices for which a registration certificate for a medical device issued in accordance with the law of the Eurasian Economic Union is submitted, or until

December 31, 2021 a registration certificate for medical device (medical equipment), issued in accordance with Russian legislation.

The Decree of the Government of the Russian Federation of September 30, 2015 No. 1042 specifies the list of codes of goods exempted from value-added tax in accordance with the All-Russian Classifier of Products by Economic Activity (All-Russian classifier of products by type of economic activity) and the Commodity Nomenclature of Foreign Economic Activities of the Eurasian Economic Union (Commodity nomenclature of foreign economic activity EAEU).

In view of the foregoing, exemption from VAT in respect of medical products sold in Russia is applied if there are registration certificates for these products and they are in the list approved by the aforementioned decree of the Government of Russia.