Government Decree of 27/12/2012 N 1416 "On Approval of the state registration of medical products"

GOVERNMENT OF THE RUSSIAN FEDERATION

JUDGMENT
on 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 **resolves**:

1. To approve the Rules of 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 prior to 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 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 appropriation to the Service in the federal budget for governance and management in the established functions.
5. This Resolution 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 in circulation in the Russian Federation.

2. Any medical appliances, apparatuses, devices, equipment, materials, and other products used for medical purposes either seperately or in combination with each other and with other accessories required for the use of these products as intended, including customized software, and designed manufacturer (producer) for the prevention, diagnosis, treatment and aftercare of diseases, monitoring of the human body for medical research, medical tests, rehabilitation, replacement, modification of anatomy or physiological functions of the body, pregnancy prevention or termination, the functional purpose of which is not implemented by 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 the personal use of a particular patient only, shall not be subject to state registration.

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

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

"medical device safety" - the absence of an unacceptable risk of harm to human life, health or the environment associated with the medical device use for its intended purpose as envisaged by the manufacturer (producer);

"medical device quality" – the set of features and characteristics of the medical device that influence its ability to function as intended if the requirements of the regulatory, technical and operational documentation of the manufacturer (producer) are met;

"Clinical trials" – a developed and planned continuous trial, involving, in particular, human subjects to evaluate the safety and effectiveness of a medical device;

"Normative documents" - documents governing the requirements of safety, quality, and proposed efficacy of the proposed 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 state registration, making amendments to the registration certificate of a medical device, as well as copies of the resolutions adopted by the registration authority for a particular medical device;

"Manufacturer’s (producer’s) Technical Documentation" - the documents governing medical device design, establishing technical requirements and providing the data for their development, production, use, operation, maintenance, repair, disposal or destruction;

"Technical trials" - trials to determine whether the characteristics (properties/features) of the medical device meet the requirements of regulatory, technical and operational documentation of the manufacturer (producer) and making the subsequent decision on the possibility of clinical trials;

"Toxicological studies" – trials aimed at assessing the biological safety of a medical device and subsequent decision on the possibility of clinical trials;

"Manufacturer’s (producer’s) authorized representative" - a legal entity registered in the Russian Federation, which is authorized by a medical device manufacturer (producer) to represent its interests in connection with circulation of the medical device in the Russian Federation, including those pertaining to the conformity assessment procedures and state registration, and the name of which the registration certificate of a medical device may be issued;

"Manufacturer’s (producer’s) operating documents" - documents intended to introduce the user to a medical device design, which govern the rules of operation (intended use, maintenance, repairs, storage

and transportation), values of key parameters and features of the medical device guaranteed by the manufacturer, the warranty policy, as well as information about its disposal or destruction;

"Medical device efficacy" - the set of medical device features and characteristics to guarantee the achievement of the administration purposes established by the manufacturer (producer) and confirmed by the practice of clinical use.

5. The state registration of medical devices is carried out based on the results of technical trials, toxicology 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 application, and examination of the quality, efficacy and safety of medical devices, taking into account their classification based on the potential risk of their use, as well as trials aimed at approving the type approval 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).

Provision of the organization of work on the development and operation of nomenclatural classification of medical devices by type is facilitated by the registration authority.

6. The document confirming the fact of state registration of a medical device, is a registration certificate for medical device (hereinafter – "registration certificate"). The format of the registration certificate is approved by the registration authority.

Registration certificate issued for an indefinite period.

7. The state fee shall be paid in accordance with Russian Federation laws on taxes and fees.
The information on payment of the state fee requested by the registration authority by way of inter-departmental exchange, in accordance with the Federal Law "On the organization of state and municipal services."

8. For state registration of a medical device the developer or the manufacturer (producer) of a medical device ~~manufacturer~~ or the authorized representative of the manufacturer (producer) (hereinafter – "the applicant") ~~is or send~~ either presents or sends the application for state registration of medical device as well as the documents referred to in paragraph 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 (with the accessories required for use of a medical device as intended);

b) with respect to the developer, full and (if applicable) abbreviated name, including the company name, the legal form of incorporation of the legal entity, the address (location), as well as phone numbers, and (if applicable) email address the legal entity;

c) with respect to the manufacturer (producer) of a medical device - a full and (if applicable) abbreviated name, including the company name, legal form of incorporation of the legal entity, the address of the location or last name, first name (and, if applicable) patronymic name, document details confirming identity, residential address of individual entrepreneur, as well as phone numbers, and (if any) email address of the legal entity or of the individual entrepreneur;

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

e) with respect of the legal entity, in the name of which the registration certificate may be issued, the full and (if applicable) abbreviated name, including the company name, legal form of incorporation of the legal entity, address (location) and 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 (producer);

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

i) the class of the potential risk of a medical device administration, in accordance with the nomenclature classification of medical devices;
j) the code of National Classification of products for the medical device;
k) information on the method of obtaining the registration certificate, as well as information relating to the procedure of state registration of a medical device.

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

a) a copy of the document confirming the authority of an manufacturer's (producer's) authorized representative
b) information on the normative documentation for the medical device;
c) technical documentation of the manufacturer (producer) for the medical device;
d) maintenance documentation of the manufacturer (producer) for the medical device, including the user manual or operation manual of the medical device;
e) picture of the visual appearance of the medical device with all accessories required for the administration of a medical device as intended (min. size 18 x 24 cm);
f) documents evidencing the findings of technical trials with the medical device;
g) documents evidencing the findings of toxicological 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 government regulation of uniformity of measurements, the list of which is approved by the Ministry of Health of the Russian Federation);
i) the list of documents.
j) information supporting clinical effectiveness and safety of medical devices (if available);
k) draft plan of clinical trials for the medical device with any substantiating materials (if available).

11. If the ~~original documents referred to~~ documents referred to in paragraph 10 of these Rules, are made in a foreign language, they shall be presented with a duly certified translation into Russian.

12. The deadlines and the sequence of administrative procedures and administrative efforts taken by the registering 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 referred to in paragraph 10 of the 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 contents or in electronically, signed by electronic signature.

Registration authority shall receive the registration application and the documents referred to in by paragraph 10 of these Rules, according to the list of contents, a copy of which is marked with the receipt date of the application and documents on the date of receipt, shall be given to the applicant or sent to the applicant by registered mail with return receipt requested or ~~by electronic means~~ via telecommunication channels.

14. The registration authority shall not require the applicant to indicate any information that is not provided for by paragraph 9 of these Rules, or submit documents not provided for by paragraph 10 of the Rules.

15. Within ~~3~~ 5 business days from the receipt of the registration application and the documents required by paragraph 10 of these Rules, the registration authority shall verify the completeness and accuracy of the information contained in them, in particular, by comparing such information with the information presented by way of inter-departmental information exchange.

16. If the registration application is executed in violation of the provisions of paragraph 9 of these Rules, and (or) in a statement given false information or documents required by paragraph 10 of these Rules, have not been provided in in full, the registration authority awarding the applicant shall send a notice to rectify the detected violations and/or to submit the missing documents within a 30-days period, or send such notice by registered mail, with return receipt, or in the form of an electronic document signed by electronic signature, or in electronic form via telecommunication channels.

17. Within 3 business days from the date of submission of the duly issued registration application and of the full set of documents required by paragraph 10 of these Rules, and also if the detected violations are eliminated and/or the submission of documents paragraph 10 of these Rules are provided within the 30-day period, the registration authority shall make a decision to start state registration of the medical device.

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 documents required by paragraph 10 of these Rules, with a justification of reasons for return.

19. State registration of medical devices shall be carried out by the registration authority within a period of 50 business days following the date when the decision to start the state registration of medical devices was made.
The duration of the clinical trials of the medical device shall not be included into this 50-days' period.

20. Within 3 business days from the date of making a decision as to 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 (hereinafter the "expert institution").

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

a) as Stage I, the expert examination of the registration application and the documents referred to in paragraph 10 of these Rules, to determine the possibility (impossibility) to carry out clinical trials of the medical device;

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

21(1). During the examination of the quality, efficacy and safety of the medical device (at any stage), expert institution cannot demand any materials that are necessary for carrying out the examination from the applicant or from any other individuals.

In the event that there is insufficient information and material contained in the statement submitted by the applicant for registration, and in the documents referred to in paragraph 10 of this Regulation for the expert to reach a conclusion, the expert raises the question of being provided the necessary materials and information to the head of the expert institution, who then refers the request to the registration authority that issued the order for conducting the examination. The registering authority, within 2 working days of receipt of request of the head of the expert institution, sends the applicant a request for the necessary information indicating the nature of the comments and how to resolve them. Said request shall be sent only once and can be transmitted to the authorized representative of the applicant personally with signature upon receipt, sent by registered mail or transmitted in electronic form via telecommunication channels or in the form of an electronic document signed by electronic signature.

The applicant must submit a response to the request of the registration authority within a period not exceeding 50 business days from the date of receipt of the request. Within 2 working days of receipt of the applicant's response

to the request, the registration authority shall send a reply to the expert institution. If the applicant's response is not received within 50 business days, the registration authority (within two business days) sends a notice of non-response regarding their request (for the preparation of a conclusion to be reached by the expert agency based on documents available), to the expert institution.

Time from the date of the registration authority's request to the date of receiving an answer to the request, or a notice of non-response, is not considered when calculating the term of the examination of efficiency and safety of the medical device.

22. On the Stage 1 of the expert examination of medical device quality, efficacy and safety, the expert institution shall, within a period not of 20 business days following receipt of the assignment, perform the following actions:

a) expert examination of the registration application and documents referred to by paragraph 10 of these Rules, to determine the possibility (impossibility) to carry out clinical trials of the medical device;

b) issuance and sending of the opinion as to the possibility (impossibility) of clinical trials of the medical device (indicating the reasons for and justifying 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 the making of the opinion by the expert institution on the impossibility of conducting clinical trials of a medical device or impossibility of governmental registration of a medical device:

a) non-conformity of the medical device regulatory requirements, technical and/or operating documentation of the manufacturer (producer);

b) lack of evidence of the ~~biological~~ safety of the medical device.

24. The registration authority shall, within 5 business days following the receipt of the conclusions about the possibility (impossibility) of clinical trials of a medical device from the expert institution, take the following actions:

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

b) making a decision to issue a permit to conduct clinical trials of a medical device or refusal to carry out state registration of the medical device, issued by order of the registration authority, and notified the applicant as to the decision made;

c) issuing (sending by registered mail, with return receipt, or in the form of an electronic document signed by electronic signature) to the applicant the permit to conduct clinical trials of a 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 is approved by the registration authority, or a notice of refusal to carry out state registration of the medical device, indicating the 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 sate registration.

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

Clinical trials of a medical device shall be conducted based on the permit to conduct clinical trials, issued by the registration authority, as well as the conclusions on the ethical substantiation of clinical trials, issued by the ethics council of the Ministry of Health of the Russian Federation, in the cases established in these Rules.

The composition of said ethics council 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. The registration authority establishes conformity of medical institutions to these requirements as envisaged by this Ministry.

27. The list of medical institutions with the right to conduct clinical trials of medical devices, and the registry 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 information and telecommunications network "Internet".

28. When deciding whether to issue a permit to conduct clinical trials of a medical device, the registration authority shall decide on to suspend state registration of the medical device until the date when the registration authority decides to resume the state registration of the medical device, in accordance with paragraph 30 of these Rules.

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

30. Upon completion of the clinical trials of a medical device applicant submits an application to the registration authority for the resumption of state registration of medical device and clinical trials of a medical device, as well as the documents referenced in sub-paragraphs "b" - "h", "j" and "k" of paragraph 10 of this Regulation, if changes are introduced to them based on clinical trial results of a medical device.

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

32. At Stage II of the expert examination of medical device quality, efficacy and safety, the registration authority shall, within 2 business days from the date of the decision on the resumption of the state registration of the medical device on the basis of the assignment to conduct expert examination of the medical device quality, efficacy and safety, given in accordance with paragraph 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 paragraph 32 of these Rules, carry out the expert examination of the 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 the receipt of the opinion indicated in paragraph 33 of these Rules, the registration authority shall complete the following activities:

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

c) execution and delivery (sending by registered mail with return receipt or in the format of an electronic document signed by electronic signature, or electronic transmission via telecommunication channels) of the registration certificate or the notice of refusal of state registration of the medical device, indicating the 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 date and/or that the risk of hard 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 the decision as to the state registration of the medical device, the registration authority shall enter the data on the registered medical device in the state registry of medical devices and organizations (individual entrepreneurs) engaged in the production and manufacturing of medical devices, as envisaged in Resolution No. 615 by 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 the information on the applicant, including information on restructuring of the legal entity:
change in its name (full and (if any) abbreviated, including company name), address (location);
in changing the last name, first name and patronymic name, residential address of the individual entrepreneur, requisites of the document proving his identity;
b) change in address (place of manufacturing) 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).
d) change of details of the legal entity in whose name may be issued a registration certificate, including the following information:
regarding the reorganization of the legal entity
regarding changing its name (full and (if available) abbreviated, including company name), address (location);
e) indication of the type medical device in accordance with the nomenclature classification of medical devices (in the event of its absence).

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 an application to amend the registration certificate (hereinafter the "certificate for making amendments"), issued in accordance with ~~the provisions of~~ paragraph 9 of these rules to the registration authority, with the attachment of ~~these~~ specified amendments and ~~indicating~~ confirmation that amendments to the registration certificate shall not entail any changes in the properties and features that influence the medical device quality, efficacy and safety, or improve the properties and characteristics at constant functionality and (or) the principle of operation of the medical device, ~~as well as~~ and the following documents:

a) copy of the document confirming the authority of an authorized representative of the manufacturer (producer);
b) registration file number;
c) record statement.

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

a) if amendments are mead 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 devices changes and (or) indicate the nature of the medical device in accordance with the nomenclature classification of medical devices (in the event of its absence)
information on regulations on the medical device;
technical documents of the manufacturer (producer) for the medical device, in accordance with the new medical device name;
operating documents of the manufacturer (producer) for the medical device, including the user's manual or operation manual of the medical device, adjusted in accordance the 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 x 24 cm).

40. If the ~~original~~ documents required by paragraphs 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 by paragraphs 38 and 39 of these rules shall be received by the registration authority according to the list on enclosures, a copy of which is marked with the receipt date of the 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 an electronic signature, or in electronic form via telecommunication channels.

42. The registration authority shall not be entitled to require that the applicant provides documents not envisaged by paragraphs 38 and 39 of these Rules.

43. Within ~~3~~ 5 business days from receipt of the application for making amendments and the documents envisaged by paragraphs 38 and 39 of these Rules, the registration authority shall verify the completeness and reliability of the information contained in them, including by comparing such information with the information provided by way of inter-departmental information exchange.

44. If the documents listed in sub-paragraph "a" of paragraph 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 by paragraphs 38 and 39 of these, are not in full , the registration authority shall provide the applicant a notice of the need to rectify detected violations and/or provide the missing documents within 30 days, or send a notice in the form of an electronic document signed by electronic signature, in electronic form via telecommunication channels, or by registered mail with return receipt.

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

47. Amendment are made to the registration certificate by the registration authority within ~~10~~ 15 business days following the date of making a decision to consider the application for making amendments and the documents envisaged by paragraphs 38 and 39 of these Rules.

48. The period for making the decision by the registration authority to amend the registration certificate shall be calculated from the date of receipt of the duly issued application for making amendments and a full set of documents envisaged by paragraphs 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~~ 15 business days, undertake the following activities:

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

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

c) drafting and issuing (sending by registered mail with return receipt or in the format of an electronic document signed with an 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 a registration certificate to the applicant and make an inscription on the previously issued registration certificate as to its invalidity (indicating the date), the original of which is shall be returned (by registered mail with return

receipt, or in the form of an electronic document signed with an electronic signature) by the applicant upon receipt of a new registration certificate.

51. Within 1 business day after making the decision to amend the registration certificate, the appropriate information is entered in the state register of medical devices and (individual entrepreneurs) engaged in the production and manufacturing 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 damaged, the applicant shall be entitled to apply to the registration authority for issue of a duplicate registration certificate (hereinafter the “application for a duplicate”).
In case the registration certificate is damaged, the damaged registration certificate shall be attached to the application for a duplicate.

53. Within ~~3~~ 7 business days from the receipt of the documents listed in paragraph 52 of these Rules, the registration authority shall issue a duplicate registration certificate on the registration certificate form marked "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 dossier comprising of the following documents:

a) the registration application and documents envisaged by paragraph 10 of these Rules, application for the renewal of state registration of the medical device, requests and documents specified in paragraphs 21 (1) and 30 of this Regulation, the statement for making amendments as envisaged by paragraphs 38 and 39 , as well as the application for duplicate;

b) a copy of the assignment for expert examination of the 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;

d) copies of orders, issued by the registration authority;

e) 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 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.~~

In the event of necessary (at applicant's request) introduction of changes to the documents under sub-paragraph "a" of paragraph 54 of these Rules, the applicant shall send to the registration authority a statement to amend the submission of documents confirming such changes.

In the event of necessary introduction of changes to documents under sub-paragraph “c” and “d” of paragraph 10 of these Rules, the introduction of changes is carried out based on results of the examination, conducted in a manner similar to the procedures for examination of the medical device quality, efficacy and safety for state registration in accordance with paragraph 21 of these Rules.

55(1). The basis for the expert institution issuing a conclusion of not being able to introduce changes into the documents provided for in subparagraphs "c" and "d" of paragraph 10 of these Rules are:

a) the inaccuracy of any information justifying the introduction of changes;
b) the absence of evidence to support the invariability of functionality and/or the principle of operation of a medical device, in connection with the amendments introduced to the documentation.

55(2). Registration Authority, within 2 business days of receiving the expert's conclusions, makes a decision regarding the possibility (or impossibility) of implementing changes to the documents provided in sub-paragraph "a" of paragraph 54 of these Rules and shall notify the applicant of their decision by registered mail with return receipt or electronically via telecommunication communication channels.

The basis for the decision to refuse to amend documents of the medical device is the registration authority receiving conclusions of the impossibility of introducing changes to documents of medical devices by the expert institution.

Storage of the registration dossier is carried out by the registration body in accordance with the legislation of the Russian Federation on archives.

56. The registration certificate shall include the following information:

a) name of the medical device (with 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 whose name of which the registration certificate may be issued, the full and (if applicable) abbreviated name, including the company name, legal form of incorporation of the legal entity and the address (location);

d) with respect to the manufacturer (producer),the full and (if applicable) the abbreviated name, including the corpoarte name, legal form and ~~the address (location)~~ the location or last name, first name and (if applicable) patronymic name, requisites of the document proving his identity, residential address of the individual entrepreneur;

d) the place of manufacturing of the medical device;

e) registration dossier number;

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

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

57. Registration authority shall decide to cancel the 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 as to a violation of the right holders' rights to the deliverables of intellectual property and similar means of individualization 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 the administration and operation of the medical devices based on findings of its governmental control over circulation of medical devices.

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

59. Decisions and actions/inactions of the registration authority, which led to the violation of the rights of a legal entity, individual entrepreneur, may be appealed by the applicant as envisaged by the law of the Russian Federation.