MINISTRY OF HEALTH AND SOCIAL DEVELOPMENT
OF THE RUSSIAN FEDERATION

ORDER
October 30, 2006 No. 735

On approval of the Administrative rules of the Federal service
for supervision in the sphere of health and social development
of performance of the state duty of registration of medical products

Pursuant to the Decree of the Russian Federation Government dated November 11,
2005 No. 679 “On development and approval of administrative rules of performance of state
duties and administrative rules of provision of state services” (Corpus of legislative acts of
the Russian Federation, 2005, No. 47, art. 4933) and Regulations on the Ministry of health
and social development of the Russian Federation, approved by the decree of the Russian
Federation Government dated June 30, 2004 No. 321 “On approval of Regulations on the
Ministry of health and social development of the Russian Federation (Corpus of legislative
19, art. 2080), I hereby order:

1. To approve the Administrative rules of the Federal service for supervision in the
sphere of health and social development of performance of the state duty of registration of
medical products.

2. That the Federal service for supervision in the sphere of health and social
development (R.U. Khubariev) arrange registration of medical products in accordance with
the Administrative rules approved hereby.

3. To find invalid orders of the Ministry of health of the Russian Federation dated July
2, 1999 No. 274 “On procedure of registration of home-produced medical products and
medical equipment in the Russian Federation” (registered by the Ministry of Justice of
Russia on November 10, 1999 No. 1970), dated May 10 2000 No. 156 “On permissions to
use for medical purposes of home-produced or foreign-made medical products and medical
equipment in the Russian Federation” (Registered by the Ministry of Justice of Russia on
organization and arrangement of state registration of foreign-made medical products and
medical equipment in the Russian Federation” (Registered by the Ministry of Justice of
Russia on July 26, 2000 No. 2326), and dated December 13, 2001 No. 444 “On duration of
registration certificates for medical products and medical equipment” (Registered by the
Ministry of Justice of Russia on February 21, 2002 No. 3263).

4. To charge deputy Minister of health and social development of the Russian
Federation V.I. Starodubov with the duty to control enforcement of this order.

Minister
M.Y. Zurabov
(signature)

APPROVED
by Order of the Ministry of
health and social development
of the Russian Federation
dated October 30, 2006 No. 735
I. General provisions


1.2. Registration of medical products is a controlling and supervisory state duty performed by the Federal service for supervision in the sphere of health and social development in order to permit production, import, sale and application of medical products in the territory of the Russian Federation.

1.3. Registration is mandatory for all medical products designed for medical application in the territory of the Russian Federation and including devices, apparatuses, instruments, appliances, kits, complexes, systems with software, equipment, accessories, dressing and suture, dental materials, sets of reagents, referencing materials and standard samples, calibrators, analyzer consumables, products of polymeric, rubber and other materials, software applied for medical purposes either apart or in combination with each other, and which are designed for:
- preventive treatment, diagnostics (in vitro), sickness treatment, aftertreatment, medical procedures, medical research, replacement and modification of parts of human body tissues, organs, recovery or compensation of disrupted or lost physiological functions, impregnation control;
- production of effect on human organism so that their designated purpose is not implemented through chemical, pharmacological, immunological or metabolic interaction with human organism, but of which effect can be supported by such means.

1.4. Registration of a medical product is performed in favor of a legal person or an individual entrepreneur specified in the registration application.

1.5. In state registration Russian and foreign medical products are subject to equal requirements.

1.6. Classification of medical products depending on potential risk of their application for medical purposes in the following four classes is an integral part of medical products registration procedure:
- class 3 – high-risk medical products;
- class 2b – increased-risk medical products;
- class 2a – medium-risk medical products;
- class 1 – low-risk medical products.

Medical products being diagnostics kits (in vitro) are classified as follows:
- class 3 and class 2b include diagnostica for determination of HIV-1/HIV-2, HTLV I, HTLV II, hepatitis B, C and D, German measles, toxoplasmosis, CMV, clamidiosis, HLA DR, A and B, PSA, blood glucose (self-diagnostics), trisomy 21 risk;
- class 2a includes diagnostica for individual use by end consumers;
- class 1 includes all other diagnostica (in vitro).
1.7. Registration is performed by the Federal service for supervision in the sphere of health and social development on the basis of results of appropriate tests and assessments justifying quality, efficiency and safety of the products.

In registration of medical products efficiency is determined as degree of achievement by medical product of its designated purpose; safety is represented by balance of risk of damage to patient, personnel, equipment or the environment in case of its correct application, and significance of the purpose of its application; quality is defined as compliance of actual characteristics of the medical product with statutory document requirements.

Class 1 and 2a medical products, which are a copy of an analog produced in the territory of the Russian Federation (any medical product of any manufacturer attributed to the same potential risk class, applied in the same manner (by the same methods) and having the same efficiency characteristics) are registered on the basis of a document drawn up by applicant acknowledging lack of differences from such analog (analog equivalence) or on the basis of certificates of technical testing, safety evaluation, which show lack of significant differences of a registered product from the analogue (analog identity).

All class 2b and 3 medical products, as well as class 1 and 2a medical products, having no analogs registered in the territory of the Russian Federation, may be registered on the basis of certificates of technical testing, safety evaluation and medical tests certifying acceptability of product quality, efficiency and safety characteristics.

The Federal service for supervision in the sphere of health and social development controls the procedure of medical and other testing of medical products.

1.8. Information on medical product registration number and date must be available to consumer (indicated on packing, label, application instructions, directions for use, and be included in advertising products intended for end consumer).

1.9. In performance of the state duty of medical products registration the following administrative procedures must be arranged:


II. State duty performance requirements

2.1. Procedure of informing of the state duty of medical products registration.

2.1.1. Document certifying medical product registration is a registration certificate. A registration certificate is valid, provided only all information on a medical product and person, in favor of which such medical product has been registered, remains unchanged. Validity period of registration certificate is not limited.

2.1.2. Documents and information for registration of medical products and (or) modification of registration documents for medical product are sent, and registration certificates are issued at:

the Federal service for supervision in the sphere of health and social development, medical products registration department: 4, stroenie 1, Slavyanskaya ploschad, Moscow, 108074. Working hours: from 9 am to 6 pm on weekdays.
Place of acceptance of documents necessary for performance of the state duty of medical products registration must be equipped with telephone, computer with Internet access and text of these rules.

Telephone numbers for inquires and preliminary registration: +7(495) 298-4305; +7(495) 298-2290.
E-mail: deviceregistration@roszdravnadzor.ru
Reference service: +7(495) 298-4628.

Information on filed registration applications, procedure of consideration of documents submitted by applicants for registration of medical products or modification of registration documents, as well as decisions taken under paragraph 2.2 of these Rules must be available to applicants at request or at the official Internet site: www.roszdravnadzor.ru

2.1.3. Lists of documents submitted for registration of medical products or modification of medical products registration documents, as well as requirements to such documents are set forth in corresponding sections on administrative procedures of these Rules.

Documents are reviewed in accordance with consecutive sequence of their acceptance for registration. In presentation of documents, head of the Federal service for supervision in the sphere of health and social development may establish another sequence of their review for a specific medical product or types of such products on the following grounds:

1) product undergoing registration is included into list of medical products delivered under priority national projects of the Russian Federation pursuant to Federal laws, Decrees of the President of the Russian Federation and Decrees of the Russian Federation Government;

2) it has been proven that the product undergoing registration improves quality and efficiency of treatment of high lethal or disability rate diseases.

Head of Federal service for supervision in the sphere of health and social development may by written resolution suspend the procedure of document review and registration approval for the period, during which applicant provides additional information requested, when such information is necessary for reasonable decision allowing lawful circulation of a medical product in the territory of the Russian Federation.

2.3. Grounds for refusal to review documents or register a medical product are set forth in corresponding sections on administrative procedures of these Rules.

2.4. Actions or inaction of the Federal service for supervision in the sphere of health and social development in connection with registration of medical products may be appealed against in accordance with established procedure. Minister of health and social development of the Russian Federation revokes decisions of the Federal service for supervision in the sphere of health and social development being in conflict with federal laws, unless federal law provides for another decision revocation procedure.

III. Administrative procedures

3.1. Structure and interrelation of administrative procedures implemented in registration of medical products are shown in the chart (Appendix 1).

3.2. Heads of divisions of the Federal service for supervision in the sphere of health and social development responsible under these Rules for registration of medical products, must maintain documentary record of each stage of administrative procedures with indication of its completion date and a responsible person’s signature.

3.3. Administrative procedure “Documents review and medical products registration approval” is implemented in connection with receipt from applicant of a set of documents for medical product registration as described below (administrative procedure chart is given in Appendix 2).

3.3.1. Documents review and medical products registration approval must take place within 4 months upon submission of a set of documents stipulated in paragraph 3.3.3 hereof, to the Federal service for supervision in the sphere of health and social development.

In case a class 1 or 2a medical product subject to registration is equivalent to or identical with its analog, a procedure of accelerated documents review and medical products registration approval must be applied. An accelerated procedure is accomplished by the Federal service for supervision in the sphere of health and social development within 2
months upon submission of a complete set of documents prescribed by these Rules to the Federal service for supervision in the sphere of health and social development.

Term of documents review and medical products registration approval may be extended for up to 3 months to enable applicant to run additional tests and evaluations at its request. A notice permitting to carry out additional tests and evaluations is forwarded to applicant. If applicant fails to provide necessary documents upon expiration of the said term, the Federal service for supervision in the sphere of health and social development may deny registration.

3.3.2. Documents submitted by applicant for medical product registration are registered within 1 business day from their receipt. A set of documents may be sent by registered mail (parcel) with advice of receipt accompanied by list of enclosures. The second copy of such list and application form with file number note is sent (handed over) to applicant. Head of the medical product registration department must control registration of received documents.

3.3.3. For registration of a medical product applicant provides to the Federal service for supervision in the sphere of health and social development the following documents:
1) application for registration of a medical product;
2) document certifying payment of state duty;
3) medical product information sheet;
4) documents certifying registration of manufacturing organization as a legal person;
5) power of attorney or a certified copy of agreement, if applicant is not manufacturer of a medical product;
6) documents certifying compliance of medical product manufacturing conditions with laws of the Russian Federation;
7) draft statutory document accompanied by documents certifying compliance of a medical product with its requirements, technical conditions or standards;
8) directions for use of a medical product;
9) draft instructions for medical application in registration of physiotherapeutical equipment and reagents (kits) for diagnostics (in vitro), individually used by end consumer;
10) in cases described in paragraph 1.7 hereof, documents certifying medical product equivalence to or identity with its analog;
11) in cases described in paragraph 1.7 hereof, results of technical tests, safety evaluation and medical testing of efficiency and safety of a medical product.

All medical product registration documents must be provided in Russian or accompanied with a certified translation into Russian.

List of information included in submitted documents, which is necessary for appraisal of quality, efficiency and safety of a medical product, or its equivalence to or identity with the analog, is given in Appendix 3. No other documents may be required from applicant.

Medical product registration application contains applicant’s name; name of a legal person or an individual entrepreneur, in favor of which registration is made; name of registered medical product; intended field of application of a product; acknowledgement of responsibility for possible negative effects of correct application of a medical product; acknowledgement of responsibility for infringement of other persons’ rights in production, import and sale of a medical product in the territory of the Russian Federation; expected potential risk class of a medical product; information on product analogs registered in the Russian Federation (if any).

3.3.4. Head of medical product registration department must within 4 calendar days upon receipt of documents appoint from department staff an executive officer responsible for review of documents submitted for medical product registration. At applicant’s request, written or oral, such applicant must be informed of the executive officer’s surname, first name and patronymic, its place of work and work telephone number.

Head office of the Federal service for supervision in the sphere of health and social development, responsible for medical product registration, with provision for these Rules decides for or against application of an accelerated document review procedure. Applicant must be informed of such decision in written form.

3.3.5. The executive officer must within 15 calendar days upon its appointment check completeness and structure of documents submitted, so as to ensure that:
- a compete set of documents prescribed by paragraph 3.3.3 hereof has been provided,;
- information contained in separate documents of the set is consistent;
- each document signed by the applicant's executive officer is valid;
- due content and details of information contained in submitted documents are provided, and results of tests and assessments are duly justified;
- registration application is lawful under laws applicable governing entities involved in circulation of medical products in the territory of the Russian Federation.

In case incomplete set of documents has been submitted or a registration application is unlawful, a justified refusal to perform further review of documents is prepared with indication of grounds for such refusal; the refusal is signed by head of the Federal service for supervision in the sphere of health and social development and sent to the applicant.

3.3.6. The executive officer must classify the medical product under paragraph 1.7 hereof within 5 calendar days after completeness and structure of documents submitted for registration has been checked.

3.3.7. The executive officer must determine, where it is necessary to submit additional information (tests results) and (or) perform quality, efficiency and safety assessment in accordance with product class within 5 calendar days upon completion of medical product classification.

Additional information may only be requested if structure and content of presented test results do not correspond to product class. In this case further review of documents may be suspended pursuant to paragraph 3.3.1 hereof.

Assessment of quality and (or) efficiency and (or) safety of a medical product may be required on the following grounds:
- registered medical product is attributed to 2b or 3 class;
- there is no analog registered in the Russian Federation;

If there are grounds for assessment, the executive officer must within terms fixed for this stage of the administrative procedure prepare a project of assignment for medical product quality, efficiency and safety assessment, specify organization, which will perform the assessment, fix deadlines and issues for which expert opinion must be obtained. Assignment project is agreed by head of medical product registration department and approved by a person authorized for this purpose by head of the Federal service for supervision in the sphere of health and social development. Assessment of medical product quality, efficiency and safety must be held within 75 calendar days, or within 15 calendar days (within accelerated procedure) upon approval of assignment.

3.3.8. Within 10 calendar days after expert organization opinion has been obtained, or in case assessment is not necessary, after checking completeness and structure of documents and information submitted for registration of a medical product, the executive officer must prepare an opinion on registration of a medical product with provision for:
- results of documentary examination of a set of documents and information submitted for registration of a medical product;
- materials of medical product quality, efficiency and safety assessments held;
- additional information provided by applicant.

In case of positive opinion, a draft order on registration and registration certificate are prepared and signed by head of the Federal service for supervision in the sphere of health and social development.

In case of negative opinion, a notice of denial in registration specifying grounds for such denial is prepared, signed by head of the Federal service for supervision in the sphere of health and social development and sent to the applicant.

3.3.9. Registration of a medical product may be denied on the following grounds:
1) set or structure of documents and information submitted by applicant, described in paragraph 3.3.3 hereof, is incomplete or a registration application is unlawful;
2) applicant has provided false or invalid information on a medical product (except for product class determined by the applicant, which is finally fixed by the Federal service for supervision in the sphere of health and social development); 3) in case of expert opinion on lack of safety, inefficiency or on lack of proof of safety or efficiency of a medical product, provided it has been provided by at least two independent experts and shows that:
- product application risk exceeds the expected efficiency;
- there is not enough proof of efficiency;
- information contained in documents submitted for registration does not reflect actual situation.
3.3.10. Within 5 calendar days upon signing of order and registration certificate, the executive officer informs the applicant that the registration certificate has been prepared.

3.3.11. Within 10 business days upon signing of the order and registration certificate, the executive officer sends information on registration for modification of the registered medical products database, and for archiving thereof.

3.3.12. The Federal service for supervision in the sphere of health and social development must issue duplicate copies of medical product registration certificate upon request of persons, in favor of which it has been registered, within 1 month upon receipt of such request.

3.3.13. Documents and information submitted for registration of a medical product, whether registered or not, are kept with the Federal service for supervision in the sphere of health and social development along with corresponding expert opinions, copies of registration orders and registration certificates (hereinafter collectively referred to as the registration documentation), with information confidentiality requirements being observed within the registration term and within 5 years upon its expiration.

3.4. Administrative procedure “Modification of medical product registration documentation” is implemented in connection with receipt from a person specified in a registration certificate (or its legal assignee) of a set of documents justifying modification of registration documentation, or in connection with detection by the Federal service for supervision in the sphere of health and social development of information related to medical product efficiency or safety as described below (administrative procedure chart is given in Appendix 4):

3.4.1. Modifications to medical product registration documentation related to medical product quality, efficiency or safety are introduced by the Federal service for supervision in the sphere of health and social development within terms indicated in paragraph 3.3.1 hereof. In all other cases, including in case of inclusion of information on side effects or use limitations, alteration of rights to a medical product, its trade name, packing, modifications to registration documentation are introduced within 1 month upon receipt of an appropriate set of documents.

3.4.2. Documents received from applicant for modification of medical product registration documentation are registered within 1 business day upon receipt thereof. A set of documents may be sent by registered mail (parcel) with advice of receipt accompanied by list of enclosures. Head of the medical product registration department must control registration of received documents.

All documents necessary for modification of registration documentation must be submitted in Russian, or be accompanied with a certified translation into Russian.

3.4.3. Head of medical product registration department must within 4 calendar days upon receipt of documents appoint from department staff an executive officer responsible for review of documents submitted for medical product registration. At applicant’s request, written or oral, such applicant must be informed of the executive officer’s surname, first name and patronymic, its place of work and work telephone number.

3.4.4. The executive officer must within 10 calendar days upon its appointment check completeness and structure of documents submitted, so as to ensure that:
- information contained in separate documents of the set is consistent;
- all duly certified documents are valid;
- due content and details of submitted information are provided, and results of tests and assessments are duly justified.

3.4.5. The executive officer must classify the medical product under paragraph 1.7 hereof within 5 calendar days after completeness and structure of documents submitted for registration has been checked.

3.4.6. The executive officer must determine, where it is necessary to submit additional information (tests results) and (or) perform quality, efficiency and safety assessment in accordance with product class within 5 calendar days upon completion of medical product classification.

Additional information may only be requested if structure and content of presented test results do not correspond to product class. In this case further review of documents may be suspended pursuant to paragraph 3.3.1 hereof.

Assessment of quality and (or) efficiency and (or) safety of a medical product may be required on the following grounds:
- upon introduction of modifications to registration documentation, a medical product is attributed to 2b or 3 class;
- there is no analog registered in the Russian Federation;

If there are grounds for assessment, the executive officer must within terms fixed for this stage of the administrative procedure prepare a project of assignment for medical product quality, efficiency and safety assessment, specify organization, which will perform the assessment, fix deadlines and issues for which expert opinion must be obtained. Assignment project is agreed by head of medical product registration department and approved by a person authorized for this purpose by head of the Federal service for supervision in the sphere of health and social development. Assessment of medical product quality, efficiency and safety must be held within 75 calendar days, or within 15 calendar days (within accelerated procedure) upon approval of assignment.

3.4.7. Within 5 calendar days after expert organization opinion has been obtained, or in case assessment is not necessary, after checking structure of documents submitted, the executive officer must prepare an opinion on introduction of modifications to registration documentation for a medical product with provision for:
- results of documentary examination of a set of documents and information submitted for introduction of modifications to standard technical documentation for a medical product;
- materials of medical product quality, efficiency and safety assessments held;
- additional information provided by applicant.

In case of positive opinion, a draft order on introduction of modifications to registration documentation for a medical product and registration certificate are prepared and signed by head of the Federal service for supervision in the sphere of health and social development.

In case of negative opinion, a notice of denial in modification of registration documentation specifying grounds for such denial is prepared, signed by head of the Federal service for supervision in the sphere of health and social development and sent to the applicant.

3.4.8. Modification of registration documentation for a medical product may be denied on the following grounds:
1) applicant has failed to provide or has provided an incomplete set of documents justifying introduction of modifications to registration documentation;
2) applicant has provided false or invalid information justifying introduction of modifications to registration documentation;
3) expert opinion on possible decrease in quality, efficiency and safety of a medical product has been provided, in case of introduction of modifications to registration documentation.

3.4.9. Modification of registration documentation for a medical product may not be denied in case:
1) modifications pertain to name, address or organizational legal form of applicant;
2) modifications are related to transfer of rights to a medical product, provided place of its manufacture remains unchanged;
3) applicant increases requirements to medical product quality characteristics or reduces (restricts) field of its application within permitted limits;
4) modifications result from the need to meet requirements prescribed by laws of the Russian Federation.

3.4.10. Within 5 calendar days upon signing of order and registration certificate, the executive officer informs the applicant that the registration certificate has been prepared.
3.4.11. Within 10 business days upon signing of the order and registration certificate, the executive officer sends information on registration for modification of the registered medical products database, and for archiving thereof.
3.4.12. The Federal service for supervision in the sphere of health and social development must issue duplicate copies of medical product registration certificate upon request of persons, in favor of which it has been registered, within 1 month upon receipt of such request.
3.4.13. Documents and information submitted for registration of a medical product, whether registered or not, are kept with the Federal service for supervision in the sphere of health and social development along with corresponding expert opinions, copies of registration orders and registration certificates, with information confidentiality
requirements being observed within the registration term and within 5 years upon its expiration.

3.5. Administrative procedure “Review of facts and circumstances endangering human life and health in application of registered medical products” is implemented in connection with detection of facts and circumstances (receipt of appropriate documents from persons involved in medical product circulation) endangering human life and health in correct application of medical products as described below (administrative procedure chart is given in Appendix 5):

3.5.1. In case of detection of facts and circumstances endangering human life and health in correct application of medical product, including without limitation any unfavorable clinical implications, which in application of a medical product in accordance with directions (instructions) for use (application) result in death, pose threat to life, require hospitalization or its extension, lead to sustained or severe loss of ability to work and (or) physical disability, or result in anomalous reproductive effects, or clinical implications, of which character and seriousness do not correspond to available information on a medical product, head of medical product registration department must within 5 business days upon detection of such circumstances prepare a corresponding memorandum addressed to the head of the Federal service for supervision in the sphere of health and social development.

In case such circumstances are caused by specific features of effect of a medical product, this administrative procedure may apply to all medical products equivalent to or identical with the same.

3.5.2. Within 5 business days upon receipt of memorandum or additional information on circumstances revealed, head of the Federal service for supervision in the sphere of health and social development may take the following decisions:

1) order that additional information on revealed negative effects of medical product application be gathered;
2) order that additional medical product quality, efficiency and safety assessment be performed with provision for revealed negative effects of its application;
3) consider modification of registration documentation for a medical product;
4) suspend decision on registration of a medical product;
5) withdraw registration certificate for a medical product;
6) refrain from any additional actions, in case revealed negative effects of medical product application are accidental.

3.5.3. Collection of additional information and additional assessment of quality, efficiency and safety of a medical product with provision of revealed negative effects of its application are held within terms fixed by head of the Federal service for supervision in the sphere of health and social development.

3.5.4. Matters of modification of registration documentation related to detection of negative effects of medical product application are considered in accordance with administrative procedure “Modification of medical product registration documentation” described herein.

3.5.5. Federal service for supervision in the sphere of health and social development suspends decision on medical product registration with the purpose to enable a person specified in a registration certificate to hold additional technical tests and (or) safety assessment and (or) medical testing of a medial product in connection with revealed negative effects.

In case a person indicated in registration certificate refuses to hold additional technical tests and (or) safety assessment and (or) medical testing, and if additional medical product quality, efficiency and safety assessment confirms that there are negative effects of medical product application, the Federal service for supervision in the sphere of health and social development withdraws the registration certificate. Information on registration certificate withdrawal is entered into the registered medical products database.

3.6. Administrative procedure “Control of medical and other tests of medical products” is held only in course of implementation of administrative procedures “Documents review and medical product registration approval”, “Modification of registration documentation for medical products” and “Review of facts and circumstances endangering human life and health in application of registered medical products” provided herein as described below (administrative procedure chart is given in Appendix 6):
3.6.1. Within 5 calendar days upon decision on obligatory provision of additional information (results of technical, medical tests or safety assessment) by applicant and (or) in course of medical product quality, efficiency and safety assessment in accordance with medical product class, the executive officer prepares an assignment for tests or assessment, agreed by head of medical product registration department and approved by person authorized for this purpose by head of the Federal service for supervision in the sphere of health and social development.

The assignment is handed over to applicant.

The assignment must specify organizations, which may perform necessary tests and give required opinions, selected from a list maintained by the Federal service for supervision in the sphere of health and social development with provision for specialization, technical equipment and expertise of staff of organizations having entered into corresponding agreements. The assignment also includes terms of tests and (or) assessments in accordance with these Rules. Assignment for medical tests is prepared only after receipt of positive results of technical tests and safety assessment of a medical product.

3.6.2. Head of medical product registration department must ensure arrangement of inspection of medical and other tests of a medical product in course of the same.

3.6.3. Documents received from applicant and including certificates (protocols) of tests and (or) opinions of quality, efficiency and safety assessment of a medical product, are registered with 1 business day from their receipt. A set of documents may be sent by registered mail (parcel) with advice of receipt accompanied by list of enclosures. Head of the medical product registration department must control registration of received documents.
Requirements
to content of documents submitted
for registration of medical products

A. A medical product information sheet must contain the following information:

- product description;
- description of product effect principle, or reference to its scientifically justified mechanism;
- information on all functional characteristics of a product relevant to its effect principle (or mechanism), such as design, used materials and physical characteristics;
- information on fields of product application, including a brief description of diseases or conditions of a human, in which this product may be used for diagnostics, treatment, preventive treatment or improvement of condition, including, if possible, determination of incidence of such diseases or conditions.

B. Documents certifying equivalence to or identity with its analog of a medical product must contain the following information:

- table of all functional characteristics of a registered product relevant to its effect principle (or mechanism) compared with similar characteristics of analog. If there are any differences, it is necessary to explain, why such differences, in the applicant’s opinion, do not affect quality, efficiency or safety of a medical product;
- in case suggested fields of application of a registered medical product differ from fields of application of analog, the applicant must justify each difference and explain, why such differences cannot affect its efficiency or safety. Restriction of fields of application of a registered medical product compared with analog is not considered as deviation.

C. Documents certifying results of technical tests, safety assessments and medical testing of efficiency and safety of a medical product must contain the following information:

- description of type and object of research (as per applicability) (technical testing of product physical characteristics; microbiological research; toxicity research; immunobiological research; bioequivalence research; efficiency research; stability research (definition of validity) etc.);
- researcher’s opinion on test results;
- in addition, documents certifying results of medical testing of efficiency and safety of a medical product must contain a research report; general information on product efficiency and safety; side effects and complicating diseases; breakdown of medical products in course of medical tests, which resulted in repair or replacement thereof; information on patients taking involved in tests (number, sex, age, diagnosis), including confirmation of the patients’ written consent to participation in research; patients’ complaints; quantitative information for each patient in table form; results of statistical processing of data received in course of research.

D. A statutory document of a medical product (which is filled by applicant and is not subject to any mandatory requirements as to the form) constitutes a document setting out specific features of a product, which describe in the most complete and specific detail its purpose and application (effect principle or mechanism, functional purpose, efficiency characteristics, validity and linearity of parameters, physical or chemical characteristics of used materials etc.)

This document is aimed at description of specific characteristics of a medical product, its novelty or confirmation of its equivalence to or identity with analog, which has already been registered.
E. A list of constituent elements necessary for product operation or maintenance, its configuration (accessories). (Registration certificate and medical product are assigned the same number).

Appendix 4 to Administrative rules of performance of the state duty of registration of medical products

Chart of administrative procedure “Modification of registration documentation for medical products”

Appendix 5 to Administrative rules of performance of the state duty of registration of medical products

Chart of administrative procedure “Review of facts and circumstances endangering human life and health in application of registered medical products.”

Appendix 6 to Administrative rules of performance of the state duty of registration of medical products

Chart of administrative procedure “Control of medical and other tests of medical products”