GOVERNMENT OF THE RUSSIAN FEDERATION

DECREE
of December 27, 2012 N 1416

On 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. To approve the rules of state registration of medical devices.

2. Establish that:

a) registration for medical devices and medical equipment to the fixed term of the issued before the coming into force of this Regulation, in force until the expiration of the period of validity in them;

b) registration for medical devices and medical equipment indefinite action, issued before the entry into force of this Regulation shall be valid and must be replaced prior to January 1, 2014 on the registration certificate in the form approved by the Federal Service for Supervision of Health.
Replacement of the registration certificate of the procedure is carried out without state registration of medical devices based on the application submitted by the applicant to the Federal Service for Supervision of Health, including the data provided by the Rules, approved this decision.

3. The state registration of medical products submitted for state registration before the coming into force of this Regulation, on the basis of documents submitted to the entry into force of this Regulation, as well as the application for state registration of medical products, the claimant in accordance with the rules approved by this Decision, 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 the central office of the Federal Service on Surveillance in Healthcare and the budget allocations to the Service in the federal budget for management and administration in the field of statutory functions.

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

Prime Russian Federation
DMITRY MEDVEDEV

Approved by
the Government Russian Federation
on December 27, 2012 N 1416

RULES
STATE REGISTRATION OF MEDICAL PRODUCTS

1. These Rules establish the procedure for state registration of medicinal products to be treated in the Russian Federation.

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

Medical products, custom tailored patients have to meet special requirements for the appointment of medical workers and intended solely for the personal use of the individual 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" - the absence of unacceptable risk of harm to human life, health and the environment by using a medical device for its intended purpose as prescribed by the manufacturer;

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

"Clinical trials" - designed and planned systematic study undertaken, including those involving human subjects to evaluate the safety and effectiveness of a medical device;

"Normative documents" - documents governing the requirements of safety, quality, and efficiency provided by the intended use and methods of control of conformity of the medical device with these requirements;

"Registration file" - a set of documents to be submitted for registration, changes in registration for the medical device, as well as copies of the decisions adopted by the registration authority for a particular medical device;

"Technical Documentation" - the documents governing 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 requirements of the regulatory, technical and operational documentation and subsequent decision on the possibility of clinical trials;

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

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

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

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

5. The state registration of medical devices is carried out on the basis of results of technical tests, toxicology studies, clinical trials, is a form 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 type approval of measuring instruments (in relation to medical devices 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 fact of state registration of a medical device, is a registration certificate for medical device (hereinafter - the certificate of registration). The form of the registration certificate is approved by the registration authority.

Registration certificate issued indefinitely.

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

Information on payment of the fee requested by the registration authority in order interdepartmental interaction in accordance with the Federal Law "On the organization of state and municipal services."

8. For state registration of a medical device developer, manufacturer of a medical device manufacturer or his authorized representative (hereinafter - the applicant) is or send the registration authority application for 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 for registration) shall contain the following information:

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

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

c) in relation to the manufacturer of a medical device - a full and (if applicable) the abbreviated name, including the brand name, the 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 applicable) the abbreviated name, including the brand name, the 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;

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

f) the place of production of medical products;

g) the appointment of a medical device, installed by the manufacturer;

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

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

k) the code of National Classificator of products for the medical device;

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

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

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

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

c) the technical documentation for the medical device;

d) maintenance documentation for the medical device, including the instruction manual or operating instructions of the medical device;

e) the general form of a photographic image of the medical device with the accessories necessary for the application of a medical device for the purpose (of at least 18 x 24 cm);

e) proof of the results of technical tests of the medical device;

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

h) proof of the test results of a medical device for type approval of measuring instruments (in relation to medical devices 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 original documents referred to in paragraph 10 of this Regulation, in a foreign language, they are presented with a duly certified translation into Russian.

12. Timing and sequence of administrative procedures and administrative activities of the registering authority set developed in accordance with the Government of the Russian Federation on May 16, 2011 N 373 administrative regulations providing public services to the state registration of medical devices.

13. Registration statement and the documents referred to paragraph 10 of this Regulation, shall be submitted by the applicant to the registering body directly on paper or sent by registered mail with return receipt requested, and the list of contents or in electronic form, signed by electronic signature.

Registration authority receives the application for registration and the documents required by paragraph 10 of this Regulation, according to the list, a copy of which is with the receipt date of the

application and documents on the day of the reception given to the applicant or sent to him by registered mail with return receipt requested or by electronic means.

14. The registering authority may not require the applicant to indicate on the registration information that is not provided for by paragraph 9 of these Rules, and submit documents not provided for by paragraph 10 of this Regulation.

15. Within 3 working days from the receipt of the registration application and documents required by paragraph 10 of this Regulation, the registration authority shall verify the completeness and accuracy of information contained therein, including by comparing these data with the data presented in the order of interdepartmental cooperation.

16. If the application for registration executed in violation of the provisions of paragraph 9 of this Regulation, and (or) in a statement given false information or documents required by paragraph 10 of this Regulation, are not in full, the registration authority awarding the applicant a notice to remove the 30-day period of violations, and (or) the submission of documents that do not exist, or send the 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 the duly registration application in full and documents required by paragraph 10 of this Regulation, and in the case of elimination of the 30-day period of violations, and (or) the submission of documents under paragraph 10 of this Regulation, the registration authority shall decide on the beginning of the state registration of medical devices.

18. If in 30 days, not eliminated the violations, and (or) no documents are missing, the registration authority shall decide on the return of the registration application and documents required by paragraph 10 of this Regulation, with a reasoned justification for reasons of return.

19. The state registration of medical devices by the registering authority within a period not exceeding 50 working days from the date when 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 when the decision on the state registration of medical devices registration body prepares and provides reference for the examination of the quality, effectiveness and safety of the medical device of State Organization, held by the registration authority (hereinafter - the expert institution).

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

a) I stage, the examination of the registration application and the documents referred to in paragraph 10 of this Regulation, to determine the possibility (impossibility) of clinical trials of a medical device;

b) in the II stage, the complete examination and the results of technical tests, toxicology studies, clinical trials, as well as tests for type approval of measuring instruments (in relation to medical devices 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 complete examination and test results and research).

22. On the I stage of the examination of quality, efficacy and safety of a medical device expert institution in a period not exceeding 20 working days from receipt of the job, perform the following actions:

a) examination of the registration application and documents required by paragraph 10 of this Regulation, to determine the possibility (impossibility) of clinical trials of a medical device;

b) the design and direction of the registration authority to enter into the possibility (impossibility) of clinical trials of a medical device (with the reasons and justification for their conduct can not), the shape of which is approved by the Ministry of Health of the Russian Federation.

23. The basis for the conclusions made by the expert agency on the impossibility of conducting clinical trials of a medical device is:

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

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

24. Registration authority within 5 working days of receipt of the expert institution conclusions about the possibility (impossibility) of clinical trials of a medical device performs the following actions:

a) evaluation of the job to determine if on examination of quality, effectiveness and safety of a medical device;

b) the decision to issue a permit to conduct clinical trials of a medical device or to refuse the registration of a medical device, issued by order of the registering authority, and notified the applicant of the decision;

c) issuing (direction by certified mail, return receipt requested, 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 permits to conduct clinical trials of medical product, the order of which is approved by the registration authority, or a notice of denial of state registration of the medical device with the reasons for refusal.

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

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

Clinical trials of medical devices are conducted on the basis of permission to conduct clinical trials, issued by the registering authority, as well as conclusions about the ethical validity of clinical trials, issued by the Council on 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 medical organizations that meet the requirements approved by the Ministry of Health. The mapping of health facilities to these requirements by the registration authority in the manner prescribed by the Ministry.

27. The list of medical institutions with the right to conduct clinical trials of medical devices, and the registry of permits to conduct clinical trials of medical devices publishes the registration authority in the manner prescribed on its 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 the medical device to the date of the decision of the registering authority to renew the state registration of medical devices in accordance with paragraph 30 of these Regulations.

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

30. Upon completion of the clinical trials of a medical device applicant submits an application to the registration authority for the reopening of state registration of medical device and clinical trials of a medical device.

31. Registration authority within two working days of receipt of an application to renew the state registration of medical device and clinical trials of a medical device makes a decision on the resumption of the state registration of a medical device.

32. At the II stage of the examination of quality, effectiveness and safety of the medical device registration authority within two working days from the date of the decision on the resumption of the state registration of a medical device based on the job to an examination of the quality, effectiveness and safety of a medical device, issued in accordance withparagraph 20 of these Regulations , sends expert institution in the claimant clinical trials of a medical device.

33. Expert institution in a period not exceeding 10 working days of receipt of the documents mentioned in paragraph 32 of this Regulation, examines the completeness and the results of tests and studies, and prepares and sends to the registration authority conclusion of the examination of quality, effectiveness and safety of the medical products, which form is approved by the Ministry of Health.

34. In a period not exceeding 10 working days 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 job to determine if on examination of quality, effectiveness and safety of a medical device;

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

c) the execution and delivery of (the direction of 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 the medical device with 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 institution conclusion of the examination of quality, efficacy and safety of a medical device, which indicates that the quality and (or) the 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 the efficiency of its use.

36. Within 1 business day after the decision on the state registration of the 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 manufacturing of medical devices, in the manner prescribed by the Government of the Russian Federation on June 19, 2012 N 615.

37. Changes to the marketing authorization in the following cases:

a) changes in the information about the applicant, including information: on the reorganization of the legal entity;

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

b) change of Address (production) of the medical device;

c) the change of the name of the medical device (if not changed the properties and characteristics that affect the quality, efficacy and safety of a medical device).

38. To make changes to the registration certificate the applicant not later than 30 working days after making the appropriate changes is either forwarded to the registration authority an 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 these changes and indicating that changes in the registration certificate does not change 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 an authorized representative of the manufacturer;

b) the number of the registration dossier;

a) the list of documents.

39. In addition to the statement of changes and documents provided by paragraph 38 of this Regulation shall also be submitted:

a) in the case of change of information about the applicant, as well as the place of manufacture of a medical device - evidence of such changes;

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

information on the standard 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 the instruction manual or operating instructions of the medical device harmonized with the new name of the medical device;

photographic image of the general form of a medical device with accessories necessary for the application of a medical device for the purpose (of at least 18 x 24 centimeters).

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

41. Statement of changes 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 the application and documents on the day of the reception given to the applicant or sent to him by registered mail with return receipt or in the form electronic document signed with an 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 receipt of the statement of changes 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 by comparing such data with the information presented in the order of interagency information exchange.

44. If 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 inaccurate information or documents required by paragraphs 38 and 39 of this Regulation, are not in full, the registration authority awarding the applicant a notice to remove the 30-day period of 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 with return receipt requested.

45. Within 3 working days from the date of submission of a properly issued statements on the amendments and the full documents required by paragraphs 38 and 39 of this Regulation, the registration authority shall decide on the review of the application and documents, or (if not in compliance with the provisions of paragraphs 38 and 39 of the Regulation) on their return with a reasoned justification for reasons of return.

46. If in 30 days, not eliminated the violations, and (or) no documents are missing, the registration authority shall decide on the return of the application to amend and documents required by paragraphs 38 and 39 of this Regulation, with a reasoned justification for reasons of return.

47. Amendment of registration certificate by the registering 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 the decision by the registration authority to amend the certificate of registration shall be calculated from the date of receipt of the registration authority of the duly statements for changes in full and documents required by paragraphs 38 and 39 of this Regulation.

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

a) a decision to amend the certificate of registration, issued by order of the registering authority;

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

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

50. When making the decision to amend the registration certificate registration authority draws up and issues a registration certificate to the applicant with the stamp on the previously issued registration certificate, the original of which is submitted or sent (by registered mail with return receipt requested, or in the form of an electronic document signed by electronic signature), the applicant for receive a new registration certificate, the mark of its invalidity (with date).

51. Within 1 business day after the decision to amend the registration certificate relevant information entered in the state register of medical devices and organizations engaged in the production and manufacturing of medical devices, in the manner prescribed by the Government of the Russian Federation on 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 - the application for a duplicate.)

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

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

54. Registration body shapes registration dossier of the following:

a) the application for registration and documents required by paragraph 10 of this Regulation, a statement of changes 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 a medical device;

d) conclusion decorated expert institution during the examination of quality, efficacy and safety of a medical device;

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

e) a copy of the registration certificate or notification, designed by the registering authority;

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

55. If you change the documents specified in subparagraph "a" of paragraph 54 of these Rules, the applicant within a period not exceeding 30 working days after 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 accordance with the legislation of the Russian Federation on the archives.

56. The registration certificate shall contain the following information:

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

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

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

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

d) the place of production of medical products;

e) the number of registration dossiers;

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

i) Code National Classification of products for the medical device.

57. Registration authority decides 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 a violation of the rights holder of intellectual property and similar means of identification when accessing medical devices;

a) submission by the Russian Federation authorized federal executive body for the results of their ongoing 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. Registration agency publishes information related to the implementation of state registration of the medical device amendments to the registration certificate and a duplicate registration certificate, on its official 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 entity, may be appealed by the applicant in accordance with the legislation of the Russian Federation.