RESOLUTION

CABINET OF MINISTERS OF THE REPUBLIC OF UZBEKISTAN

ON APPROVAL OF THE PROVISION ON THE ORDER OF PUBLIC REGISTRATION OF MEDICINES, MEDICAL APPLICATIONS AND MEDICAL TECHNOLOGY AND ISSUANCE OF REGISTRATION CERTIFICATION

In accordance with the Law of the Republic of Uzbekistan “On Medicinal Products and Pharmaceutical Activities”, as well as pursuant to the Presidential Decree of the Republic of Uzbekistan dated June 12, 2017 No. PP-3052 “On measures to further improve the activities of health authorities”, January 23, 2018 PP-3489 "On measures to further streamline the production and importation of medicines and medical products" and February 14, 2018 number PP-3532 "On additional measures to accelerate the development of the pharmaceutical industry" Cabinet of Ministers ostanovlyaet:

1. To approve the Regulations on the procedure for state registration of medicines, medical devices and medical equipment and the issuance of a registration certificate in accordance with the annex.

2. To the ministries and departments, within one month, bring the normative legal acts adopted by them in accordance with this resolution.

3. Resolution of the Cabinet of Ministers of December 22, 2014 No. 352 “On Approval of the Regulations on the Procedure for Registration of Medicinal Products and Medical Products and Issue of a Registration Certificate” (JV of the Republic of Uzbekistan, 2014, No. 12, Article 126) shall be declared invalid.

4. Control over the execution of this resolution is to be entrusted to the Deputy Prime Minister of the Republic of Uzbekistan K.V. Akmalov and Minister of Health of the Republic of Uzbekistan A.K. Shadmanova.

Prime Minister of the Republic of Uzbekistan A. ARIPOV

Tashkent,

March 23, 2018 No. 213

ATTACHMENT

to the Resolution of the Cabinet of Ministers of March 23, 2018, No. 213

POSITION

on the procedure for state registration of medicines, medical devices and medical equipment and the issuance of a registration certificate

Chapter 1. General Provisions

1. These Regulations determine the procedure for state registration (hereinafter - registration) of medicinal products, medical devices and medical equipment and the issuance of a registration certificate (hereinafter - certificate).

2. The following basic concepts and terms are used in this Regulation:

medicinal products - products derived from medicinal substances (substances) and excipients, medicinal substances (substances), medicinal products permitted for use in medical practice for the prevention, diagnosis and treatment of diseases, as well as to change the state and functions of the human body

medicinal substances (substances) - substances of natural or synthetic origin, possessing pharmacological, immunological or metabolic activity or used for diagnostic purposes, allowed for use in medical practice;

medical devices - products approved for use in medical practice for the prevention, diagnosis and treatment of diseases, as well as for changing the state and functions of the human body;

medical equipment - devices, equipment, devices, instruments, devices and complexes permitted for use in medical practice for the prevention, diagnosis and treatment of diseases, as well as for identifying and changing the state and functions of the human body;

pharmacological agents - substances or a mixture of substances that have a specific dosage form, with established pharmacological activity and safety in preclinical studies, which are objects of a clinical study;

The State Center for Expertise and Standardization of Medicinal Products, Medical Products and Medical Equipment of the Agency for the Development of the Pharmaceutical Industry under the Ministry of Health of the Republic of Uzbekistan (hereinafter referred to as the State Center) is the working body of the Agency for the Development of the Pharmaceutical Industry, ensuring state registration, quality control, standardization and certification medicines, medical devices and medical equipment;

the applicant is a business entity, a legal entity (or a trustee acting on its behalf) who applied to the State Center for state registration of a medicinal product, a medical device and medical equipment and obtaining a certificate;

registration documents - documents submitted to the State Center during the registration of medicines, medical devices, medical equipment;

medicinal plant raw materials - plants or their parts containing biologically active substances used for the production and manufacture of medicines;

A prescription is a written instruction from a doctor, a specialist with a pharmaceutical education, on the manufacture and (or) delivery of a medicinal product and a method for its use.

3. Registration of a medicinal product, medical devices and medical equipment provides for issuing certificates to applicants.

Registration of a medicinal product, medical devices and medical equipment and the issuance of certificates are carried out by the State Center according to the scheme in accordance with Appendix 1 to this Statute.

4. Registrations are subject to: drugs; new combinations of medicines registered in the Republic of Uzbekistan; medicinal products previously registered in the Republic of Uzbekistan, but produced in other dosage forms, dosages or other manufacturer; medical products; Medical equipment.

5. Registration of medicinal products with different medicinal substances under the same trade name is not allowed, as well as registration of medicinal products of the same manufacturer, having the same composition of medicinal substances, under different trade names.

Drugs and medical products manufactured in pharmacies, as well as imported for research, preclinical, clinical studies, state registration procedures, exhibiting at exhibitions, fairs, international forums, are not subject to registration.

6. According to the results of registration of medicines, medical devices and medical equipment, a certificate is issued for a period of five years.

7. The certificate is a document confirming the fact of state registration and authorization of the Ministry of Health of the Republic of Uzbekistan for the right to use a medicinal product, a medical device and medical equipment in medical practice.

8. Registration and issuance of a certificate for a foreign medicinal product, a medical product and medical equipment are carried out in accordance with these Regulations.

Chapter 2. Permits and Terms

9. The permissive requirements and conditions that are mandatory for the applicant in the application in medical practice of a medicinal product, a medical device and medical equipment on the basis of a registration certificate include:

unconditional compliance with legislation by the applicant who applied for the registration of a medicinal product, a medical device and medical equipment when applied in medical practice;

during the validity period of the certificate to the State Center, the applicant submits comprehensive information on changes and additions to registration documents;

Mandatory compliance with the requirements of regulatory documents in the field of technical regulation (hereinafter referred to as regulatory documents) for medicines, medical devices and medical equipment and data provided in registration documents;

timely elimination of deficiencies indicated by the State Center, as well as the submission of samples of medicines, medical devices and medical equipment and other materials in the time provided for by paragraph 15 of these Regulations.

Chapter 3. Documents and samples required to obtain a certificate

10. To obtain a certificate, the applicant submits to the State Center:

a) a statement on the form in accordance with Appendix 2 (for medicinal products) and Appendix 2a (for medical devices and medical equipment) to these Regulations;

b) the registration documents of the medicinal product or medical product and medical equipment in two identical copies, completed in the manner prescribed in Annex 3 (for medicines) and 3a (for medical devices and medical equipment) to this Regulation, grouped in parts, page by page, numbered in parts, respectively, certified by the applicant’s signature and seal;

c) samples of the medicinal product in the quantity necessary for carrying out triple tests in one industrial series;

d) samples of medical devices or medical equipment in an amount necessary for testing in accordance with regulatory documents;

e) standard samples of active substances, medicinal substances (substances), impurities and related substances, control materials, specific reagents and documents confirming their quality.

When conducting clinical trials of medicinal products submitted for state registration, the applicant submits to the clinical bases (medical institutions) documents (clinical research protocol, researcher's brochure, etc.) and drug samples in accordance with the requirements of the GCP rules (good clinical practice), necessary for clinical trials of drugs.

11. The requirement from the applicant to submit documents and samples not provided for by paragraph 10 of these Regulations is not allowed.

12. Documents required for obtaining a certificate shall be submitted to the State Center directly, by means of postal services or in electronic form with notification of their receipt. Documents submitted in electronic form are confirmed by the applicant's electronic digital signature.

Samples of medicines, medical devices and medical equipment are presented directly or through the means of postal communication.

13. The State Center is responsible for disclosing confidential information contained in registration documents.

Chapter 4. Consideration of the application and the decision to issue a certificate or to refuse to issue it

14. For consideration of the application for issuance of a certificate, a fee of 10 times the minimum wage on the day of application is charged.

The amount of the fee is credited to the account of the National Center.

In the event of the applicant's refusal from the submitted application for issuing a certificate, the sum of the paid collection shall not be refunded.

Fees for considering the application of a foreign manufacturer of medicines, medical devices and medical equipment (or a person acting on his behalf) and issuing a certificate, for making changes and additions, extending the validity period, re-issuing and issuing a duplicate certificate, approved by the Ministry of Health of the Republic of Uzbekistan price list based on the expenses of the State Center for the implementation of these procedures.

15. The application for issuance of a certificate shall be considered by the State Center for a period not exceeding:

50 days - for medicinal substances (substances);

120 days - for medicinal products in the form of prepackaged and packaged pharmacopoeia medicinal plant materials, dressings, products for punctures, injections, transfusions and suction, contraceptives, rubber, rubber rubber, latex, polymeric medical products, medical products for first aid ; nursing items;

155 days - for other medicines, medical devices and medical equipment.

The above terms do not include:

a period not exceeding 45 days, established to eliminate the shortcomings identified in the process of examination of the medicinal product, medical devices and medical equipment;

a period not exceeding 45 days set for the applicant to submit to the clinical databases of clinical research programs, drug samples, medical devices and medical equipment, agreed in an appropriate manner for conducting clinical trials;

directly the timing of clinical trials, not exceeding three years for original medicines and one year for generics.

When registering medicinal substances (substances) clinical trials are not conducted.

16. For issuing a certificate, a double minimum wage is charged. The amount of the fee is credited to the account of the National Center.

17. The State Center is obliged to issue (send) to the applicant a certificate or notify him in writing, including in electronic form through the information system, about the refusal to issue a certificate no later than one working day from the date of the decision.

18. The State Center for the purpose of making a decision on the registration of a medicinal product, a medical device and medical equipment as part of the evaluation of the registration documents of a medicinal product, a medical device and medical equipment, production conditions, a quality assurance system, compliance of a medicinal product, a medical device and medical technology requirements of regulatory documents, quality, efficiency and safety, the ratio of the expected benefits and risks when using NII to human health can hold their own or with the assistance of a third party or independent experts, following the expert work, surveys, tests, analyzes, research, studies and scientific and technical assessment in the form of:

examinations of the registration documents of a medicinal product, a medical device and medical equipment; inspection control for the purpose of assessing and determining the compliance of the conditions of production of a medicinal product, medical devices and medical equipment with the requirements of the rules of production organization and quality control, the quality management system; testing and research of samples of medicines, medical devices and medical equipment; examination of the documents of medicinal products containing narcotic drugs, psychotropic substances and precursors; pharmacological and toxicological studies; preclinical studies and bioequivalence testing.

19. Registration is carried out by the State Center in the time specified in Appendix 1 to this Regulation, in the following order:

a) Registration Department:

after acceptance of the application for registration, conducts an initial (preliminary) examination of the application and registration documents attached to it and samples of medicinal products, medical devices and medical equipment;

conducts corresponding correspondence with the applicant regarding the registration of medicines, medical devices and medical equipment;

on the basis of the positive results of the initial (preliminary) examination (verification), ensures the conclusion of a contract between the State Center and the applicant and issues an invoice for payment;

after the applicant pays the set amount of the fee, he submits the application and the samples and documents attached to it in the laboratory of the State Center, Pharmacological, Pharmacopoeia Committees, the Committee for New Medical Equipment, the Drug Control Committee (if the drug contains substances and precursors) for examination;

b) State Center laboratories:

carry out an examination of the chemical, pharmaceutical, biological and technical parts of the registration documents of a medicinal product, a medical device and medical equipment;

assess regulatory documents, conduct tests to determine the compliance of samples of a medicinal product, a medical device or medical equipment with the requirements of regulatory documents;

transfer test reports, registration documents to the Pharmacopoeia, Pharmacological Committees and the Committee on New Medical Equipment;

c) Pharmacopoeia committee:

examines the administrative, chemical, pharmaceutical and biological parts of medicinal product registration documents, laboratory test reports;

requires the applicant to include alternative and (or) additional indicators, standards and test methods in the draft regulatory documents of the drugs in order to bring them in compliance with national and international requirements;

conducts examination and re-examination of documents of pharmacological and (or) medicines with the involvement of independent experts;

sends samples and documents of the medicinal product to the laboratories of the National Center for additional tests;

approves regulatory documents for medicines and medical products;

on the basis of the submitted documents and expert opinions, makes recommendations to the Expert Council established in accordance with the established procedure by the Ministry of Health of the Republic of Uzbekistan (hereinafter - the Expert Council) on the registration of drugs or the refusal of their registration;

d) Pharmacological Committee:

examines the administrative, pharmacological, toxicological and clinical parts of pharmacological and (or) medicinal products;

conducts examination and re-examination of documents of pharmacological and (or) medicines with the involvement of independent experts;

decides on the use of the drug without clinical studies in cases of:

- availability of information on registration of the medicinal product in the producing country, as well as in other countries (countries);

- availability of documents confirming the production of a medicinal product in accordance with the requirements of GMP (good manufacturing practice) and conducting clinical studies in accordance with the requirements of the GCP (good clinical practice) immunobiological preparations - prequalification of the drug by WHO;

decides to conduct clinical studies of pharmacological and (or) drugs on humans;

determines the types of studies, approves the clinical bases for conducting clinical studies, makes recommendations on the development of the program and protocol of clinical studies and approves them;

on the basis of the submitted documents and expert opinions, makes for consideration by the Expert Council recommendations on the registration of medicines without clinical studies or with clinical studies or on refusal to register them;

approves and approves the instructions for the medical use of drugs or changes to them;

carries out pharmacological supervision activities;

e) New Medical Equipment Committee:

conducts an examination of the administrative, chemical, biological, technical parts of the registration documents for medical devices and medical equipment, laboratory testing protocols, as well as the examination of clinical research materials;

conducts examination and re-examination of registration documents of medical devices and medical equipment with the involvement of independent experts;

based on the specifics of the medical device and medical equipment, it provides for testing in accredited laboratories or at the place of installation of the medical device and medical equipment;

advises on the development of clinical research programs and coordinates clinical research programs;

determines the types of research, approves the clinical bases (medical institutions) for conducting clinical trials of medical devices and medical equipment;

coordinates instructions for use (on operation) and labeling of medical products and medical equipment of domestic production or changes or additions made to them;

prepares for approval or approval regulatory documents for medical devices and medical equipment;

on the basis of the submitted documents and expert opinions, makes for consideration by the Expert Council recommendations on registration of medical devices and medical equipment without clinical studies or with clinical studies, or refusal to register them;

(e) Drug Control Board:

Examines the registration documents of medicines containing narcotic drugs, psychotropic substances and precursors;

during the examination of registration documents of medicinal products containing narcotic drugs, psychotropic substances and precursors, examines the presence of these substances in the list of narcotic drugs, psychotropic substances and precursors under state control, permission for their medical use, as well as the need for prescription physician and makes proposals to the Pharmacological and Pharmacopoeia committees;

g) Pharmaceutical inspection:

in the case of the organization of production, quality control of a new dosage form or type of medical product, conducts a survey of the conditions of production and quality control for compliance with the rules of production organization and quality control at enterprises producing a medicinal product and a medical product;

based on the results of the survey, he issues a certificate on the availability of production conditions and quality control of the relevant type of medicinal product and medical product;

h) The Department for the Coordination of the Implementation of International Standards in the Pharmaceutical Industry, based on the results of the inspection, gives an opinion on the compliance of foreign enterprises producing drugs, medical devices and medical equipment with the requirements of international standards.

Inspection is carried out by the decision of the Expert Council.

20. The Expert Council, on the basis of the conclusions of the Pharmacopoeia Committee, the Pharmacological Committee, the Committee on New Medical Equipment, as well as other departments of the State Center, makes a decision on whether or not to use a medicine, medical product and medical equipment in medical practice.

21. The State Center is obliged to issue (send) to the applicant a certificate in the form according to Annex 4 (for medicines) and 4a (for medical devices and medical equipment) or to notify him in writing, including in electronic form through the information system, about refusal to issue a certificate no later than one working day from the date of the decision made by the Expert Council.

22. The grounds for refusing to issue a certificate may be the following:

the applicant’s submission of documents required for the issuance of certificates, samples of medicines, medical devices and medical equipment and other required materials, not in full;

inconsistency of the applicant with permissive requirements and conditions;

the presence in the documents submitted by the applicant, false or distorted information;

obtaining a substantiated negative opinion on the results of: laboratory tests, clinical studies, production inspections or other scientific and technical assessments (examinations of medicinal products, medical devices and medical equipment registration documents) characterizing the quality, safety and efficacy of medicinal products, medical devices and technology.

Refusal to issue a certificate for other reasons, including those based on inexpediency, is not allowed.

23. Notification of the refusal to issue a certificate shall be sent (delivered) to the applicant in writing, including electronically through the information system, indicating the reasons for refusal, specific legislation, and the period during which the applicant, having eliminated the above reasons, can submit documents for re-review. The period during which the applicant is entitled to eliminate the reasons for the refusal and submit documents for reconsideration may not be less than ten working days from the date of receipt of a written or electronic notification of the refusal to issue the certificate.

24. If the applicant has eliminated the reasons that served as the basis for the refusal to issue the certificate, within the prescribed time period, the documents are reviewed again and the examination process is continued by the State Center within a period not exceeding ten working days from the date of receipt of the application for the elimination of the reasons for the refusal elimination of the reasons for refusal, except for the cases provided for in paragraph three of this clause.

For re-consideration of the application fee is not charged.

If the elimination of the reasons that led to the refusal to issue a certificate entails a change in the properties of medicines, medical devices and medical equipment that affect quality, effectiveness and safety, the application is considered to be re-submitted and considered by the National Center on a general basis.

25. When re-examining documents, it is not allowed for the State Center to give reasons for refusal that were not previously stated in writing, including in electronic form through the information system, to the applicant, except for the reasons for refusal associated with the documents certifying the elimination of the previously mentioned reasons.

26. The application submitted by the applicant after the expiration of the period specified in the notification of the refusal to issue a certificate is considered to be again submitted and considered by the State Center on a general basis.

27. The applicant has the right to appeal, in the established manner, the refusal to issue a certificate, as well as the actions (inaction) of an official of the State Center.

28. Upon expiry of the certificate validity period, it is allowed to sell and use medicinal products, medical devices and medical equipment in medical practice, provided they are produced during the validity period of their certificate. At the same time, it is allowed to conduct quality control of medicines, medical devices and medical equipment for compliance with the requirements of regulatory documents approved during the period of validity of their certification.

Chapter 5. Amendments and additions to registration documents

29. In the event of a change in the information indicated in the registration documents during the validity period of the certificate, the applicant applies to the State Center with a statement on the introduction of changes and additions with the attachment of the relevant documents, samples and standards (if necessary).

The State Center refuses to make changes and additions to registration documents in case changes and additions result in deterioration of the quality, efficacy and safety of the medicinal product, medical devices and medical equipment.

30. The applicant's application for making amendments and additions to the registration documents within the authority of the relevant departments of the State Center is considered within a period not exceeding:

45 days - for medicinal substances (substances);

60 days - drugs in the form of prepackaged and packaged pharmacopoeial medicinal plant materials for dressings, products for punctures, injections, transfusions and suction, contraceptives, rubber, rubber rubber, latex, polymeric medical products, medical products for first aid nursing items;

90 days - for other medicines, medical devices and medical equipment.

For consideration of the applicant's application for making changes and additions to the registration documents, a fee is charged at half the amount paid for consideration of the application for issuing a certificate.

31. In the event that a change in the registration documents requires a change in the information given in the certificate, the relevant changes in the certificate are also made in accordance with clauses 32, 33 and 34 of Chapter 6 of these Regulations.

Chapter 6. Renewal of the certificate, extension of its validity, issuance of duplicates

32. In the event of the applicant’s conversion, change of his name or location, the applicant or his successor shall, within seven working days after passing the re-registration, submit to the State Center an application for reissuing the certificate with attachment of documents confirming the specified information.

Documents are submitted by the applicant to the State Center directly, via postal services or in electronic form with notification of their receipt. Documents submitted in electronic form and (or) are confirmed by an electronic digital signature of the applicant.

The requirement from the applicant to submit documents that are not provided for in this clause is not allowed.

33. Before reissuing the certificate, the applicant or his successor, who submitted the application for reissuing the certificate, uses the medicinal product, medical device or medical equipment on the basis of the submitted application for certificate re-issuance marked by the National Center on the date of receipt of the application.

34. When reissuing a certificate, the State Center shall make the appropriate changes in the register of certificates issued.

Renewal and issuance of certification shall be carried out within a period not exceeding 5 days from the date of receipt by the State Center of an application for renewal of the certificate with attachment of relevant documents.

35. For re-issuance of the certificate a fee is charged at half the amount paid for the consideration of the application for issuing the certificate. The amount of the fee is credited to the account of the National Center.

36. The period of validity of the certificate may be extended upon an application submitted by the applicant to the State Center. An application for the renewal of the certificate must be submitted to the

State Center three months before its expiration. Extension of the validity of the certificate is carried out in the manner prescribed for the issuance of a certificate.

For the extension of the validity period of the certificate, a fee is charged at half the amount paid for the consideration of the applicant’s application for certification. The amount of the fee is credited to the account of the National Center.

37. In case of loss or damage to the certificate, a duplicate shall be issued upon the applicant’s application.

The State Center is obliged to issue (send) a duplicate certificate in no more than five working days from the date of receipt of the application, as well as the original certificate in case of its damage and a document confirming that the applicant has paid a fee for issuing a duplicate certificate.

For issuing a duplicate certificate a fee is charged at half the amount paid for consideration by the State Center of the applicant's application for issuing a certificate on the date of filing the application for issuing a duplicate. The amount of the fee is credited to the account of the National Center.

Chapter 7. Suspension, termination and revocation of certificate

38. Suspension, termination and annulment of the certificate shall be carried out in the cases and procedure provided for in Articles 22, 23 and 25 of the Law of the Republic of Uzbekistan “On Permitting Procedures in the Sphere of Entrepreneurial Activities”.

39. The one-time gross violation of authorization requirements and conditions, which gives rise to the termination of the certificate in the prescribed manner, include:

evasion of audits of compliance with permissive requirements and conditions carried out in accordance with the established procedure;

causing harm to the life and health of citizens or the creation of a real threat of causing such harm as a result of committing an action and (or) carrying out a certain type of activity for which an appropriate permit has been issued.

Chapter 8. Register of issued certificates

40. The State Center keeps a register of issued certificates and places it on its official website.

The following information is indicated in the register of issued certificates:

the name of the applicant, its legal form, address, telephone number;

trade, internationally non-proprietary name of the medicinal product, dosage form, dose, dosage form of the medicinal product, name of medical devices and medical equipment;

date of issue and serial number of the certificate;

validity of the certificate;

the grounds and dates of renewal, renewal of the certificate;

the grounds and dates for the suspension and renewal of the certificate;

the grounds and dates of termination of the certificate;

the grounds and dates for the cancellation of the certificate;

the grounds and dates for issuing duplicate certificates.

41. The information contained in the register of issued certificates is open for legal entities and individuals to familiarize themselves with it.

APPENDIX № 1

to the Regulations on the procedure for state registration of medicines, medical devices and medical equipment and the issuance of a registration certificate

SCHEME

state registration of medicinal products, medical devices and medical equipment

APPENDIX № 2

to the Regulations on the procedure for state registration of medicines, medical devices and medical equipment and the issuance of a registration certificate

APPENDIX № 2a

to the Regulations on the procedure for state registration of medicines, medical devices and medical equipment and the issuance of a registration certificate

APPENDIX № 3

to the Regulations on the procedure for state registration of medicines, medical devices and medical equipment and the issuance of a registration certificate

Documents submitted for state registration of medicines

Part 1. Administrative Documents

1.1. Content

1.2. Copies of certificates (notarized)

1.2.1. Copy of certificate for pharmaceutical product or certificate of registration (registration certificate) of a medicinal product in the country of origin

1.2.2. * GMP Certificate

1.2.3. Certificates confirming registration in other countries

1.3 Brief description of the medicinal product, labeling and instructions for medical use.

1.3.1. Brief description of the drug

1.3.2. Marking

1.3.3. A copy of the instruction on the medical use of the medicinal product approved in the country of origin in Russian and the draft instruction on the medical use of the medicinal product in the state language.

1.3.4. Color layouts of packaging on paper and electronic media on a scale of 1: 1

1.4. Regulatory document of the medicinal product (if the registration is extended, a copy of the approved regulatory document), as well as the Explanatory Note to the regulatory document

1.5. Detailed description of pharmacological supervision and risk management system for the medical use of the drug

1.5.1. A document confirming the presence of a qualified person in charge of pharmacovigilance for collecting and recording adverse reactions detected in the Republic of Uzbekistan

1.5.2. Periodic Safety Update Report

1.6. Information on possible environmental hazards

1.6.1 Information on the presence in the composition of the drug genetically modified organisms (GMOs)

When participating in the production process of a number of manufacturers, the documents referred to in clauses 1.3.2 and 1.3.4 are submitted for all production participants;

Note.

* Submission of a GMP certificate with a copy of the results of the latest inspection is mandatory only for foreign manufacturers.

APPENDIX № 3a

to the Regulations on the procedure for state registration of medicines, medical devices and medical equipment and the issuance of a registration certificate

SCROLL

documents submitted for state registration of medical devices and medical equipment

1. Content

2. When registering through a representative - a power of attorney executed in the prescribed manner

3. General information about the medical device or medical equipment, its manufacturer

4. Copy of the registration certificate of a medical device or medical equipment in the country of origin, as well as in other countries (if available)

5. Regulatory document, including the procedure and methods for testing medical devices or medical equipment, international, interstate or national product standard

6. Passport, instruction manual for medical equipment, instructions for use of a medical product in Russian (for medical devices, also in the official language)

7. Technical description of medical equipment

8. Protocols of laboratory tests, technical tests, technical tests of measuring instruments for medical purposes, preclinical and clinical studies

9. Information on the compliance of the conditions of production of medical devices and medical equipment with international standards (if any).

10. Information on the absence of infectious agents in in vitro diagnostic products prepared from biological materials.

11. Storage stability information for medical devices

12. Illustrated advertising materials, prospectuses, catalogs, photos not less than 13 x 18 cm in size

13. Color graphic layouts of primary and secondary packaging (for medical products)

14. Additional information about the quality, efficacy and safety of medical equipment, medical devices.

Note. When extending the period of certification of a medical device, medical equipment, it is necessary to submit reviews of clinics of the Republic of Uzbekistan on the effectiveness and safety of a medical device, medical equipment in the prescribed manner.

APPENDIX № 4

to the Regulations on the procedure for state registration of medicines, medical devices and medical equipment and the issuance of a registration certificate