



**GOVERNMENT OF THE RUSSIAN FEDERATION
RESOLUTION**

from December 27, 2012 N 1416

**APPROVAL OF THE RULES
STATE REGISTRATION OF MEDICAL PRODUCTS**

In accordance with Article 38 of the Federal Law "On the basis of health protection in the Russian Federation," the Government of the Russian Federation decrees:

1. Approve the attached rules of state registration of medical devices.
2. Establish that:

a) registration for medical devices and medical technology with the established validity issued before the date of entry into force of this Regulation shall apply until the expiration of the period of validity in them;

b) registration for medical devices and medical equipment indefinite action issued prior to the date of entry into force of this Regulation shall be valid and must be replaced prior to January 1, 2014 on the registration certificate on the form approved by the Federal Service for Supervision of Health.

Replacement registration certificate is carried out without completing the procedure of state registration of medical devices on the basis of the application submitted by the applicant to the Federal Service for Supervision of Health, including the data provided by the Regulations approved by this Resolution.

3. The state registration of medical devices submitted for state registration to the date of entry into force of this Regulation, on the basis of documents submitted to the entry into force of this regulation, as well as the application of state registration of medical products furnished by the applicant in accordance with the rules approved by this Resolution, the Federal Service for Supervision of Health.

4. The implementation of the powers conferred by this Resolution shall be in the range established by the Government of the Russian Federation, the maximum number of employees of the central office of the Federal Service on Surveillance in Healthcare and the budget allocations to the Service in the federal budget for the leadership and governance of its functions.

5. This Decision shall enter into force on 1 January 2013

Prime Minister
The Russian Federation
D.MEDVEDEV
Approved

Government Resolution
The Russian Federation
from December 27, 2012 N 1416

RULES

STATE REGISTRATION OF MEDICAL PRODUCTS

1. These Rules shall govern the state registration of medical products to be treated in the territory of the Russian Federation.

2. Subject to state registration any instrument, apparatus, appliances, equipment, materials and other products used for medical purposes, alone or in combination with each other as well as with other accessories necessary for the application of these products to the destination, including special software and designed manufacturer for the prevention, diagnosis, treatment and rehabilitation of diseases, monitoring of the human body for medical research, restoration, replacement, modification of anatomical structures or physiological functions of the body, preventing or interrupting pregnancy whose function is not implemented by pharmacological, immunological, genetic or metabolic effects on the human body (hereinafter - medical devices).

Medical products made by individual orders patients have to meet special requirements for the appointment of medical staff and are intended solely for the personal use of the particular patient, are not subject to state registration.

3. The state registration of medical devices by the Federal Service for Supervision of Health (hereinafter - the registration authority).

4. In these Rules, the following definitions:

"The safety of medical products" - no unacceptable risk of harm to life, health or the environment when used for its intended purpose of a medical device under the conditions prescribed by the manufacturer;

"The quality of the medical device" - the totality of features and characteristics of a medical device that may affect its ability to function as intended if they meet the requirements of the regulatory, technical and operational documentation;

"Clinical trials" - designed and planned a systematic study undertaken, including with the participation of human subjects to evaluate the safety and efficacy of medical products;

"Normative documents" - documents governing the requirements of safety, quality, and efficiency of the alleged intended use and methods of monitoring compliance with these requirements of the medical device;

"Registration file" - a set of documents submitted for state registration, amendments to the registration certificate for the medical device, as well as copies of the decisions taken by the registering authority in respect of the medical device;

"Technical documents" - documents that govern the design of medical products, establishing technical requirements and provide the data for their development, production, use, operation, maintenance, repair, disposal or destruction;

"Technical test" - a test to determine whether the characteristics (properties) of the medical device regulatory requirements, technical and operational documentation and a further decision on the possibility of conducting clinical trials;

"Toxicological studies" - a study to assess the biological safety of medical products and a further decision on the possibility of conducting clinical trials;

"Authorized representative of the manufacturer" - a legal entity registered in the territory of the Russian Federation authorized by the manufacturer of the medical device to represent him on the treatment of medical products in the Russian Federation, including those pertaining to the conformity assessment procedures and the state registration, the name of which may be issued registration certificate for medical device;

"Operation documents" - documents intended to familiarize the user with the design of a medical device, subject to the terms and rules of operation (proper use, maintenance, maintenance, storage and transportation), guaranteed by the manufacturer values of the basic parameters, characteristics (properties) of the medical device, warranties, as well as information on proper disposal or destruction;

"The effectiveness of a medical device" - the totality of features and characteristics of the medical device to ensure the achievement of the destination specified by the manufacturer and confirmed by the practice of clinical applications.

5. The state registration of medical devices is carried out on the basis of results of technical tests, toxicological studies, clinical trials, which are forms of conformity assessment of medical devices with the classification depending on the potential risk of their application, and examination of the quality, effectiveness and safety of medical devices, as well as tests for approval of measuring instruments (in terms of health care products related to measuring instruments in the field of state regulation of traceability, the list of which is approved by the Ministry of Health of the Russian Federation).

6. The document confirming the state registration of medical device registration certificate for a medical device (hereinafter - the registration certificate.) Form registration certificate is approved by the registration authority.

Registration certificate shall be issued in perpetuity.

7. The state fee shall be paid in accordance with the legislation of the Russian Federation on taxes and fees.

Information about the payment of the fee requested by the registration authority in order interdepartmental cooperation in accordance with the Federal Law "On the organization of public and municipal services."

8. For state registration of medical device developer, manufacturer of the medical device manufacturer or his authorized representative (hereinafter - the applicant) is or send to the registering authority a statement on the state registration of medical products, as well as the documents referred to in paragraph 10 of this Regulation.

9. In a statement on the state registration of medical products (hereinafter - the application of registration) shall contain the following information:

a) the name of the medical device (with the accessories required for use of the medical device to the destination);

b) in respect of the developer - the complete and (if available) abbreviated name, including company name, legal form of a legal entity, the address (location), as well as phone numbers and (if applicable) Address E-mail address of the legal entity;

c) in relation to the manufacturer of a medical device - complete and (if available) abbreviated name, including company name, legal form of a legal entity, the address (location), as well as phone numbers and (if there is) e-mail address of the legal entity;

d) in relation to an authorized representative of the manufacturer - the full and (if available) abbreviated name, including company name, legal form of a legal entity, the address (location), as well as phone numbers and (if there is) e-mail address of the legal entity;

d) in respect of the legal person in whose name may be issued a registration certificate - full and (if available) abbreviated name, including company name, legal form of a legal entity, the address (location), and telephone numbers (if applicable) email address entity;

f) the place of production of medical products;

g) the appointment of a medical device, the manufacturer's;

h) the form of a medical device in accordance with the nomenclature classification of medical devices;

i) the class of the potential risk of using a medical device in accordance with the nomenclature classification of medical devices;

a) the code of the All-Russian classifier of products for the medical device;

l) information about how to obtain a registration certificate, as well as information relating to the procedure of state registration of medical products.

10. For state registration of medical products, the following documents:

a) a copy of the document confirming the authority of the authorized representative of the manufacturer;

b) information on the regulatory documentation for the medical device;

c) the technical documentation of the medical device;

g) maintenance documentation for the medical device, including instructions for use, or manual of the medical device;

d) photographic image of generic medical products, including accessories required for use of a medical device for its intended purpose (measuring at least 18 x 24 cm);

e) documents confirming the results of technical tests of the medical device;

g) documents confirming the results of toxicological studies of medical products, the use of which requires contact with the human body;

h) documents certifying the test results of the medical device to the type approval of measuring instruments (in terms of health care products related to measuring instruments in the field of state regulation of traceability, the list of which is approved by the Ministry of Health of the Russian Federation);

and) the list of documents.

11. If the originals of the documents mentioned in paragraph 10 of this Regulation, in a foreign language, they appear with a certified in the prescribed manner a Russian translation.

12. The timing and sequence of administrative procedures and administrative actions developed by the registering authority shall be established in accordance with the decision of the Government of the Russian Federation dated May 16, 2011 N 373 administrative regulations of the public service for the state registration of medical devices.

13. Application for registration and documents required by paragraph 10 of this Regulation, shall be submitted by the applicant to the registering authority on paper, either directly or sent by registered mail, return receipt requested, and a list of contents or in electronic form, signed by electronic signature.

The registration authority receives the application for registration and documents required by paragraph 10 of this Regulation, according to the list, a copy of which is with the receipt date of these statements and documents on the day of the reception given to the applicant or sent to him by registered mail, return receipt requested, or in electronic form.

14. The registering authority may not require the applicant to indicate in the application for registration of the information is not provided for by paragraph 9 of this Regulation and to submit documents not provided for by paragraph 10 of this Regulation.

15. Within 3 working days from the date of receipt of application for registration and documents required by paragraph 10 of this Regulation, the registration authority shall verify the completeness

and accuracy of the information contained therein, including by comparing these data with the data presented in the order of interdepartmental interaction.

16. If the application for registration executed in violation of the provisions of paragraph 9 of this Regulation, and (or) in the application are false information or documents required by paragraph 10 of this Regulation are not in full, the registration authority awards the applicant a notice of the need to eliminate the 30-day deadline violations and (or) the submission of documents that do not exist, or send such notice by certified mail, return receipt requested, or in the form of an electronic document signed by electronic signature.

17. Within 3 working days from the date of submission of duly executed application for registration in full and documents required by paragraph 10 of this Regulation, and in the case of elimination in the 30-day deadline violations and (or) the submission of documents required by paragraph 10 of this Regulation, the registration authority shall decide on the beginning of the state registration of medical devices.

18. If the 30-day period does not eliminate the revealed violations, and (or) no documents are missing, the registration authority shall take a decision on the return of the application for registration and the documents provided by paragraph 10 of this Regulation, a reasoned justification for reasons of return.

19. The state registration of medical devices carried by the registering authority within a period not exceeding 50 working days from the date of the decision on the state registration of medical devices.

The duration of the clinical trials of a medical device in the 50-day period is not included.

20. Within 3 working days from the date of the decision on the state registration of medical devices registration authority prepares and issues of reference for the examination of the quality, effectiveness and safety of the medical device of State Organization administered by the registration authority (hereinafter - the expert institution).

21. Examination of quality, efficacy and safety of a medical device expert institution conducted in stages in accordance with the procedure approved by the Ministry of Health of the Russian Federation:

a) Stage I is the examination of the registration application and the documents referred to in paragraph 10 of this Regulation to determine if the (impossible) to conduct clinical trials of medical products;

b) Phase II examination is complete and the results of technical tests, toxicological research, clinical trials, as well as tests for type approval of measuring instruments (in terms of health care products related to measuring instruments in the field of state regulation of traceability, the list of which is approved Ministry of Health of the Russian Federation) (hereinafter - the completeness of the examination and the results of tests and studies).

22. Stage I examination of the quality, effectiveness and safety of a medical device expert institution in a period not exceeding 20 working days from the date of receiving the task, perform the following actions:

a) examination of the registration application and documents required by paragraph 10 of this Regulation to determine if the (impossible) to conduct clinical trials of medical products;

b) the design and direction of the registering authority to enter into the possibility of (impossible) to conduct clinical trials of medical devices (with the reasons and justification for their inability to carry out), the form of which is approved by the Ministry of Health of the Russian Federation.

23. The basis for making expert institution conclusion about the impossibility of conducting clinical trials of a medical device is:

a) non-compliance of the medical device regulatory requirements, technical and (or) the operational documentation;

b) the absence of evidence to the biological safety of medical products.

24. Registration authority within 5 working days of receipt of the expert body report on capability (impossible) to conduct clinical trials of a medical device performs the following actions:

a) Evaluation of the task to determine whether to conduct examination of the quality, effectiveness and safety of medical products;

b) the decision to grant permission to conduct clinical trials of a medical device or to refuse the registration of a medical device, which is made by order of registration body, and notified the applicant of the decision;

c) issuing (the direction of a registered mail with return receipt or in the form of an electronic document signed by electronic signature) to the applicant permission to conduct clinical trials of a medical device, the form of which is approved by the registration authority, and make the appropriate data in the register of issued permits to conduct clinical trials of medical products, conduct which is approved by the registration authority, or a notice of refusal of state registration of medical products and the reasons for refusal.

25. The basis for the decision to refuse the registration is to obtain the registration authority of the expert institution conclusion about the impossibility of conducting clinical trials of a medical device.

26. Clinical trials of medical devices are made within the framework of the conformity assessment procedures of which is approved by the Ministry of Health of the Russian Federation.

Clinical trials of medical devices are carried out with the authorization to conduct clinical trials, issued by the registering authority, as well as conclusions about the ethical justification for clinical trials, issued by the Board of Ethics of the Ministry of Health of the Russian Federation, in the cases established by the said Rules.

The composition of this Council on Ethics and the position shall be approved by the Ministry of Health of the Russian Federation.

Clinical trials of medical devices are held in health care organizations that meet the requirements approved by the Ministry of Health of the Russian Federation. The mapping of health facilities to these requirements is the registration authority in the manner prescribed by the Ministry said.

27. The list of health organizations authorized to conduct clinical trials of medical devices, and register of permits to conduct clinical trials of medical devices publishes the registering body in the established order on its official website in the information and telecommunications network "Internet".

28. In deciding whether to issue a permit to conduct clinical trials of a medical device registration authority shall decide on the suspension of state registration of medical products to the date of the decision to renew the registration authority of state registration of medical devices in accordance with paragraph 30 hereof.

29. On the clinical trials of a medical device registration authority shall notify the applicant within 5 working days from the start of their meeting.

30. Upon completion of clinical trials of medical products the applicant shall submit to the registering authority application for the renewal of state registration of the medical device and the results of clinical trials of a medical device.

31. Registering Authority within 2 working days of receipt of the application for renewal of the state registration of medical products and the results of clinical trials of a medical device shall decide on the resumption of state registration of medical products.

32. Phase II examination of the quality, effectiveness and safety of a medical device registration authority within two working days from the date of the decision on the resumption of state registration of medical devices on the basis of reference for the examination of the quality, effectiveness and safety of a medical device, issued in accordance with paragraph 20 of these Rules should send to the expert institution by the applicant the results of clinical trials of a medical device.

33. Expert institution in a period not exceeding 10 working days from the date of receipt of the documents referred to in paragraph 32 of this Regulation, examines the completeness and the results of tests and studies, and prepares and sends to the registering authority conclusion of the examination of quality, efficiency and safety of health product form approved by the Ministry of Health of the Russian Federation.

34. In a period not exceeding 10 working days from the date of receipt of the opinion referred to in paragraph 33 of this Regulation, the registration authority shall perform the following activities:

a) Evaluation of the task to determine whether to conduct examination of the quality, effectiveness and safety of medical products;

b) decision on the state registration of medical products or to refuse the registration of a medical device, which is made by order registration authority, and notified the applicant of the decision;

c) the design and delivery of (the direction of a registered mail with return receipt or in the form of an electronic document signed by electronic signature) to the applicant registration certificate or notice of denial of state registration of medical products and the reasons for refusal.

35. The basis for the decision to refuse the registration of a medical device is to obtain the registration authority of the expert body report on the results of examination of quality, efficacy and safety of medical products, which indicates that the quality and (or) efficiency and (or) the safety of a medical device is not detected confirmed the findings, and (or) that the risk of harm to public health and medical professionals due to the use of a medical device exceeds its effectiveness.

36. Within 1 business day after the decision on the state registration of medical device registration authority shall enter the data on the registered medical device in the state register of medical devices and organizations engaged in the production and manufacture of medical devices, in the manner prescribed decree of the Government of the Russian Federation on June 19, 2012 N 615.

37. Amendment of registration certificate in the following cases:

a) changes in the information about the applicant, including information:

the reorganization of the legal entity;

to change its name (full and (if available) abbreviated, including company name), address (location);

b) change of address (place of production) of the medical device;

c) the change of the name of the medical device (in case you have not changed the properties and characteristics that affect the quality, efficacy and safety of medical products).

38. To make changes in the registration certificate of the applicant not later than 30 working days from the date of making the appropriate changes is either sends the registration authority the application to amend the registration certificate (hereinafter - the request for the change), drawn up in accordance with the provisions of paragraph 9 of this Regulation , with the application of such changes and indicating that changes in the certificate of registration does not entail a change in the properties and characteristics that affect the quality, efficacy and safety of medical products, as well as the following documents:

a) a copy of the document confirming the authority of the authorized representative of the manufacturer;

b) the number of the registration dossier;

a) the list of documents.

39. In addition to statements on amendments and documents required by paragraph 38 of this Regulation shall also be submitted:

a) in the case of changes in information about the applicant, as well as the place of production of medical products - documents confirming such changes;

b) in the case of change of name of the medical device:

information on the regulatory documentation for the medical device;

technical documentation for the medical device, harmonized with the new name of the medical device;

operational documentation for the medical device, including instructions for use, or operation manual of the medical device, harmonized with the new name of the medical device;

photographic image of the common types of medical products, including accessories required for use of a medical device for its intended purpose (measuring at least 18 x 24 centimeters).

40. If the original documents provided by paragraphs 38 and 39 of this Regulation, in a foreign language, they are presented with a certified in the prescribed manner a Russian translation.

41. Statement on amendments and documents required by paragraphs 38 and 39 of this Regulation shall be adopted by the registration authority according to the list, a copy of which is with the receipt date of these statements and documents on the day of the reception given to the applicant or sent to him by registered mail, return receipt requested, or in the form of an electronic document signed by electronic signature.

42. The registering authority may not require the applicant to furnish documents not covered by paragraphs 38 and 39 of this Regulation.

43. Within 3 working days from the date of receipt of applications for amendments and documents required by paragraphs 38 and 39 of this Regulation, the registration authority shall verify the completeness and accuracy of the information contained in them, including through comparison of such data with the information submitted in the order of interdepartmental information exchange.

44. In the event that the application for modification is not accompanied by the documents in accordance with sub-paragraph "a" of paragraph 39 of these Regulations, and (or) in the statement of changes are false information or documents required by paragraphs 38 and 39 of this Regulation are not in full, the registration authority awards the applicant a notice of the need to eliminate the 30-day deadline violations and (or) the submission of documents that do not exist, or send a notice in the form of an electronic document signed by electronic signature or by registered mail, return receipt requested.

45. Within 3 working days from the date of submission of duly executed application for amendments in full and documents required by paragraphs 38 and 39 of this Regulation, the registration authority shall take a decision on the review of these documents or statements, and (in the case of non-compliance with the provisions of paragraphs 38 and 39 of the Regulation) on their return to the reasoned justification for reasons of return.

46. If the 30-day period does not eliminate the revealed violations, and (or) no documents are missing, the registration authority shall take a decision on the return of the application of the amendments and documents required by paragraphs 38 and 39 of this Regulation, a reasoned justification for reasons of return.

47. Amendment of registration certificate is the registration authority within a period not exceeding 10 working days from the date of the decision on the review of applications for amendments and documents required by paragraphs 38 and 39 of this Regulation.

48. Timing of registering authority to amend the certificate of registration shall be calculated from the date of receipt of the registration authority duly issued statements on changes and the full documents required by paragraphs 38 and 39 of this Regulation.

49. When changes are made in the registration certificate registration authority within 10 working days of undertaking the following activities:

a) a decision to amend the registration certificate, which is issued the order the registration authority;

b) a notice in writing to the applicant of the decision by certified mail with return receipt or in the form of an electronic document signed by electronic signature;

c) the design and delivery of (the direction of a registered mail with return receipt or in the form of an electronic document signed by electronic signature) registration certificate to the applicant.

50. When making the decision to amend the registration certificate registration authority prepares and issues a registration certificate to the applicant with putting on a previously issued registration certificate, the original of which is either sent (by registered mail with return receipt or in the form of an electronic document signed by electronic signature) by the applicant at receive a new registration certificate, a mark of his invalidity (with date).

51. Within 1 business day after the decision to amend the certificate of registration related information entered in the state register of medical devices and organizations engaged in the production and manufacture of medical devices, in the manner prescribed decree of the Government of the Russian Federation dated June 19, 2012 N 615.

52. In case of loss of the registration certificate or its damage the applicant may apply to the registering authority with the statement for a duplicate registration certificate (hereinafter - application for a duplicate).

In case of damage of the registration certificate to an application for a duplicate registration certificate is attached spoiled.

53. Within 3 working days from the date of receipt of the documents referred to in paragraph 52 of this Regulation, the registration authority draws up a duplicate registration certificate registration certificate on the form marked "duplicate" and "original registration certificate is recognized as invalid," and presents a duplicate copy to the applicant or send it by registered mail mail with return receipt requested.

54. Registration body forms a registration dossier of the following documents:

a) the application for registration and the documents provided by paragraph 10 of this Regulation, the application for modification and documents required by paragraphs 38 and 39 , as well as an application for a duplicate;

b) a copy of reference for the examination of the quality, effectiveness and safety of a medical device, issued by the registering authority;

c) a copy of the permit issued by the registering authority to conduct clinical trials of medical products;

g) a statement furnished expert institution in the examination of quality, efficacy and safety of medical products;

d) copies of orders, designed by the registering authority;

e) a copy of the registration certificate or notice furnished by the registering authority;

g) a duplicate copy of registration certificate issued by the registering authority.

55. In case of change of the documents provided in subparagraph "a" of paragraph 54 of these Rules, the applicant within a period not exceeding 30 working days from the date of making the appropriate changes, notify the registration authority in the submission of documents confirming such changes.

Keeping the registration dossier is the registration authority in the manner prescribed by the legislation of the Russian Federation on archives.

56. The registration certificate shall contain the following information:

a) the name of the medical device (with the accessories required for use of the medical device to the destination);

b) the date of the state registration of medical products and its registration number;

c) in respect of a legal person in whose name the registration certificate - full and (if available) abbreviated name, including company name, legal form and the address (location);

d) in relation to the manufacturer - the full and (if available) abbreviated name, including company name, legal form and the address (location);

d) the place of production of medical products;

e) The number of registration dossiers;

g) the type of medical device in accordance with the nomenclature classification of medical devices approved by the Ministry of Health of the Russian Federation;

h) the class of potential risk of using a medical device in accordance with the nomenclature classification of medical devices approved by the Ministry of Health of the Russian Federation;

i) Code of All-Russian classifier of products for the medical device.

57. The registration authority shall take a decision to cancel the state registration of medical products in the following cases:

a) the applicant filing the application to cancel the state registration of medical products;

b) a court to violating the rights holder to the results of intellectual activity and means of individualization in handling medical products;

a) Submission of the Government of the Russian Federation authorized federal executive body, of its state control over the management of medical devices, information confirming the facts and circumstances that threaten the lives and health of citizens and health professionals in the application and operation of medical devices.

58. Registering Authority publishes information related to the implementation of state registration of a medical device, tampering, registration certificate and issue of duplicate registration certificate on its website in the information and telecommunications network "Internet".

59. Decisions and actions (inaction) of the registration authority, which led to the violation of the rights of a legal person may be appealed by the applicant in the manner prescribed by the legislation of the Russian Federation.