

# **GOVERNMENT OF THE RUSSIAN FEDERATION**

## **RESOLUTION**

of December 27, 2012, No. 1416

MOSCOW

### **On Approval of the Rules for State Registration of medical devices**

Pursuant to Article 38, Federal Law on Public Health Fundamentals in the Russian Federation, the Government of the Russian Federation **resolves:**

1. To approve the attached Rules for State Registration of medical devices.
2. To establish that:
  - a) medical device and medical equipment registration certificates with a fixed validity period, issued before the effective date of this Resolution, shall be valid until the expiry date specified therein;
  - b) medical device and medical equipment registration certificates with an unlimited validity period, issued before the effective date of this Resolution, shall be valid until and be replaced on January 1, 2014, with registration certificates in the format approved by the Federal Service for Healthcare Supervision.

A registration certificate shall be replaced without the repeated state registration of medical devices, on the basis of the application submitted by the applicant to the Federal Service for Healthcare Supervision and containing the information envisaged in the Rules provided for by this Resolution.

3. State registration of the medical devices presented for state registration before the effective date of this Resolution shall be carried out on the basis of the documents made available before the effective date of this Resolution and of the application for medical device state registration, which was submitted by the applicant in accordance with the Rules provided for by this Resolution to the Federal Service for Healthcare Supervision.

4. The powers set forth in this Resolution shall be exercised by the headquarters employees of the Federal Service for Healthcare Supervision, not exceeding the maximum headcount established by the Government of the

Russian Federation and within the budget appropriations to the Service in the federal budget for governance and management in the established functions.

5. This Resolution shall inure on January 1, 2013.

Chairman, Government of  
the Russian Federation

D. Medvedev

APPROVED  
By Resolution of the Russian  
Federation Government  
of December 27, 2012,  
No. 1416

**R U L E S**  
**for State Registration of medical devices**

1. These Rules establish the procedure for state registration of medical devices to be in circulation in the Russian Federation.

2. Any medical appliances, apparatuses, devices, equipment, materials and other products applied for medical purposes either separately or in combination with each other as well as with other accessories required for administration of these products as intended, including customized software, and designed by the manufacturer for prevention, diagnosis, treatment and aftercare of diseases, health status monitoring, medical tests, recovery/ replacement of or change in the anatomy or physiological functions of the body, pregnancy prevention or termination, the functional purpose of which is not implemented through pharmacological, immunological, genetic or metabolic impact on the human body (hereinafter “medical devices”), shall be subject to state registration.

medical devices customized to patients’ individual orders, to which special requirements apply at the prescription of medical professionals and which are intended for personal use by a particular person only, shall not be subject to state registration.

3. State registration of medical devices shall be carried out by the Federal Surveillance Service for Healthcare (hereinafter the ‘registration authority’).

4. The following principal notions shall also be used in these Rules:

"medical device safety" means the absence of an unacceptable human life, health or environmental risk associated with the medical device use for its intended purpose in the conditions envisaged by the manufacturer;

"medical device quality" means a set of features and properties of a medical device that influence its ability to act as intended if the requirements of regulatory, technical and operational documents are met;

"Clinical trials" means a developed and planned continuous trial involving, in particular, a human being as its subject and held to assess a medical device safety and efficacy;

"Regulations" means the documents that govern safety, quality, proposed efficacy of the proposed administration and the methods of control over conformity of a medical device with these requirements;

"Registration file" means a set of documents provided for state registration, making amendments to the registration certificate of a medical device as well as to copies of the resolutions taken by the registration authority on a particular medical device;

"Technical documents" means the documents that govern a medical device design, establish technical requirements and contain data for its development, production, administration, operation, maintenance, repairs, disposal or destruction;

"Technical trials" means the trials aimed at determining whether or not the properties/ features of a medical device meet the requirements of regulatory, technical and operating documents and making a subsequent decision as to the possibility of clinical trials;

"Toxicity studies" means the trials aimed at assessing biological safety of a medical device and making subsequent decision as to the possibility of clinical trials;

"Manufacturer's authorized representative" means a legal entity registered in the Russian Federation, which is authorized by a medical device manufacturer to represent its interests in connection with circulation of the medical device in the Russian Federation, in particular, in connection with conformity assessment and state registration, and in the name of which the registration certificate of a medical device may be issued;

"Operating documents" means the documents intended to introduce the consumer to a medical device design, which govern operating conditions and rules (the medical device use as intended, maintenance, current repairs, storage and transportation), values of the main parameters and features/ properties of the medical device guaranteed by the manufacturer, the warranty policy as well as information on its disposal or destruction;

"medical device efficacy" means the set of medical device properties and features that guarantee achievement of the administration purposes established by the manufacturer and of clinical administration proved by practice.

5. State registration of medical devices is carried out based on the findings of technical trials, toxicity studies and clinical trials, which represent the forms of conformity assessment for medical devices, taking into account the classification, depending on the potential risk of their administration, and of the expert examination of quality, efficacy and safety of medical devices as well as of the trials aimed at approving the type of measuring tools (with respect to medical devices classified as measuring tools in governmental regulation of the

uniformity of measurements, the list of which is approved by the Ministry of Health of the Russian Federation).

6. The registration certificate for a medical device (hereinafter the 'registration certificate') shall be the document confirming actual state registration of a medical device. The format of the registration certificate shall be approved by the registration authority.

The registration certificate shall be issued for an indefinite period.

7. The state duty shall be paid in accordance with Russian law on taxes and charges.

The information on payment of the state duty shall be requested by the registration authority by way of inter-departmental information exchange, in accordance with the Federal Law on Provision of Federal and Municipal Services.

8. For state registration of a medical device, the developer or the manufacturer of the medical device or the manufacturer's authorized representative (hereinafter the 'applicant') shall submit or send the application for state registration of the medical device as well as the documents listed in Section 10 of these Rules to the registration authority.

9. The application for state registration of a medical device (hereinafter the 'registration application') shall contain the following information:

a) name of the medical device (indicating the accessories required for administration of the medical device as intended);

b) with respect to the developer, the full and (if any) abbreviated name, in particular, corporate name, legal form of incorporation of the legal entity, address (location), telephone numbers and (if any) email address of the legal entity;

c) with respect to the manufacturer of the medical device, the full and (if any) abbreviated name, in particular, the corporate name, legal form of incorporation of the legal entity, address (location), telephone numbers and (if any) email address of the legal entity;

d) with respect to the manufacturer's authorized representative, the full and (if any) abbreviated name, including corporate name, legal form of incorporation of the legal entity, address (location), as well as telephone numbers and (if any) email address of the legal entity;

e) with respect to the legal entity, in the name of which the registration certificate may be issued, the full and (if any) abbreviated name, including corporate name, legal form of incorporation of the legal entity, address (location), telephone numbers and (if any) email address of the legal entity;

f) place of manufacturing of the medical device;

g) medical device indication as established by the manufacturer;

h) type of the medical device, in accordance with the stock classification of medical devices;

i) category of the potential risk of a medical device administration, in accordance with the stock classification of medical devices;

j) code in the All-Russian Products Classifier for the medical device;

k) information on the method of obtaining the registration certificate and information on the state registration procedure for the medical device.

10. The following documents shall be provided for state registration of a medical device:

a) a copy of the proxy evidencing powers of the manufacturer's authorized representative;

b) information on regulations on the medical device;

c) technical documents on the medical device;

d) operating documents on the medical device, including user's manual or operation manual of the medical device;

e) picture of the visual appearance of the medical device with all accessories required for administration of the medical device as intended (min. size 18 cm × 24 cm);

f) documents evidencing the findings of technical trials with the medical device;

g) documents evidencing the findings of toxicity studies with the medical device, which is administered by contact with a human body;

h) documents evidencing the findings of the medical device trials for the purpose of approval of the type of measuring tools (with respect to medical devices classified as measuring tools in governmental regulation of the uniformity of measurements, the list of which is approved by the Ministry of Health of the Russian Federation);

i) record statement.

11. If the original documents set forth in Section 10 of these Rules are made in a foreign language, they shall be provided with duly certified Russian translation.

12. The deadlines and the succession of administrative procedures and efforts taken by the registration authority shall be set forth in the Administrative Regulations on Provision of the Governmental Service Involving State Registration of medical devices as developed in accordance with Resolution No. 373 of the Government of the Russian Federation dated May 16, 2011.

13. The registration application and the documents envisaged in Section 10 of these Rules shall be submitted by the applicant to the registration authority as hard copy by hand or sent by registered mail with return receipt and the list of enclosures or electronically with electronic signature.

The registration authority shall receive the registration application and the documents envisaged in Section 10 of these Rules on the basis of the list of enclosures, a copy of which, marked with the date of receipt of the said application and documents on the date of receipt, shall be handed in to the applicant or sent to the applicant by registered mail, with return receipt, or electronically.

14. The registration authority shall have no right to require that the applicant indicates any information not envisaged in Section 9 of these Rules in the registration application or submits the documents not envisaged in Section 10 of these Rules.

15. Within 3 business days following receipt of the registration application and the documents envisaged in Section 10 of these Rules, the registration authority shall verify completeness and reliability of the information contained in them, in particular, by comparing such information with the information provided by way of inter-departmental information exchange.

16. If the registration application is drafted in violation of Section 9 of these Rules and/or the application provides unreliable information or the documents envisaged in Section 10 of these Rules have not been provided in full, the registration authority shall send the notice as to the need to rectify the detected violations and/or to submit missing documents within 30 days to the applicant, or send such notice by registered mail, with return receipt, or as electronic document signed with electronic signature.

17. Within 3 business days from presentation of a duly issued registration application and of the full set of documents envisaged in Section 10 of these Rules, and also if the detected violations are eliminated and/or the documents envisaged in Section 10 of these Rules are provided within 30 days, the registration authority shall make a decision to start state registration of the medical devices.

18. If the detected violations have not been rectified and/or the missing documents have not been provided within 30 days, the registration authority shall make a decision to return the registration application and the documents envisaged in Section 10 of these Rules, with substantiation of reasons for return.

19. State registration of medical devices shall be carried out by the registration authority within 50 business days following the date when the decision as to the start of state registration of medical devices was made.

The period of clinical trials of the medical device shall not be included into this 50-days' period.

20. Within 3 business days from making a decision as to the start of state registration of medical devices, the registration authority shall issue and make available the assignment for expert examination of medical device quality,



efficacy and safety to the federal state budgetary institution that reports to the registration authority (hereinafter the ‘expert institution’).

21. The expert institution shall carry out the expert examination of medical device quality, efficacy and safety on a stage-by-stage basis, in accordance with the procedure established by the Ministry of Health of the Russian Federation:

a) at Stage I, the expert examination of the registration application and the documents set forth in Section 10 of these Rules is carried out, to determine if it is possible (impossible) to carry out clinical trials of the medical device;

b) at Stage II, the expert examination of completeness and findings of conducted technical trials, toxicity studies and clinical trials, as well as the trials intended to approve of the type of measuring tools (with respect to medical devices classified as measuring tools in governmental regulation of the uniformity of measurements, the list of which is approved by the Ministry of Health of the Russian Federation) (hereinafter, the ‘expert examination of completeness and findings of trials and studies’) is carried out.

22. At Phase I of the expert examination of medical device quality, efficacy and safety, the expert institution shall, within 20 business days following the receipt of the assignment, take the following efforts:

a) expert examination of the registration application and documents set forth in Section 10 of these Rules, to determine if it is possible or impossible to carry out clinical trials of the medical device;

b) issue and sending of the opinion as to the possibility/ impossibility of clinical trials of the medical device (indicating reasons for and substantiating the impossibility to hold them), the format of which shall be approved by the Ministry of Health of the Russian Federation, to the registration authority.

23. The following shall substantiate making by the expert institution of the opinion as to the impossibility to hold clinical trials of a medical device:

a) non-conformity of the medical device to regulatory, technical and/or operating documents;

b) lack of proofs of biological safety of the medical device.

24. The registration authority shall, within 5 business days following the receipt of the opinion as to the possibility/ impossibility of clinical trials of a medical device from the expert institution, take the following efforts:

a) assessment of the opinion, to determine its conformity to the assignment for expert examination of medical device quality, efficacy and safety;

b) making a decision as to issue of the permit for clinical trials of the medical device or as to refusal to carry out state registration of the medical

device, which is made by order of the registration authority, with a notice to the applicant as to the decision made;

c) issue (sending by registered mail, with return receipt, or in the form of electronic document signed with electronic signature) of the permit to the applicant to conduct clinical trials of the medical device, the format of which shall be approved by the registration authority, and entry of the appropriate information into the register of issued permits to conduct clinical trials of a medical device, the procedure of which shall be approved by the registration authority, or a notice as to refusal to carry out state registration of the medical device, indicating reasons for refusal.

25. Receipt by the registration authority of the opinion as to the impossibility to carry out clinical trials of the medical device from the expert institution shall substantiate making a decision as to refusal to carry out state registration.

26. Clinical trials of a medical device shall be held as part of the conformity assessment, the procedure for which shall be approved by the Ministry of Health of the Russian Federation.

Clinical trials of a medical device shall be carried out based on the permit to conduct clinical trials, issued by the registration authority, as well as the opinion on the ethical substantiation of clinical trials, issued by the ethical board at the Ministry of Health of the Russian Federation, in cases established in these Rules.

The composition of the said ethical board and the regulations on it shall be approved by the Ministry of Health of the Russian Federation.

Clinical trials of a medical device shall be carried out in medical institutions that meet the requirements approved by the Ministry of Health of the Russian Federation. The registration authority establishes conformity of medical institutions to these requirements as envisaged by this Ministry.

27. The list of medical institutions entitled to hold clinical trials of medical devices and the register of issued permits to conduct clinical trials of medical devices shall be published and posted by the registration authority as established by such registration authority, on its official site in the Internet information and telecommunications network.

28. When making a decision as to issue of the permit to conduct clinical trials of a medical device, the registration authority shall make a decision to suspend state registration of the medical device till the date when the registration authority makes a decision to resume state registration of the medical device, according to Section 30 of these Rules.

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

30. At the end of clinical trials of a medical device, the applicant shall submit the application for resumption of state registration of the medical device and the findings of clinical trials of the medical device to the registration authority.

31. The registration authority shall, within 2 business days from receipt of the application for resumption of state registration of the medical device and of the findings of clinical trials of the medical device, make a decision as to resumption of the state registration of the medical device.

32. At Phase II of the expert examination of medical device quality, efficacy and safety, the registration authority shall, within 2 business days from making a decision as to resumption of state registration of the medical device on the basis of the assignment to conduct expert examination of medical device quality, efficacy and safety, which was given in accordance with Section 20 of these Rules, send the findings of clinical trials of the medical device, which were submitted by the applicant, to the expert institution.

33. The expert institution shall, within 10 business days following the date of receipt of the documents indicated in Section 32 of these Rules, carry out the expert examination of completeness and the findings of conducted trials and studies and shall issue the opinion on the findings of expert examination of medical device quality, efficacy and safety, the format of which is approved by the Ministry of Health of the Russian Federation, and send the same to the registration authority.

34. Within 10 business days following receipt of the opinion indicated in Section 33 of these Rules, the registration authority shall take the following efforts:

a) assessment of the opinion to determine its conformity to the assignment to conduct the expert examination of medical device quality, efficacy and safety;

b) making a decision as to state registration of the medical device or refusal to carry out state registration of the medical device, which is made as an order of the registration authority, and notification to the applicant of the decision made;

c) drafting and issue (sending by registered mail with return receipt or in the format of an electronic document signed with an electronic signature) of the registration certificate or the notice as to refusal to carry out state registration of the medical device, indicating reasons for refusal, to the applicant.

35. Receipt by the registration authority of the conclusion on the findings of the expert examination of medical device quality, efficacy and safety, which suggests that the quality and/or efficacy of the registered medical device are not confirmed by obtained data and/or that the risk of harm to health of individuals and medical professionals due to the medical device administration exceeds the

efficacy of its administration, from the expert institution shall substantiate making a decision as to refusal to carry out state registration of a medical device.

36. Within 1 business day from making a decision as to state registration of the medical device, the registration authority shall incorporate data on the registered medical device into the state register of medical devices and manufacturers of medical devices as envisaged in Resolution No. 615 of the Government of the Russian Federation dated June 19, 2012.

37. Amendments are made to the registration certificate in the following cases:

- a) change in information on the applicant, including information on: restructuring of the legal entity; change in its name (full and (if any) abbreviated, including corporate name), address (location);
- b) change in address (place of manufacturing) of the medical device;
- c) change in the name of the medical device (if its properties and features that influence medical device quality, efficacy and safety did not change).

38. To have the registration certificate amended, the applicant shall, within 30 business days following the date of making the appropriate amendments, submit or send the application for making amendments to the registration certificate (hereinafter the 'certificate for making amendments'), issued in accordance with Section 9 of these Rules to the registration authority, with attachment of such amendments and with indication that making amendments to the registration certificate shall not entail any changes in properties and features that influence medical device quality, efficacy and safety, as well as the following documents:

- a) copy of the proxy of the manufacturer's authorized representative;
- b) registration file number;
- c) record statement.

39. In addition to the application for making amendments and the documents envisaged in Section 38 of these Rules, the following shall also be provided:

- a) if amendments are made to information on the applicant and on the place of manufacturing of the medical device, the documents evidencing such changes;
- b) if the name of the medical device change:
  - information on regulations on the medical device;
  - technical documents on the medical device adjusted in accordance with the new medical device name;

operating documents on the medical device, including the user's manual or operation manual of the medical device, adjusted in accordance with the new medical device name;

picture of the visual appearance of the medical device with all accessories required for administration of the medical device as intended (min. size 18 cm × 24 cm).

40. If the original documents set forth in Sections 38 and 39 of these Rules are made in a foreign language, they shall be supplemented with duly certified Russian translation.

41. The application for making amendments and the documents envisaged in Sections 38 and 39 of these Rules shall be received by the registration authority on the basis of the list of enclosures, a copy of which marked with the date of receipt of the said application and the documents shall be handed in to the applicant on the receipt date or sent to the applicant by registered mail, with return receipt, or in the format of electronic document signed with electronic signature.

42. The registration authority shall not be entitled to require that the applicant provides documents not envisaged in Sections 38 and 39 hereof.

43. Within 3 business days from receipt of the application for making amendments and the documents envisaged in Sections 38 and 39 of the Rules, the registration authority shall verify completeness and reliability of the information contained in them, in particular, by comparing such information with the information provided by way of inter-departmental information exchange.

44. If the documents listed in paragraph (a) Section 39 of these Rules are not attached to the application for making amendments and/or the application for making amendments provides unreliable information or the documents envisaged in Sections 38 and 39 of these Rules are provided other than in full, the registration authority shall provide the applicant with the notice as to the need to rectify detected violations and/or provide missing documents within 30 days, or send such notice in the form of an electronic document signed with electronic signature, or by registered mail with return receipt.

45. Within 3 business days from submission of a duly issued application for making amendments and a full set of documents envisaged in Sections 38 and 39 of these Rules, the registration authority shall make a decision as to consideration of the said application and the documents or (in case of their non-conformity to provisions of Sections 38 and 39 of these Rules) as to their return, with substantiation of reasons for return.

46. If the detected violations have not been eliminated and/or missing documents have not been provided within 30 days, the registration authority

shall make a decision as to return of the application for making amendments and the documents envisaged in Sections 38 and 39 of these Rules, with substantiation of reasons for return.

47. Amendments are made to the registration certificate by the registration authority within 10 business days following the date of making a decision to consider the application for making amendments and the documents envisaged in Sections 38 and 39 of these Rules.

48. The period for making by the registration authority of the decision to amend the registration certificate shall be calculated from the date when a duly issued application for making amendments and a full set of documents envisaged by Sections 38 and 39 of these Rules were received by the registration authority.

49. If amendments are made to the registration certificate, the registration authority shall, within 10 business days, take the following efforts:

a) making a decision to amend the registration certificate, which is certified by order of the registration authority;

b) sending a written notice to the applicant of the decision made, by registered mail, with return receipt, or in the form of electronic document signed with electronic signature;

c) drafting and issue (sending by registered mail with return receipt or in the format of electronic document signed with electronic signature) of the registration certificate to the applicant.

50. If the decision is made to amend the registration certificate, the registration authority shall draft and issue the registration certificate to the applicant and make an inscription as to its invalidity (indicating the date) on the earlier issued registration certificate, the original of which shall be returned (by registered mail, with return receipt, or in the form of an electronic document signed with electronic signature) by the applicant upon receipt of a new registration certificate.

51. Within 1 business day from making a decision to amend the registration certificate, the appropriate information is entered into the state register of medical devices and manufacturers of medical devices as envisaged in Resolution No. 615 of the Government of the Russian Federation dated June 19, 2012.

52. If the registration certificate is lost or spoilt, the applicant shall be entitled to apply to the registration authority for issue of a duplicate registration certificate (hereinafter, the 'application for duplicate').

If the registration certificate is spoilt, the spoilt registration certificate shall be attached to the application for duplicate.

53. Within 3 business days from receipt of the documents listed in Section 52 of these Rules, the registration authority shall issue a duplicate registration certificate on the registration certificate form, making with such marks as 'duplicate' and 'original registration certificate is deemed invalid', and shall deliver such duplicate to the applicant or send it by registered mail with return receipt.

54. The registration authority shall create a registration file comprising the following documents:

a) the registration application and the documents envisaged in Section 10 of these Rules, the application for making amendments and the documents envisaged in Sections 38 and 39, as well as the application for duplicate;

b) a copy of the assignment for expert examination of medical device quality, efficacy and safety, duly issued by the registration authority;

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

d) conclusions issued by the expert institution during expert examination of medical device quality, efficacy and safety;

e) copies of orders issued by the registration authority;

f) copy of the registration certificate or notices issued by the registration authority;

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

55. If the documents envisaged in Section 54(a) of these Rules change, the applicant shall, within 30 business days following the date of making the appropriate amendments, notify the registration authority thereof, with provision of documents evidencing such changes.

The registration files shall be kept by the registration authority as envisaged in the Russian archive business law.

56. The registration certificate shall include the following information:

a) name of the medical device (with indication of the accessories required for administration of the medical device as intended);

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

c) with respect to the legal entity, in the name of which the registration certificate may be issued, the full and (if any) abbreviated name, including corporate name, legal form of incorporation of the legal entity and address (location);

d) with respect to the medical device manufacturer, the full and (if any) abbreviated name, in particular, the corporate name, legal form of incorporation of the legal entity and address (location);

e) place of manufacturing of the medical device;

f) registration file number;

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

h) category of potential risk of a medical device administration, in accordance with the stock classification of medical devices approved by the Ministry of Health of the Russian Federation;

i) code of the All-Russian Products Classifier for the medical device.

57. The registration authority shall make a decision as to cancellation of state registration of a medical device in the following cases:

a) the applicant's submission of the application for cancellation of state registration of a medical device;

b) passing by a court of law of a judgment as to violation of the right holders' rights to the deliverables of intellectual activities and to equivalent individualization means when medical devices were in circulation;

c) provision by the federal executive authority authorized by the Government of the Russian Federation of information evidencing that there are facts and circumstances threatening to life and health of individuals and medical professionals during administration and operation of the medical devices based on findings of its governmental control over circulation of medical devices.

58. The registration authority shall post the information related to state registration of a medical device, to making amendments to the registration certificate and to issue of a duplicate registration certificate on its official site in the Internet information and telecommunications network.

59. Resolutions and actions/ omission of the registration authority that entailed violation of rights of a legal entity may be appealed by the applicant as envisaged in Russian law.

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