GOVERNMENT OF THE RUSSIAN FEDERATION

DECREE
of December 27, 2012 № 1416
MOSCOW

on the adoption of the Regulations of the State Registration of Medical Articles

In accordance with Article 38 of Federal Law "On the basis of health protection of nationals of the Russian Federation", the Government of the Russian Federation hereby **decrees** as follows**:**

1. To approve the attached Regulations of the State Registration of Medical Articles.

2. To constitute that:

а) Registration Certificates for the articles intended for medical purpose and medical equipment having the stipulated shelf life, which were issued before the date of entering present Decree into force, are valid till the expiration of the shelf life to be indicated;

б) Registration Certificates for the articles intended for medical purpose and medical equipment of unlimited duration, which were issued before the date of entering present Decree into force, are valid and subject to change till January 1, 2014, for Registration Certificates according to the form approved by the Federal Service on supervision in the domain of public health.

The procedure of changing of Registration Certificates is fulfilled without passing the procedure of the State registration of medical articles, upon the grounds of the application submitted by the Applicant to the Federal Service on supervision in the domain of public health, with indication of the data stipulated by the Regulations, and adopted by the present Decree.

3. State registration of medical articles, which were submitted for the State registration before the date of entering present Decree into force, is fulfilled upon the grounds of the documents, which were submitted before the date of entering present Decree into force, and upon the grounds of the application for the State registration of medical articles submitted by the Applicant in accordance with the Regulations adopted by the present Decree, to the Federal Service on supervision in the domain of public health.

4. The implementation of powers stipulated by the present Decree is fulfilled within the scope of the limited staff of the central body of the Federal Service on supervision in the domain of public health stipulated by the Government of the Russian Federation, and budgetary funding as well, which is allocated by the Federal Service from the Federal Budget for the management and administration in the field of the functions to be established.

5. Present Decree comes into force from January 1, 2013.

Chairman of the Government
of the Russian Federation D. Medvedev

APPROVED
by the Decree of the Government of the Russian Federation
of December 27, 2012 № 1416

R E G U L A T I O N S
of the State registration of medical articles

1. Present Regulations establish the order of the State registration of medical articles, which are subject to circulation in the territory of the Russian Federation.

2. Any materials, apparatuses, devices, equipment, substances and other articles, which are used for medicinal purposes either separately or in combination with each other, and along with other facilities, which are necessary for the usage of the above articles for the intended purpose, including the special software, and intended by the manufacturing company for the prevention, diagnostics, treatment and medical rehabilitation of diseases, for monitoring of human body conditions, for the conduct of medical studies, for recovery, substitution, alteration of the anatomic structure or physiologic functions of the human body, for prevention of interruption of pregnancy, whose functional purpose is not implemented by means of pharmacological, immunological, genetic or metabolic influence on the human body (further – medical articles) are subject to the State registration.

Medical articles manufactured by the individual patients' orders, which are demanded special requirements on indications of medical specialist, and which are intended exclusively for the personal usage by a specific patient, are not subject to the State registration.

3. State registration of medical articles is conducted by the Federal Service on supervision in the domain of public health (further – Registration Authority).

4. The following main definitions are used within the present Regulations:

"safety of the medical article" – the absence of unacceptable risk of doing harm to the human life and health, and the environment in case of the usage of the medical article according to its intended purpose under conditions stipulated by the manufacturing company;

"quality of the medical article" – the combination of properties and characteristics of the medical article, which influence its capacity to act according to its intended purpose provided that the requirements of the normative, technical and maintenance documentation are met;

"clinical studies" – the developed and planned systematic study, which is made, including the participation of a human being as a subject of clinical study, for evaluation of safety and efficacy of the medical article;

"normative documentation" - documents, which regulate the requirements of safety and quality, and the potential efficacy of the intended usage, and methods of control of how the medical article meets these requirements;

"registration dossier (drug master file)" – a set of documents, which are submitted for the State registration, alterations to be made to the Registration Certificate for the medical article, and the copies of resolutions adopted by the Registration Authority referring to the specific medical article;

"technical documentation" - documents, which regulate the construction of the medical article, stipulate the technical requirements and contain the data for its development, manufacturing, usage, maintenance, technical support, repairs, utilization or destruction;

"technical testing" – tests made for the purpose of determination of compliance of characteristics (properties) of the medical article with the requirements of normative, technical and maintenance documentation and making the further decision concerning the possibility of conduct of clinical studies;

"toxicological studies" – studies conducted in order to evaluate the biological safety of the medical article and making the further decision concerning the possibility of conduct of clinical studies;

"authorized representative of manufacturing company" – the legal entity registered in the territory of the Russian Federation, which is authorized by the manufacturer of the medical article to represent its interests referring the circulation of the medical article in the territory of the Russian Federation, including the matters of evaluation of compliance and the State registration procedures, on behalf of whom the Registration Certificate for the medical article may be issued;

"maintenance documentation" - documents, which intended for the customer's getting acquainted with the construction of the medical article, regulation conditions and the rules of maintenance (usage according to its intended purpose, technical maintenance, current maintenance, storage and transportation conditions), values of main parameters, characteristics (properties) of the medical article to be guaranteed by the manufacturer, warranty package, and the data concerning its utilization or destruction as well;

"efficacy of the medical article" – the range of properties and characteristics of the medical article, which provide for the attainment of the purposes stipulated by the manufacturing company and confirmed by the clinical practice.

5. State registration of medical articles is fulfilled upon the results of the technical testing, toxicological studies, and clinical studies, which present a kind of evaluation of compliance of medical articles taking into account the classification depending on the potential risk of their usage, and of the expertise of quality, efficacy and safety of medical articles, and testing conducted for the purpose of determination of the type of measuring device (refers to medical articles related to measuring devices in the domain of the State regulation of measuring uniformity provision, with the list of which adopted by the Ministry of Health of the Russian Federation).

6. The document, which confirms the fact of the State registration of medical articles, is the Registration Certificate for the medical article (further - Registration Certificate). The form of the Registration Certificate is adopted by the Registration Authority.

Registration Certificate is issued for unlimited term.

7. State fee is payable in accordance with the tax and fees legislation of the Russian Federation.

The information on the payment of the state fee is required by the Registration Authority in the order of inter-departmental information interactions in accordance with Federal Law "On organization of state and municipal servicing".

8. For the State registration of medical articles, the developer, manufacturer of the medical article or authorized representative of manufacturing company (further - Applicant) will submit or forward the application form on the State registration of the medical article, along with the documents indicated in point 10 of present Regulations to the Registration Authority.

9. The application on the State registration of the medical article (further – Application for registration) should contain the following data:

а) name of the medical article (with indication of facilities to be needed for the usage of the medical article according to its intended purpose);

б) referring to the developer – full and (if any) contracted name, including brand name, organizational and legal form of the legal entity, address (location), and phone numbers and (if any) e-mail addresses of the legal entity;

в) referring to the manufacturer of the medical article - full and (if any) contracted name, including brand name, organizational and legal form of the legal entity, address (location), and phone numbers and (if any) e-mail addresses of the legal entity;

г) referring to the authorized representative of manufacturing company - full and (if any) contracted name, including brand name, organizational and legal form of the legal entity, address (location), and phone numbers and (if any) e-mail addresses of the legal entity;

д) referring to the legal entity, on behalf of whom the Registration Certificate for the medical article may be issued, - full and (if any) contracted name, including brand name, organizational and legal form of the legal entity, address (location), and phone numbers and (if any) e-mail addresses of the legal entity;

е) place of manufacturing of the medical article;

ж) the intended purpose of the medical article stipulated by the manufacturing company;

з) the type of the medical article in accordance with the nomenclatural classification of medical articles;

и) class of potential risk of the usage of the medical article in accordance with the nomenclatural classification of medical articles;

к) code of the All-Russian classified index of goods applied for the medical article;

л) data on the method of how the Registration Certificate is issued, and the information related to the procedure of the State registration of the medical article.

10. For the State registration of the medical article the following documents are to be submitted:

а) the copy of the documents justifying the powers of the authorized representative of manufacturing company;

б) the data on the normative documentation for the medical article;

в) the technical documentation for the medical article;

г) the maintenance documentation for the medical article, including the manual instruction or the guidance on the maintenance of the medical article;

д) photographic image of the general view of the medical article along with facilities to be needed for the usage of the medical article according to its intended purpose (in size as much as 18 × 24 centimeters);

е) the documents justifying the results of technical testing of the medical article;

ж) the documents justifying the results of toxicological studies of the medical article, which usage presupposes the contact with a human body;

з) the documents justifying the results of testing of the medical article conducted for the purpose of determination of the type of measuring device (refers to medical articles related to measuring devices in the domain of the State regulation of measuring uniformity provision, with the list of which adopted by the Ministry of Health of the Russian Federation);

и) list of documents.

11. In case if original copies of documents listed in point 10 of present Regulations are elaborated in the foreign language, they should be submitted along with the translation into the Russian language to be duly notarized.

12. The terms and the order of administrative procedures and administrative actions of the Registration Authority are specified by the administrative regulations of the state servicing on the State regulation of medical articles developed in accordance with Decree № 373 of the Government of the Russian Federation of May 16, 2011.

13. Application for registration and the documents listed in point 10 of present Regulations are to be submitted by the Applicant to the Registration Authority directly in a hard-copy form or to be forwarded either by the registered mail sent by recorded delivery with the attached list of enclosures, or by e-mail, signed by the electronic signature.

The Registration Authority receives the application for registration and the documents listed in point 10 of present Regulations according to the attached list of enclosures, which copy with the date stamp on receipt of the above application for registration and the documents at the date of receipt is handed to the Applicant or is forwarded by the registered mail sent by recorded delivery or by e-mail to him.

14. The Registration Authority does not have the right to require that the Applicant should indicate the data in the application for registration, which are not stipulated by point 9 of present

Regulations, and submit the documents, which are not stipulated by point 10 of present Regulations.

15. Within 3 working days since the date of receipt of the application for registration and the documents listed in point 10 of present Regulations, the Registration Authority should check the completeness and validity of the comprising data, including by comparison of these data with those submitted within the frames of inter-departmental information interactions.

16. If the application for registration is executed with violations of conditions stipulated by point 9 of present Regulations and/or the application for registration contains invalid data, or the documents stipulated by point 10 of present Regulations are presented incompletely, the Registration Authority will deliver the notice on the necessity of elimination within the 30-day term of the violations to be observed and/or submission of documents, which were missed, or will forward such notice by the registered mail sent by recorded delivery or by e-mail signed by the electronic signature to the Applicant.

17. Within 3 working days since the date of receipt of duly executed application for registration and full set of documents listed in point 10 of present Regulations, and in case of elimination, within the 30-day term, of the violations to be observed and/or submission of documents stipulated by point 10 of present Regulations, the Registration Authority will take the decision on the commencement of the State registration of medical articles.

18. In case if, within the 30-day term, the violations to be observed are not eliminated, and/or the documents, which were missed, are not submitted, the Registration Authority will take the decision on the return of the application for registration and the documents stipulated by point 10 of present Regulations, with giving reasons for this return.

19. The State registration of medical articles is fulfilled by the Registration Authority in the term not exceeding 50 working days since the date when the decision of the commencement of the State registration of medical articles is taken.

The duration of clinical studies of the medical article is excluded from the 50-day term.

20. Within 3 working days since the date when the decision of the commencement of the State registration of medical articles is taken, the Registration Authority will execute and give the assignment for the conduct of the expertise of quality, efficacy and safety of medical articles to the Federal state budgetary institution, which is under the authority of the Registration Authority (further – Expert Institution).

21. The expertise of quality, efficacy and safety of medical articles is conducted by the Expert Institution gradually, according to the order adopted by the Ministry of Health of the Russian Federation:

а) at the 1st stage: the expertise of the application for registration and the documents stipulated by point 10 of present Regulations is conducted, in order to determine the possibility (impossibility) of clinical studies of the medical article to be conducted;

б) at the 2nd stage: the expertise of the completeness and the documents justifying the results of technical testing, the documents justifying the results of toxicological studies, the documents justifying the results of clinical studies of the medical article, and the documents justifying the results of testing of the medical article conducted for the purpose of determination of the type of measuring device (refers to medical articles related to measuring devices in the domain of the State regulation of measuring uniformity provision, with the list of which adopted by the Ministry of Health of the Russian Federation) is conducted.

22. At the 1st stage of the expertise of the quality, safety and efficacy of the medical article, the Expert Institution within the term not exceeding 20 working days since the date of receipt of the assignment, will take the following measures:

а) the expertise of the application for registration and the documents stipulated by point 10 of present Regulations, in order to determine the possibility (impossibility) of clinical studies of the medical article to be conducted;

б) execution and forwarding of the conclusion on the possibility (impossibility) of clinical studies of the medical article to be conducted (with indication of reasons and grounds for impossibility of their conduct), which form is adopted by the Ministry of Health of the Russian Federation, to the Registration Authority.

23. The reason for the Expert Institution to make the conclusion on the impossibility of clinical studies of the medical article to be conducted is:

а) incompliance of the medical article with the requirements of the normative, technical and/or maintenance documentation;

б) unavailability of evidence for the biological safety of the medical article.

24. The Registration Authority, within 5 working days since the date when the conclusion on the possibility (impossibility) of clinical studies of the medical article to be conducted is received from the Expert Institution, will take the following measures:

а) evaluation of the conclusion in order to determine the compliance with the assignment to conduct the expertise of quality, efficacy and safety of medical articles;

б) taking the decision either on the issue the permission to conduct clinical studies of the medical article or on the refusal of the State registration of the medical article, which is executed by the order of the Registration Authority, with the notice of the Applicant on the decision to be sent;

в) issuing (or sending by the registered mail sent by recorded delivery or by e-mail signed by the electronic signature) the permission to conduct clinical studies of the medical article, which form is adopted by the Registration Authority, and introduction of appropriate data into the Register of permissions to conduct clinical studies of the medical article to be issued, whose order is adopted by the Registration Authority, or notification on the refusal of the State registration of the medical article with indication of reasons and grounds for the refusal, to the Applicant.

25. The reason for the decision on the refusal of the State registration of the medical article is the receipt of the conclusion on impossibility of clinical studies of the medical article to be conducted by the Registration Authority from the Expert Institution.

26. Clinical studies of the medical article are made within the limits of evaluation of compliance in accordance with the established procedure adopted by the Ministry of Health of the Russian Federation.

Clinical studies of the medical article are made upon the grounds of the permission to conduct clinical studies of the medical article issued by the Registration Authority, and on the conclusion of ethic validation of clinical studies to be conducted, which is issued by the Ethic Committee with the Ministry of Health of the Russian Federation, in cases stipulated by the present Regulations.

The composition of the Ethic Committee and the Ethic Committee regulations are adopted by the Ministry of Health of the Russian Federation.

Clinical studies of the medical article are made in medical institutions, which meet the requirements adopted by the Ministry of Health of the Russian Federation. The compliance of medical institutions with these requirements is determined by the Registration Authority in the order stipulated by the Ministry of Health of the Russian Federation.

27. The list of medical institutions that have the right to conduct clinical studies of the medical article, and the Register of permissions to conduct clinical studies of the medical article to be issued are published and placed by the Registration Authority in the stipulated order on its official site in "Internet" information network.

28. While taking decision on issue the permission to conduct clinical studies of the medical article, the Registration Authority takes the decision on suspending the State registration of the medical article till the date when the decision of the Registration Authority on the renewal of the State registration of the medical article should be taken, in accordance with point 30 of present Regulations.

29. The Applicant will notify the Registration Authority about clinical studies of the medical article within 5 working days since the date of their commencement.

30. After the termination of clinical studies of the medical article, the Applicant will submit the application on renewal of the State registration of the medical article and the results of clinical studies of the medical article to the Registration Authority.

31. The Registration Authority, within 2 working days since the date when the application on renewal of the State registration of the medical article and the results of clinical studies of the medical article are received, will take the decision on the renewal of the State registration of the medical article.

32. At the 2nd stage of the expertise of the quality, safety and efficacy of the medical article, the Registration Authority within 2 working days since the date when the decision on the renewal of the State registration of the medical article is taken, upon the grounds of the assignment for the expertise of the quality, safety and efficacy of the medical article, which is issued in accordance with point 20 of present Regulations, will forward the results of clinical studies of the medical article submitted by the Applicant, to the Expert Institution.

33. The Expert Institution, within the term not exceeding 10 working days since the date of receipt of the documents indicated in point 32 of present Regulations, will make the expertise of completeness and the results of testing and studies to be conducted, and will execute and forward the conclusion on the results of the expertise of the quality, safety and efficacy of the medical article, which form is adopted by the Ministry of Health of the Russian Federation, to the Registration Authority.

34. The Registration Authority, within the term not exceeding 10 working days since the date when the conclusion indicated in point 33 of present Regulations is received, will take the following measures:

а) evaluation of the conclusion in order to determine the compliance with the assignment to conduct the expertise of quality, efficacy and safety of medical articles;

б) taking the decision either on the State registration of the medical article or on the refusal of the State registration of the medical article, which is executed by the order of the Registration Authority, with the notice of the Applicant on the decision to be sent;

в) the execution and issuing (or sending by the registered mail sent by recorded delivery or by e-mail signed by the electronic signature) the Registration Certificate or notification on the refusal of the State registration of the medical article with indication of reasons and grounds for the refusal, to the Applicant.

35. The reason for the decision on the refusal of the State registration of the medical article is the receipt of the conclusion on the results of the expertise of the quality, safety and efficacy of the medical article to be conducted, which justify that the quality and/or safety and/or efficacy of the medical article to be registered are not confirmed by the data to be received, and/or the risk of doing harm to the health of patients and medical specialists due to the usage of the medical article would exceed the efficacy of its administration, by the Registration Authority from the Expert Institution.

36. The Registration Authority, within 1 working day after the decision on the State registration of the medical article is taken, introduce the data on the medical article to be registered into the State Register of medical articles and organizations, which manufacture and produce medical articles, in the order stipulated by the Decree of the Government of the Russian Federation of June 19, 2012, № 615.

37. The alterations to the Registration Certificate are made in following cases:

a) changing of the data about the Applicant, including as follows:

-- reorganization of the legal entity;

-- changing of the name full and (if any) contracted name, including brand name, organizational and legal form of the legal entity, address (location);

б) changing of the manufacturing address (manufacturing plot) of the medical article;

в) changing of the name of the medical article (provided that properties and characteristics, which may influence the quality, safety and efficacy of the medical article, are not changed).

38. For the introduction of alterations into the Registration Certificate, the Applicant, within the term not later than 30 working days since the date when the appropriate alterations are introduced, will submit or forward the application form for the introduction of alterations into the Registration Certificate (further - the application for the introduction of alterations), which is executed in accordance with point 9 of present Regulations, along with submission of alterations above and indication that the introduction of alterations into the Registration Certificate would not affect properties and characteristics, which may influence the quality, safety and efficacy of the medical article, and the following documents, to the Registration Authority:

a) the copy of the document, which confirms the powers of the authorized representative of manufacturing company;

б) number of Registration Dossier;

в) list of documents.

39. Besides the application for the introduction of alterations and documents, which are stipulated by point 38 of present Regulations, also the following documents are submitted:

a) in case of changing of the data about the Applicant, including changing of the manufacturing address of the medical article - documents, which confirm such alterations;

б) in case of changing of the name of the medical article:

- data on the Normative Documentation for the medical article;

- the technical documentation for the medical article, being in compliance with the new name of the medical article;

- the maintenance documentation for the medical article, including the manual instruction or the guidance on the maintenance of the medical article, being in compliance with the new name of the medical article;

- photographic image of the general view of the medical article along with facilities to be needed for the usage of the medical article according to its intended purpose (in size not less than 18 × 24 centimeters).

40. In case if original copies of documents listed in points 38 and 39 of present Regulations are elaborated in the foreign language, they should be submitted along with the translation into the Russian language to be duly notarized

41. The application for the introduction of alterations and the documents listed in points 38 and 39 of present Regulations are to be submitted by the Applicant to the Registration Authority directly in a hard-copy form according to the list of enclosures, which copy with the indication of the date of receipt of the Application and the documents above on the date of receipt is to be handed to the Applicant or forwarded either by the registered mail sent by recorded delivery, or by e-mail, signed by the electronic signature.

42. The Registration Authority does not have the right to require that the Applicant should indicate the data, which are not stipulated by points 38 and 39 of present Regulations.

43. Within 3 working days since the date of receipt of the application for the introduction of alterations and the documents not stipulated by points 38 and 39 of present Regulations, the Registration Authority should check the completeness and validity of the comprising data, including by comparison of these data with those submitted within the frames of inter-departmental information interactions.

44. If the application for the introduction of alterations is not accompanied by the documents, in accordance with subparagraph “a” of point 39 of present Regulations and/or the application for the introduction of alterations contains invalid data, or the documents stipulated by points 38 and 39 of present Regulations are presented incompletely, the Registration Authority will deliver the notice on the necessity of elimination within the 30-day term of the violations to

be observed and/or submission of documents, which were missed, or will forward such notice by the registered mail sent by recorded delivery or by e-mail signed by the electronic signature, to the Applicant

45. Within 3 working days since the date of receipt of duly executed application for the introduction of alterations and full set of documents stipulated by points 38 and 39 of present Regulations, the Registration Authority will take the decision on the considering the abovementioned Application and documents, or (provided that they do not correspond with stipulations of points 38 and 39 of present Regulations) on the return of the application for registration and the documents above, with giving reasons for this return.

46. In case if, within the 30-day term, the violations to be observed are not eliminated, and/or the documents, which were missed, are not submitted, the Registration Authority will take the decision on the return of the application for the introduction of alterations and the documents stipulated by points 38 and 39 of present Regulations, with giving reasons for this return.

47. The introduction of alterations into the Registration Certificate is fulfilled by the Registration Authority, within the term not exceeding 10 working days since the date, when the decision of the considering the abovementioned Application for the introduction of alterations and documents stipulated by points 38 and 39 of present Regulations, is taken.

48. The term of taking the decision on for the introduction of alterations into the Registration Certificate by the Registration Authority is calculated since the date when the duly executed Application for the introduction of alterations and a full set of documents stipulated by points 38 and 39 of present Regulations are received by the Registration Authority.

49. When introduction of alterations into the Registration Certificate, the Registration Authority within 10 working days will take the following measures:

а) taking the decision on the introduction of alterations into the Registration Certificate, which is executed by the order of the Registration Authority;

б) notification in the written form of the Applicant on the decision to be taken by the registered mail sent by recorded delivery or by e-mail signed by the electronic signature;

в) the execution and issuing (or sending by the registered mail sent by recorded delivery or by e-mail signed by the electronic signature) the Registration Certificate to the Applicant.

50. When taking the decision on the introduction of alterations into the Registration Certificate, the Registration Authority will execute and issue the Registration Certificate to the Applicant, with indication of its invalidity (with the date indication) on the Registration Certificate being issued before, which original copy is issued or forwarded (by the registered mail sent by recorded delivery or by e-mail signed by the electronic signature) by the Applicant when the new copy of the Registration Certificate is received.

51. The Registration Authority, within 1 working day after the decision on the introduction of alterations into the Registration Certificate is taken, introduce the relevant data into the State Register of medical articles and organizations, which manufacture and produce medical articles, in the order stipulated by the Decree of the Government of the Russian Federation of June 19, 2012, № 615.

52. In case if the Registration Certificate is lost or damaged, the Applicant has the right to apply to the Registration Authority and submit the application for issuing of duplicate copy of the Registration Certificate (further - Application for issuing of duplicate copy).

In case if the Registration Certificate is damaged, the Applicant applies the damaged Registration Certificate with the Application for issuing of duplicate copy.

53. Within 3 working days since the date of receipt of the documents indicated in point 52 of present Regulations, the Registration Authority will execute the duplicate copy of the Registration Certificate on the blank form of the Registration Certificate with indications that "the original copy of the Registration Certificate is considered invalid" and " duplicate copy ", and will

issue this duplicate copy to the Applicant or forward it by the registered mail sent by recorded delivery.

54. The Registration Authority will collect the Registration Dossier of the following documents:

а) the Application for registration and documents stipulated by point 10 of present Regulations, the Application for introduction of alterations into the Registration Certificate and documents stipulated by points 38 and 39 of present Regulations, and the Application for issuing of duplicate copy;

б) the copy of the assignment for the expertise of quality, efficacy and safety of the medical article executed by the Registration Authority;

в) the copy of the permission for the conduct of clinical studies of the medical article executed by the Registration Authority;

г) conclusions, which are executed by the Expert Institution, when the expertise of quality, efficacy and safety of the medical article is conducted;

д) copies of orders executed by the Registration Authority;

е) the copy of the Registration Certificate or notifications executed by the Registration Authority;

ж) the duplicate copy of the Registration Certificate executed by the Registration Authority.

55. Provided that the documents are changed, in accordance with subparagraph “a” of point 54 of present Regulations, the Applicant, within the term not exceeding 30 working days since the date when such alterations are made, will notify the Registration Authority of such alterations, and submit the documents, which confirm such alterations.

The storage of the Registration Dossier is made by the Registration Authority in accordance with standing orders of the legislation of the Russian Federation on archiving.

56. The Registration Certificate should contain following data:

а) the name of the medical article (with indication of facilities to be needed for the usage of the medical article according to its intended purpose);

б) the date of the State registration of the medical article and its Registration number;

в) referring to the legal entity, on behalf of whom the Registration Certificate is issued, - full and (if any) contracted name, including brand name, organizational and legal form of the legal entity, and address (location);

г) referring to the manufacturer of the medical article - full and (if any) contracted name, including brand name, organizational and legal form of the legal entity, and address (location);

д) manufacturing plot of the medical article;

е) number of the Registration Dossier;

ж) the type of the medical article, in accordance with the nomenclatural classification of medical articles adopted by the Ministry of Health of the Russian Federation;

з) the class of potential risk of administration of the medical article, in accordance with the nomenclatural classification of medical articles adopted by the Ministry of Health of the Russian Federation;

и) the code of the All-Russian classified index of goods applied for the medical article.

57. The Registration Authority will take the decision on the withdrawal of the State registration of the medical article under the following conditions:

а) when the Applicant submits the application for the withdrawal of the State registration of the medical article;

б) when the court delivers the judgement on the violation of the rights of the rightholder referring the results of intellectual activities and ascertainment means equated with them, under circulation of medical articles;

в) when the Federal organs of executive powers authorized by the Government of the Russian Federation, according to the results of the state supervision over the circulation of medical articles, may submit the data, which justify the facts and circumstances, which may create the life- and health-threatened conditions for nationals and medical specialists when administration and maintenance of medical articles.

58. The Registration Authority will place the information related to the State registration of the medical article, the introduction of alterations into the Registration Certificate and the issue of the duplicate copy of the Registration Certificate, in the stipulated order on its official site in "Internet" information network.

59. Decisions and actions (inactivity) of the Registration Authority, which result in the violation of the rights of the legal entity, may be appealed by the Applicant in the order stipulated by the legislation of the Russian Federation.
