MINISTRY OF HEALTH AND SOCIAL DEVELOPMENT OF THE RUSSIAN FEDERATION

ORDER of
October 30, 2006 N 735

On approval of the Administrative Regulations of the Federal Service on Surveillance in Healthcare and Social Development for the implementation of the state function for Registration of Medical Devices

In accordance with the decision of the Government of the Russian Federation of November 11, 2005 N 679 "On the Procedure for the development and approval of administrative rules on execution of state functions and administrative regulations for the provision of public services" (Collected Legislation of the Russian Federation, 2005, N 47, st.4933) and the Regulation on Ministry of Health and Social Development of the Russian Federation , approved by the Decree of the Government of the Russian Federation dated June 30, 2004 N 321 "On approval of the Ministry of Health and Social Development of the Russian Federation" (Collected Legislation of the Russian Federation, 2004, N 28, st.2898, 2005 N 2, Article 162, 2006, N 19, st.2080) order:

1. To approve the Administrative Regulations of the Federal Service on Surveillance in Healthcare and Social Development for the state function for registration of medical devices .

2. Federal Service on Surveillance in Healthcare and Social Development (R.U.Habriev) to ensure the registration of medical devices in accordance with the Administrative Rules approved by this Order.

3. To declare invalid the orders of the Ministry of Health of the Russian Federation dated July 2, 1999 N 274 "On the Procedure for registration of medical devices and medical equipment domestic production in the Russian Federation" (registered by Ministry of Justice of Russia November 10, 1999 N 1970), on May 10, 2000 N 156 "On the resolution on medical usage of medical devices and medical equipment of domestic and foreign production in the Russian Federation" (registered by Ministry of Justice of Russia July 3, 2000, registration N 2297) on June 29, 2000 N 237 "On Approval of the organization and procedure of state registration of medical devices and medical equipment of foreign production in the Russian Federation " (registered by Ministry of Justice of Russia July 26, 2000, registration N 2326), and from December 13, 2001 N 444 "On the timing of the registration certificates for medical devices and medical equipment " (registered by Ministry of Justice of Russia February 21, 2002, registration N 3263).

4. The enforcement of this Order shall be the Deputy Minister of Health and Social Development of the Russian Federation V.I.Starodubova.

Minister
M.Yu.Zurabov

Registered in the Ministry of Justice of the Russian Federation,
November 30, 2006,
registration N 8542

Administrative Regulations of the Federal Service on Surveillance in Healthcare and Social Development for the state function for registration of medical devices

App

ADMINISTRATIVE REGULATIONS

Federal Service on Surveillance in Healthcare
and Social Development for the state function
for registration of medical devices

I. General Provisions

1.1. Administrative Regulations of the Federal Service on Surveillance in Healthcare and Social Development for the state function for registration of medical products (hereinafter - Regulations) is based on sections 11 and 12 of Article 5 Principles of Legislation of the Russian Federation on the protection of public health, adopted by the Supreme Soviet of the Russian Federation 22.07 .93 N 5487-1 (Gazette of the Congress of People's Deputies of the Russian Federation and the Supreme Soviet of the Russian Federation, 1993, N 33, st.1318), in accordance with the decision of the Government of the Russian Federation of 11.11.2005 N 679 "On the Procedure for the development and approval of administrative rules performance of public functions and administrative regulations of public services " (Collected Legislation of the Russian Federation, 2005, N 47, st.4933) and within the powers established by the Regulations of the Federal Service for Supervision of Health and Social Development , approved by the Decree of the Government of the Russian Federation 30.06.2004 N 323 (Laws of the Russian Federation, 2004, N 28, st.2900).

1.2. Registration of medical devices is a public control and oversight function that executes the Federal Service on Surveillance in Healthcare and Social Development of the purpose of admission of medical products for the production, importation, sale and use in the territory of the Russian Federation.

1.3. Registration is required for all medical devices, expected for medical use in the Russian Federation and incorporating instruments, apparatus, instruments, devices, kits, systems with software, hardware, tools, dressings and suture tools, dental materials, reagent kits , control materials and standard samples, calibrators, consumables for the analyzers of plastics, rubber and other materials, the software that is used for medical purposes, alone or in combination with each other and are designed to: * 1.3) - prevention, diagnosis (in vitro), treatment of diseases rehabilitation medical procedures, medical research, replacement parts and modifications of tissue organs, repair or compensate for lost or damaged physiological functions, control conception;

- Impact on the human body, so that their functions cannot be realized by chemical, pharmacological, immunological or metabolic interaction with the human body, but the mode of action which may be maintained by such means.

1.4. Registration of medical devices is carried out in the name of the legal entity or individual entrepreneur, specified in the application for registration.

1.5. In the implementation of the state registration by the Russian and foreign medical devices subject to the same requirements.

1.6. An integral part of the registration of medical devices is their classification according to the degree of potential risk of medical uses in four classes: - Class 3 - medical products with a high degree of risk; - Class 2b - medical products with a high degree of risk; - Class 2a - medical devices with an average risk; - Class 1 - medical products with a low degree of risk. Medical devices, which are sets of diagnosis (in vitro), classified as follows: - Class 3 and Class 2b includes diagnostic tools to determine HIV -1/VICH-2, HTLV I, HTLV II,

Hepatitis B, C and D, rubella, toxoplasmosis, CMV, chlamydia, HLA DR, A and In, PSA, blood glucose (self-test), the risk of having trisomy 21 - class 2a includes a self-diagnostic tools for use by the end user; - Class 1 includes all other diagnostic tools (in vitro).

1.7. Registration is carried out by the Federal Service for Supervision of Health and Social Development on the basis of the results of relevant tests and evaluations that confirm the quality, effectiveness and safety of products. When carrying out registration of medical devices is established as the degree of effectiveness of medical devices to achieve the objectives of its intended use, safety is characterized by the relation the risk of harm to the patient, personnel, equipment or the environment when used correctly and the importance of the purpose for which it is used, the quality is determined by the relevance of the actual properties of the medical device regulatory requirements document. Medical devices 1 and 2a of classes that mimic registered in the territory of analogue of the Russian Federation (any medical product from any manufacturer, relating to the same class of potential risk that applies the same methods (methods) and those that have the same characteristics of effectiveness) are registered on the basis of a document drawn up by the applicant, confirming the absence of differences from such analog (equivalence analogue), or on the basis of certificates of technical tests, safety assessment, confirming the insignificance of the differences detected items from analog (analog identity).

All medical products 2b and 3 classes, as well as medical devices of classes 1 and 2a, unparalleled, registered in the Russian Federation may be registered on the basis of certificates of technical tests, safety assessment and medical tests to confirm the acceptability of quality, efficiency and product safety. Federal Service on Surveillance in Healthcare and Social Development oversees the arrangements for medical and other tests of medical products.

1.8. Information on the number and date of registration of medical devices should be available to the consumer (marked on the packaging, labeling, instructions for use, instruction manual, and also be contained in the advertising of products intended for the end user).

1.9. In the performance of public functions of registration of medical devices, the following administrative procedures:

1) review of the documents and the decision on registration of medical products. Base: part 11 and12 of Article 5 Principles of Legislation of the Russian Federation on health care , approved by the Supreme Soviet of the Russian Federation of 22.07.93 N 5487-1 ;

2) changes in the registration documents for medical devices. Base: part 11 and 12 of Article 5 Principles of Legislation of the Russian Federation on health care , approved by the Supreme Soviet of the Russian Federation of 22.07.93 N 5487-1 ;

3) consideration of the facts and circumstances that pose a threat to the life and health of people in the application of registered medical devices. Base: Article 41 of the Constitution of the Russian Federation ;

4) Monitoring arrangements for medical and other tests of medical products. Base: p.5.1.3.6 provisions of the Federal Service for Supervision of Health and Social Development, approved by the Government of the Russian Federation of 30.06.2004 N 323.

II. Procedural requirements for the execution of state functions

2.1. Procedure for informing the public about the functions of registration of medical devices:

2.1.1. The document confirming the fact of registration of medical devices is a registration certificate. Registration certificate is valid for maintaining the immutability of all set out therein information about medical products, and the person in whose name the medical device registered. The term of the registration certificate is not limited.

2.1.2. Submitting documents and data for the registration of medical devices and (or) changes in the registration documents for medical devices, as well as issuing registration certificates at the address: Federal Service on Surveillance in Healthcare and Social Development, the Department for registration of medical devices : 109074, Moscow, Slavic square, 4, Building 1. Hours: Weekdays from 9-00 to 18-00. place receiving the documents necessary for the execution of state functions to registration of medical devices must be equipped with a telephone, a computer with access to the Internet and the text of the Regulations. Telephones and appointment: +7 (495) 298-4305, +7 (495) 298-2290. E-mail address: deviceregistration@roszdravnadzor.ru General Enquiry Service: +7 (495) 298-4628. information submitted applications for registration, on the review of documents submitted by applicants for registration of medical devices or changes in registration documentation, as well as the decisions taken in accordance with paragraph 2.2 of this Regulation shall be made available to applicants on applications and on the official website: www.roszdravnadzor.ru Publication of medical products registered by the Federal Service on Surveillance in Healthcare and Social Development of monthly on the official website www.roszdravnadzor.ru.

2.1.3. Lists of documents submitted for registration of medical products or changes in registration documentation for medical devices, and requirements for such documents are presented in the relevant sections of the administrative procedures of this Regulation.

2.2. Terms and Conditions of the execution of state functions to registration of medical devices are presented in the relevant sections of the administrative procedures of this Regulation. Consideration of documents produced in the order due to the sequence of their arrival for check-in. Head of the Federal Service on Surveillance in Healthcare and Social Development in the presentation of documents may, by written order to establish that sequence of consideration for a specific medical devices or types of such products, taking into account the following factors:

1) The registrant product is on the list of medical products shipped within the priority national projects of the Russian Federation on the basis of federal laws, decrees of the President of the Russian Federation, the Government of the Russian Federation;

2) recorded by a medical device demonstrably improves the quality and effectiveness of the treatment of diseases with high mortality or disability. Head of the Federal Service on Surveillance in Healthcare and Social Development may, by written order to suspend the examination of documents and the registration decision for the time necessary for the applicant to answer to a request for additional information in cases where such information is necessary for an informed decision on the admission of medical products to the legal treatment in the territory of the Russian Federation.

2.3. Grounds for refusal to review documents or registration of medical devices contained in the relevant sections of the administrative procedures of this Regulation.

2.4. Action or inaction of the Federal Service for Supervision of Health and Social Development in connection with the registration of medical devices can be appealed to the established order. The Minister of Health and Social Development of the Russian Federation, federal law overrides conflicting decisions of the Federal Service on Surveillance in Healthcare and Social Development, unless otherwise cancellation decisions is established by federal law.

III. Administrative procedures

3.1. The structure and relationship of administrative procedures performed in the exercise of registration of medical devices are shown in the diagram (Appendix 1).

3.2. Heads of departments of the Federal Service on Surveillance in Healthcare and Social Development, the meeting in accordance with these Regulations for the registration of medical devices have to organize a documented record of each stage of administrative procedures

with the date of the completion of its execution and signature of the responsible person.

3.3. The administrative procedure "Document review and decision on the registration of medical products" made in connection with the receipt of documents for registration of medical devices from the applicant in accordance with the following procedure (Scheme administrative procedure is given in Appendix 2).

3.3.1. Examination of the documents and the decision on registration of medical devices within the time frame of 4 months from the date of the set of documents provided by paragraph 3.3.3 of this Regulation , the Federal Service on Surveillance in Healthcare and Social Development. As if the registrant medical devices of Class 1 and 2a is equivalent to or identical with its analog, must be applied expedited review procedure documents and the registration decision. The accelerated procedure is carried out by the Federal Service on Surveillance in Healthcare and Social Development within 2 months from the date of submission of the complete set of documents required by these Regulations to the Federal Service on Surveillance in Healthcare and Social Development. Application processing and decision on registration of medical devices may be extended for a period not exceeding three months, with the aim of enabling the applicant to conduct additional testing and evaluation by its treatment. Notice of the additional testing and evaluation to the applicant. If after this period, the applicant does not present the required documents, the Federal Service on Surveillance in Healthcare and Social Development may refuse to register the applicant.

3.3.2. Documents submitted by the applicant for the registration of medical devices registered within 1 business day from the date you receive them. A set of documents can be sent by registered mail (parcel) with a list of contents, and return receipt. The second copy of the inventory and statement marked the incoming number is sent (delivered) to the applicant. Control of accounting documents received carries the head of department, carrying out registration of medical products.

3.3.3. For registration of medical devices applicant shall submit to the Federal Service on Surveillance in Healthcare and Social Development of the following documents:

1) The application for the registration of medical devices;

2) a document certifying payment of the state fee; * 3.3.3)

3) a certificate of medical products;

4) documents confirming registration of the manufacturing organization as a legal entity;

5) the power of attorney or a certified copy of the contract in the event that the applicant is not the manufacturer of medical products;

6) documents confirming compliance with the conditions of production of medical devices with the legislation of the Russian Federation;

7) The draft regulatory document, together with proof of compliance with medical devices to its requirements or the requirements of technical specifications or standards;

8) manual of medical devices;

9) the draft package leaflet during registration physiotherapy apparatus and reagents (kits) for the diagnosis (in vitro), end-user self-employed;

10) in the cases specified by this Regulation p.1.7 - documents confirming the identity or equivalence of medical products to its analogue;

11) in the cases specified by this Regulation p.1.7 - the results of technical tests, evaluating the safety and effectiveness of medical tests and safety of medical devices. All documents for the registration of medical devices should be presented in Russian or have a certified translation into Russian. Contents of submissions of information that allow the examination of the quality, effectiveness and safety of a medical product or its equivalence or identity of analogue, is given in Annex 3. Require the applicant to submit other documents are not allowed. Application for registration of medical products contain the applicant's name, the name of the legal entity or individual entrepreneur in whose name a registration, the name of the registered medical devices, intended scope of application of the product; acknowledgment of responsibility for the possible negative effects of the right the use of medical devices; acknowledgment of responsibility for the violation of the rights of other persons in the manufacture, import and sale of medical products in the territory of the Russian Federation and the proposed class of potential risk of using medical devices, information about analogues of products registered in the Russian Federation (if available).

3.3.4. Head of the Department in charge of registration of medical devices, for 4 days from the date of receipt of documents shall designate from among employees of the department responsible officer for the review of the documents submitted for registration of medical devices. Last name, first name and patronymic of the responsible officer, his place of work and the phone must be communicated to the applicant in his written or oral treatment. Head of the Federal Service on Surveillance in Healthcare and Social Development is responsible for registration of medical devices, subject to the provisions of this Regulation takes the decision to use or non-use of accelerated procedures for handling documents. About the decision the applicant is informed in writing.

3.3.5. Executive in charge for 15 days from the date of his appointment and shall check the completeness of the documents submitted for the purpose of determining: - the availability of all of the documents specified by paragraph 3.3.3 of this Regulation ; - the consistency of the information between different sets of documents; - reliability of the documents confirmed by the authorized signature of the applicant on each document; - matching content, level of detail of the information, and evidence of the results of tests and assessments; - the

eligibility of the registration application with the applicable legal requirements imposed on entities handling medical products in the territory of the Russian Federation. When incomplete completeness, unsettled documents or otherwise of the application for registration is preparing a reasoned denial of further review of documents indicating the reasons for the refusal, which is signed by the head of the Federal Service on Surveillance in Healthcare and Social Development, and sent to the applicant.

3.3.6. Executive in charge within 5 calendar days from the date of completion of checking the delivery and composition of the documents submitted for registration, classifies medical devices in accordance with the requirements of this Regulation p.1.7.

3.3.7. Executive in charge within 5 calendar days from the date of completion of the classification of medical devices determines the need for additional information (test results), and (or) the examination of the quality, efficiency and safety in accordance with the class of the product.

Additional information is required only if the test results shown in its composition and content of the product do not correspond to the class. In this case, further review of the documents may be suspended in accordance with 3.3.1 of this Regulation. need for the examination of the quality and (or) efficiency, and (or) the safety of medical devices based on the following grounds: - if the product is registered by the medical purpose is to classes 2b or 3 - in the absence of analog, registered in the Russian Federation. If there are grounds for executive in charge of the examination within the period set aside for the present stage of the administrative procedure, a draft specification for examination of the quality, effectiveness and safety of medical products appointment with the organization, which will conduct the examination, the deadline for execution of works and issues that have to get an expert opinion. The project is coordinated tasks head of the department dealing with the registration of medical devices, and approved by a person authorized for this purpose by the head of the Federal Service on Surveillance in Healthcare and Social Development. Examination of the quality, effectiveness and safety of medical devices should be held for up to 75 calendar days, or within 15 calendar days (expedited) from the date of approval of the job.

3.3.8. Within 10 calendar days from the date of receipt of the opinion of an expert organization, or in the absence of the need for expertise - from the date of completion and checking the delivery of documents and data submitted for the registration of medical devices responsible contractor prepares a report on the registration of medical devices with the : - the results of documentary check sets of documents and data submitted for the registration of medical devices; - materials conducted assessments of quality, efficacy and safety of medical devices;

- Additional information from the applicant. the positive conclusion is preparing a draft order of registration and the registration certificate to be signed by the head of the Federal Service on Surveillance in Healthcare and Social Development. A negative conclusion is preparing a notice of refusal to register with indication of reasons, which is signed by the head of the Federal Service on Surveillance in Healthcare and Social Development, and sent to the applicant.

3.3.9. Registration of medical devices refuses the following reasons:

1) with partial completeness, unsettled by the applicant documents and data specified item 3.3.3 of this Regulation or otherwise of the application for registration;

2) the presentation by the applicant of false or invalid information about medical equipment (with the exception of the proposed class product by the applicant, the final determination is made by the Federal Service on Surveillance in Healthcare and Social Development);

3) when receiving an expert opinion about insecurity, inefficiency or lack of proof of safety and efficacy of medical products in the event that it is obtained from at least two independent experts and evidence: - the risk of use of the product is higher than expected efficiency; - about insufficient evidence of effectiveness; - of non-compliance to the information in the documents submitted for registration, the actual condition.

3.3.10. Within 5 calendar days from the date of signing the order and the registration certificate responsible contractor shall notify the applicant of the registration certificate of readiness.

3.3.11. Within 10 working days from the date of signing the order and the registration certificate executive in charge sends registration information to make changes to the database of registered medical products and archiving.

3.3.12. Federal Service on Surveillance in Healthcare and Social Development shall issue a duplicate registration certificate of medical devices by the statements of the person in whose name it is registered, within 1 month from the date of receipt of such application.

3.3.13. Documents and data submitted for the registration of medical devices, regardless of whether it is registered or not, are stored in the Federal Service for Supervision of Health and Social Development, together with the relevant expert reports, copies of orders for registration and registration certificates (collectively referred to as - registration documentation) in compliance with the confidentiality of information during the registration term and within 5 years after its expiration.

3.4. The administrative procedure "Changes in the registration documents for medical products" made in connection with the receipt from the person named in the registration certificate (or its successor), a set of documents justifying the changes to the registration documentation, or in connection with the identification of the Federal Service for Surveillance in Healthcare and Social Development on the effectiveness or safety of medical devices in accordance with the following procedure (Scheme administrative procedure is given in Annex 4)

3.4.1. Changes to the registration documents for medical devices for the quality, efficacy or safety of medical products, the Federal Service on Surveillance in Healthcare and Social Development within the time specified in 3.3.1 of this Regulation . In all other cases, including those associated with the inclusion of data on the new side effects or limitations to the application, change the rights to a medical device, its trade name, packaging, changes in registration documentation shall be made within a period not exceeding one month from the date of receipt of

appropriate set of documents.

3.4.2. Documents submitted by the applicant to amend the registration documentation of medical devices registered within 1 business day from the date you receive them. A set of documents can be sent by registered mail (parcel) with a list of contents, and return receipt. Control of accounting documents received carries the head of department, carrying out registration of medical products. All documents for amending the registration documents for medical devices to be submitted in Russian or have a certified translation into Russian.

3.4.3. Head of the Department in charge of registration of medical devices, for 4 days from the date of receipt of documents shall designate from among employees of the department responsible officer for the review of documents submitted for changes in registration documentation of medical devices. Last name, first name and patronymic of the responsible officer, his place of work and the phone must be communicated to the applicant in his written or oral treatment.

3.4.4. Executive in charge for 10 days from the date of his appointment and shall check the completeness of the documents submitted for the purpose of determining: - the consistency of the information between different sets of documents; - reliability of the documents duly certified; - matching content, level of detail of the information, and as evidence of the results of tests and assessments.

3.4.5. Executive in charge within 5 calendar days from the date of completion of the verification of the completeness and the documents submitted to amend the registration documents as necessary to re-classifies medical devices in accordance with the requirements of this Regulation p.1.7.

3.4.6. Executive in charge within 5 calendar days from the date of completion of the classification of medical devices determines the need for additional information (test results), and (or) the examination of the quality, efficiency and safety in accordance with the class of products. Additional information is requested only if the submitted Test results on the structure and contents do not correspond to the class

of product. In this case, further review of the documents may be suspended in accordance with3.3.1 of this Regulation. need for the examination of the quality and (or) efficiency, and (or) the safety of medical devices based on the following grounds: - If after making changes registration documentation in medical devices will apply to classes 2b or 3;

- In the absence of analog, registered in the Russian Federation. If there are grounds for the executive in charge of the examination in the time allocated for the implementation of this stage of the administrative procedure, a draft specification for examination of the quality, effectiveness and safety of medical devices with the organization, which will hold examination, the deadline for execution of works and issues that have to get an expert opinion. The project is coordinated tasks head of the department dealing with the registration of medical devices, and approved by a person authorized for this purpose by the head of the Federal Service on Surveillance in Healthcare and Social Development. Examination of the quality, effectiveness and safety of medical devices should be held for up to 75 calendar days, or within 15 calendar days (if analog) from the date of approval of the job.

3.4.7. Within 5 calendar days from the date of receipt of the opinion of an expert organization, or in the absence of the need for expertise - from the date of completion of the verification of the documents submitted and responsible contractor prepares a report on changes in the registration documents for medical devices based on: - the results of documentary verification kit documents and data submitted for changes in the regulatory and technical documentation for medical devices; - materials conducted assessments of quality, efficacy and safety of medical devices; - further information from the applicant. the positive conclusion is preparing a draft order amending the registration documents for medical devices and the registration certificate to be signed by the head of the Federal Service on Surveillance in Healthcare and Social Development. A negative conclusion is preparing a notice of refusal to amend the registration documents for medical devices with indication of reasons, which is signed by the head of the Federal Service for Supervision health and social development, and to the applicant.

3.4.8. To amend the registration documents for medical device refuses on the following grounds:

1) In case of failure or incomplete submission by the applicant of documents justifying the changes in the registration document;

2) make a false or invalid information justifying the changes in the registration document;

3) obtain an expert opinion on the possible decline in the quality, effectiveness and safety of medical devices in the event of changes in the registration documentation.

3.4.9. To amend the registration documents for medical devices cannot be refused if:

1) The changes relate to the name, address, or the legal form of the applicant;

2) changes associated with the transfer of rights to medical devices while maintaining a permanent place of its manufacture;

3) The applicant raises the requirements for the data quality of medical devices or decreases (restrict) the scope of its use to the extent applicable;

4) changes are related to the need to fulfill the requirements established by the legislation of the Russian Federation.

3.4.10. Within 5 calendar days from the date of signing the order and the registration certificate responsible contractor shall notify the applicant of the registration certificate of readiness.

3.4.11. Within 10 working days from the date of signing the order and the registration certificate executive in charge sends registration information to make changes to the database of registered medical products and archiving.

3.4.12. Federal Service on Surveillance in Healthcare and Social Development shall issue a duplicate registration certificate of medical devices by the statements of the person in whose name it is registered, within 1 month from the date of receipt of such application.

3.4.13. Documents and data submitted for the registration of medical devices, regardless of whether it is registered or not, are stored in the Federal Service for Supervision of Health and Social Development, together with the relevant expert reports, copies of orders for registration and registration certificates in compliance with the requirements of ensure the confidentiality of information during the registration term and within 5 years after its expiration.

3.5. The administrative procedure "Review of the facts and circumstances that pose a threat to the life and health of people registered in the application of medical products" made in connection with the discovery of the facts and circumstances (the arrival of the relevant documents on the subjects of circulation of medical products) that endanger the life and health of people with the right use of medical devices in accordance with the following procedure (Scheme administrative procedure given in Annex 5):

3.5.1. In identifying the facts and circumstances that pose a threat to life and health when properly used medical products, including, without limitation, any adverse clinical manifestations that the use of medical devices in accordance with the instruction (instruction) manual (application) lead to death, create life-threatening, requires hospitalization or prolongation, result in persistent or significant disability, and (or) disability or cause abnormal reproductive effects or such clinical manifestations, the nature and severity of which is not consistent with the available information about medical products, head of performing registration of medical devices, within 5 working days from the date of detection of such circumstances is preparing a corresponding memorandum to the head of the Federal Service on Surveillance in Healthcare and Social Development. As if the cause of such events are features of the mechanism of action of medical devices the application of this

administrative procedure can be extended to all equivalent or identical him medical products.

3.5.2. Within 5 working days of receipt of the memorandum or additional information about the circumstances identified head of the Federal Service on Surveillance in Healthcare and Social Development may take the following decisions:

1) to give an order to organize the collection of additional information on the identified negative effects of the use of medical devices;

2) give instructions to conduct an additional examination of the quality, effectiveness and safety of medical devices based on the identified adverse effects of its use;

3) to consider amending the registration documents for medical devices;

4) the suspension of the decision on the registration of medical devices;

5) to revoke the registration certificate of medical devices;

6) not to take any further action in the event that the identified negative effects of using medical devices are random.

3.5.3. Collection of additional information and additional work quality, efficiency and safety of medical devices based on the identified adverse effects of its use is made in the terms established by the head of the Federal Service on Surveillance in Healthcare and Social Development.

3.5.4. Consideration of amendments to the registration documents in connection with the identification of the adverse effects of the use of medical devices in accordance with the administrative procedure, "Changes in the registration documents for medical devices" of this Regulation.

3.5.5. Federal Service on Surveillance in Healthcare and Social Development of the decision to suspend the registration of medical devices for the purpose of providing the person named in the registration certificate, the ability to carry out additional technical tests, and (or) the safety assessment, and (or) medical test medical devices in connection with the identified adverse effects. If a person named in the registration certificate, to conduct additional technical tests, and (or) the safety assessment, and (or) medical tests, and, if confirmed in the supplementary examination of the quality, effectiveness and safety medical device adverse effects of the use of medical devices Federal Service on Surveillance in Healthcare and Social Development revokes the registration certificate. Information about the recall of the registration certificate is entered into a database of registered medical products.

3.6. The administrative procedure "Control of the arrangements for medical and other tests of medical products" is just as necessary in the course of administrative procedures "Document review and decision on the registration of medical devices," "Changes in the registration documents for medical devices" and "Considering the facts and circumstances that pose a threat to the life and health of people in the application of registered medical purpose" of this Regulation in accordance with the following procedure (Scheme administrative procedure is given in Appendix 6):

3.6.1. Within 5 calendar days from the date of recognition of the need to obtain more information (results of technical, medical tests or safety assessment) for the applicant and (or) in the examination of the quality, efficiency and safety in accordance with the class of medical devices responsible contractor prepares a referral for testing or expertise, which is coordinated head of the department dealing with the registration of medical devices, and approved by a person authorized for this purpose by the head of the Federal Service on Surveillance in

Healthcare and Social Development.

The direction is given to the applicant. It should be listed organizations that can carry out the necessary tests and give the required findings, selected from a list maintained by the Federal Service on Surveillance in Healthcare and Social Development 'specialty, technical equipment and staff competence of organizations that have concluded relevant treaties. In the direction as indicated test times and (or) the expertise to meet the requirements of this Regulation. Request for medical tests is prepared only after a positive test result of technical and safety evaluation of medical devices.

3.6.2. Head of the Department in charge of registration of medical devices should organize inspections of medical and other tests of medical products in the course of their conduct.

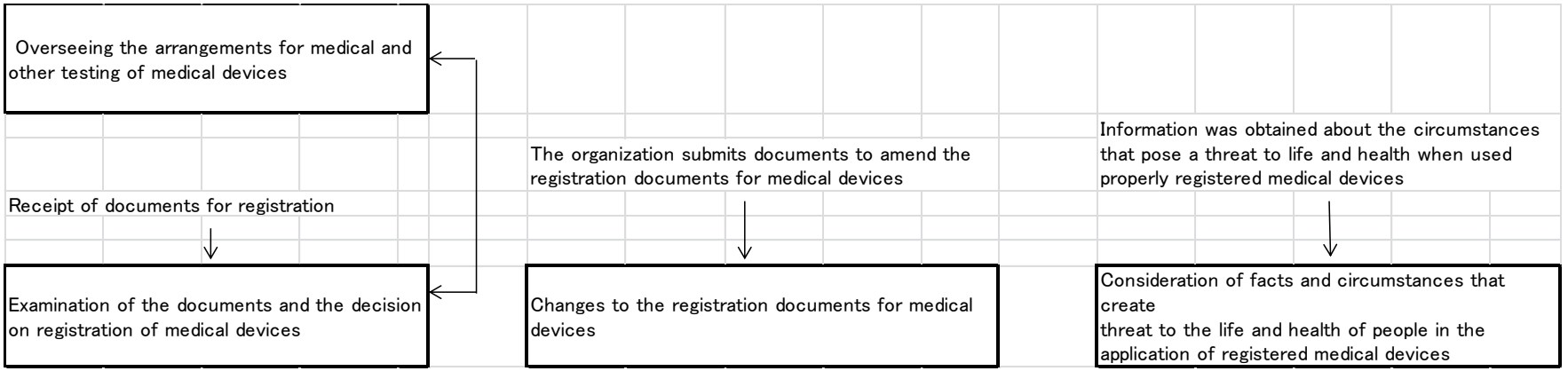
3.6.3. Documents submitted by the applicant and include acts (protocols) of the tests, and (or) the conclusions of the examination of quality, efficacy and safety of medical devices registered within 1 business day from the date you receive them. A set of documents can be sent by registered mail (parcel) with a list of contents, and return receipt. Control of accounting documents received carries the head of department, carrying out registration of medical products.

Appendix 1. Outline: The structure and the relationship of administrative procedures performed in the exercise of registration of medical devices

Appendix 1 to the Administrative Regulations

Outline: The structure and the relationship of administrative procedures performed in the exercise of registration of medical devices

Management of registration of medicines and medical equipment

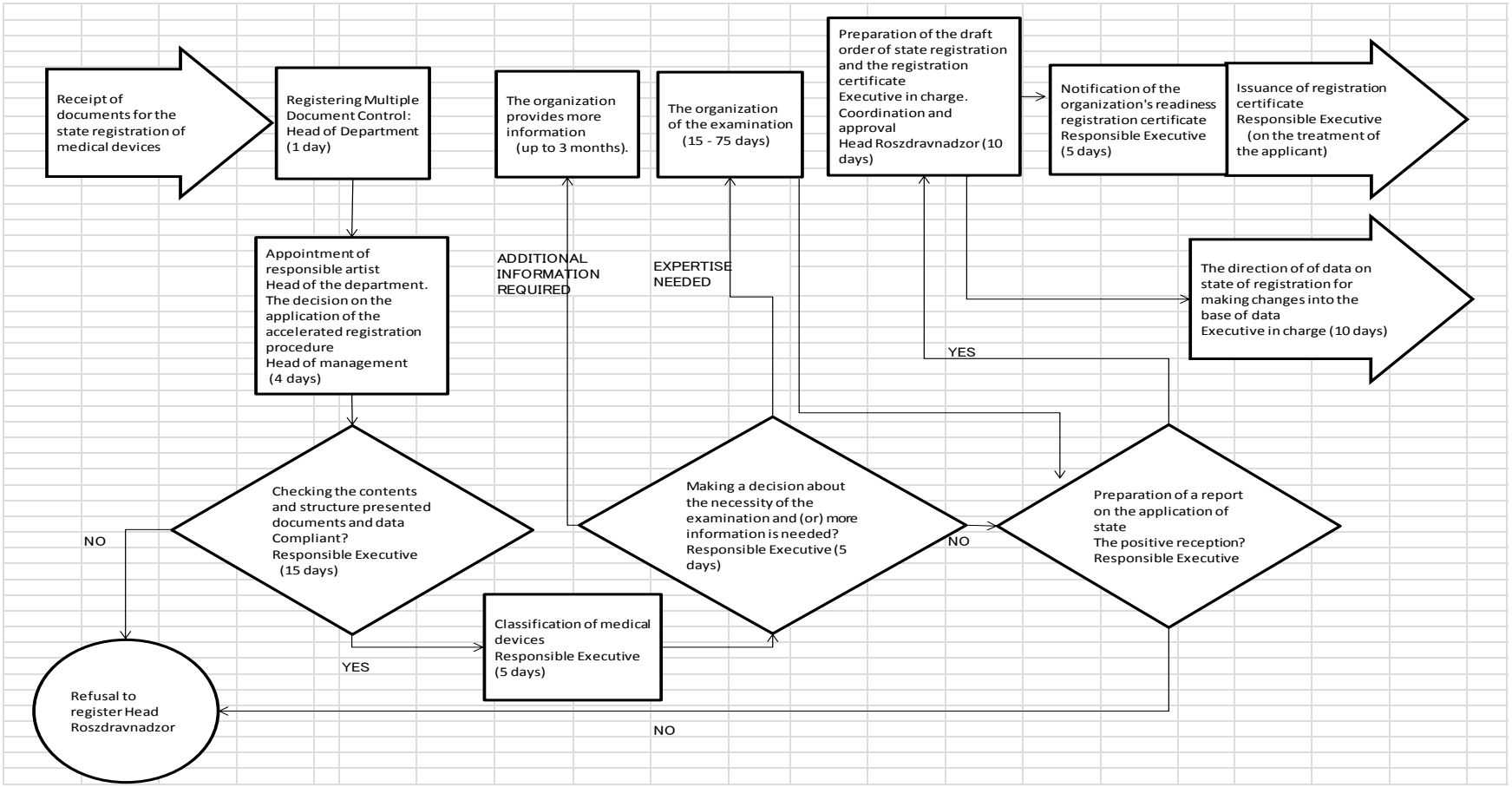


Appendix 2. A block diagram of the administrative procedure "Document review and decision on the registration of medical devices"

Annex 2 to the Administrative Regulations

A block diagram of the administrative procedure "Document review and decision on the registration of medical devices"

Management of registration of medicines and medical equipment



Appendix 3. Requirements for the content of the documents submitted for registration of medical devices

Annex 3
to the Administrative Regulations

Requirements,
imposed on the content of the documents submitted
for registration of medical devices

A. The certificate of medical devices should contain the following information: description of the product, the description of the operating principle of the product or a reference to evidence-based mechanism of action, information on all related to the principle of action (or mechanism of action) of the functional characteristics of the product, such as its design, the materials and physical properties; information fields of application products, including a brief description of human diseases or conditions in which the product can be used for diagnosis, treatment, prevention or amelioration of, including, if possible, to determine the frequency of occurrence of such diseases or conditions .

B. Proof of equivalence or identity of medical products to its equivalent should contain the following information: a comparison table of all relevant principle of action (or mechanism of action), the functional characteristics of the detected products in relation to the corresponding characteristics of the analog. In the event that there are differences, it is necessary to give an explanation as to why these differences, according to the applicant, do not affect the quality, efficacy or safety of medical products, in the event that the proposed scope of the registered medical devices are different from analog applications for each case of such deviations by the applicant shall be given an explanation of these differences and the reasons why it can not exert influence on its effectiveness and safety. Curtailment of the registered

medical products to peers is not considered a deviation.

B. Evidence of the results of technical tests, evaluating the safety and effectiveness of medical tests and safety of medical devices should contain the following information: the type and the definition of the object of research (as applicable) (technical tests of the physical properties of the product; microbiological research, toxicological studies; immune-biologic research; bioequivalence studies, research efficiency; stability studies (determination of shelf life), and so forth), the researchers concluded from the results of research;

additional documents showing the results of the medical tests the efficacy and safety of medical devices should include the study protocol, summarized information about the effectiveness and safety of the product, adverse reactions and complications; breakdowns of medical devices in medical trials that led to the repair or replacement; Information about patients who took part in the tests (number, gender, age, diagnosis), including confirmation of the written consent of patients to participate in research, patient complaints, quantitative information for each patient, as set out in tabular form, the results of statistical processing of the survey data.

G. Standard document medical products (to be completed by the applicant and has no mandatory requirements on the form of presentation) is a document showing the specific characteristics of the product, the most complete and specifically describing its purpose and the use of (a principle or mechanism of action, functionality, performance characteristics, the accuracy and linearity parameters, physical or chemical properties of the materials used, etc.). This paper aims to describe the specific medical device, its novelty or confirm the identity or equivalence already registered counterpart.

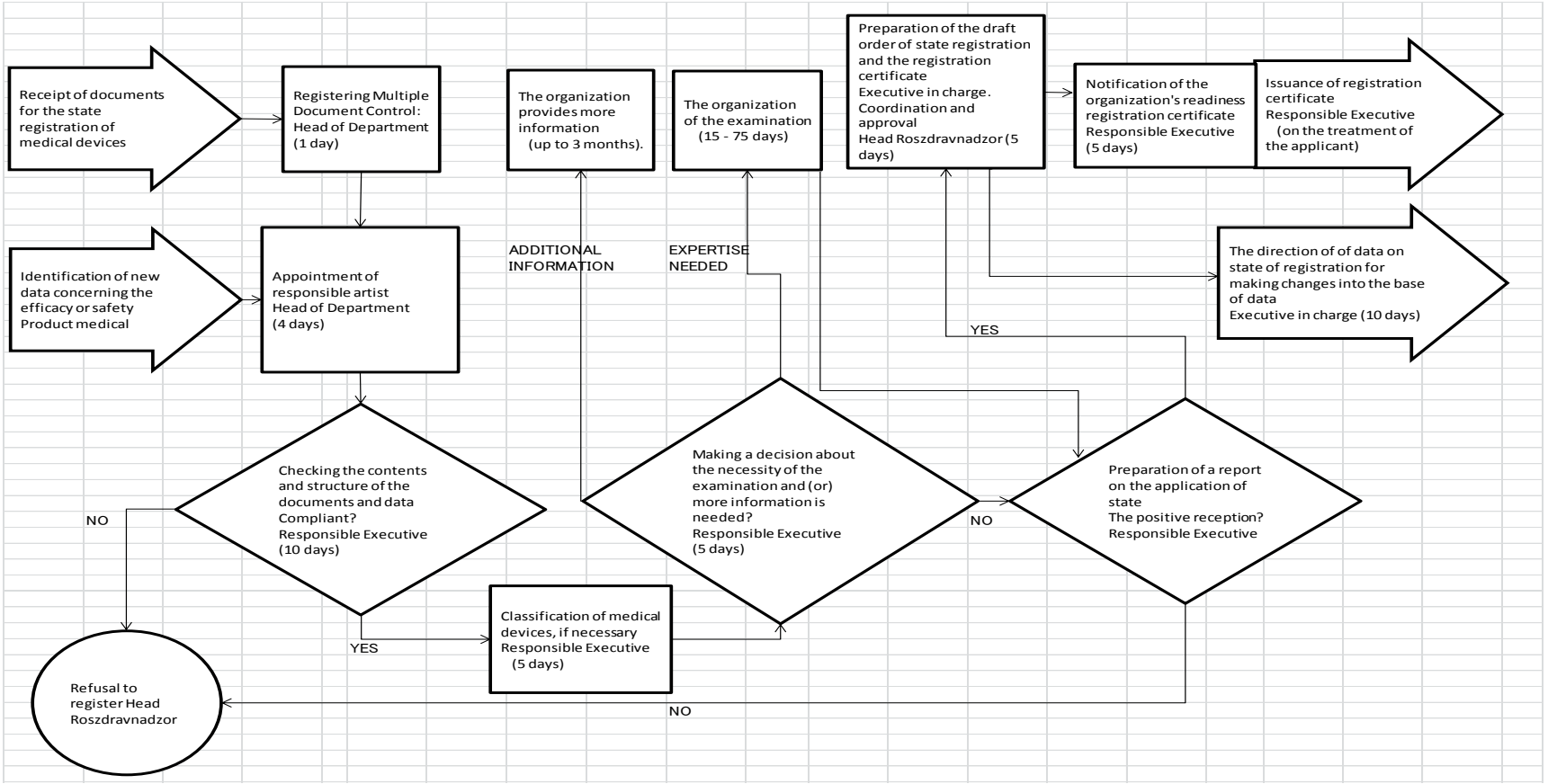
D. A list of components of components necessary for the operation of the product and its service, its equipment (accessories). (Gets a single registration certificate number with medical devices.)

Appendix 4. A block diagram of the administrative procedure, "Changes in the registration documents for medical devices"

Annex 4 to the Administrative Regulations

A block diagram of the administrative procedure, "Changes in the registration documents for medical devices"

Management of registration of medicines and medical equipment



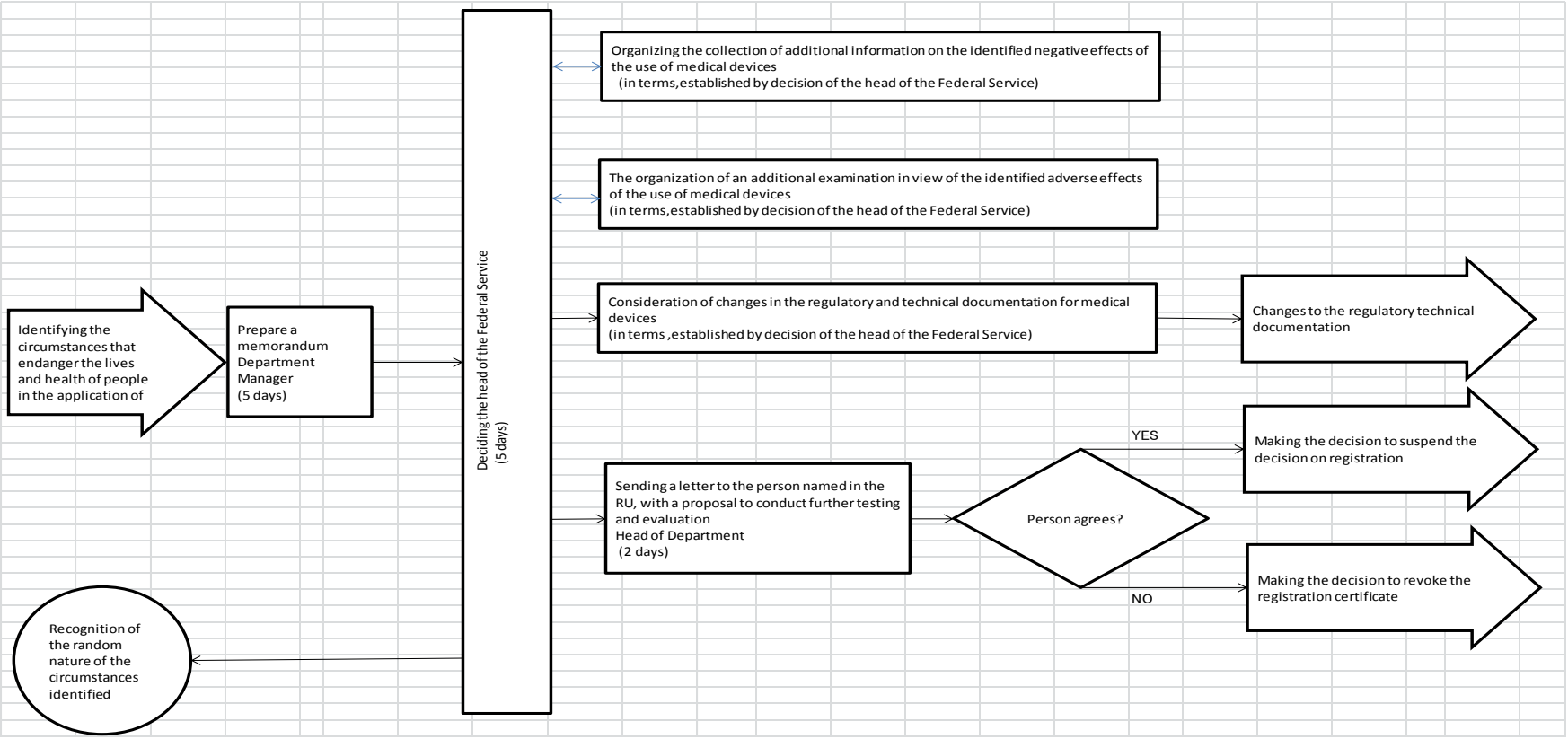
Appendix 5. A block diagram of the administrative procedure "Examination of the facts and circumstances that pose a threat to the life and health of people in the application of registered medical devices

Annex 5 to the Administrative Regulations

A block diagram of the administrative procedure

"Examination of the facts and circumstances that pose a threat to the life and health of people in the application of registered medical devices"

Management of registration of medicines and medical equipment



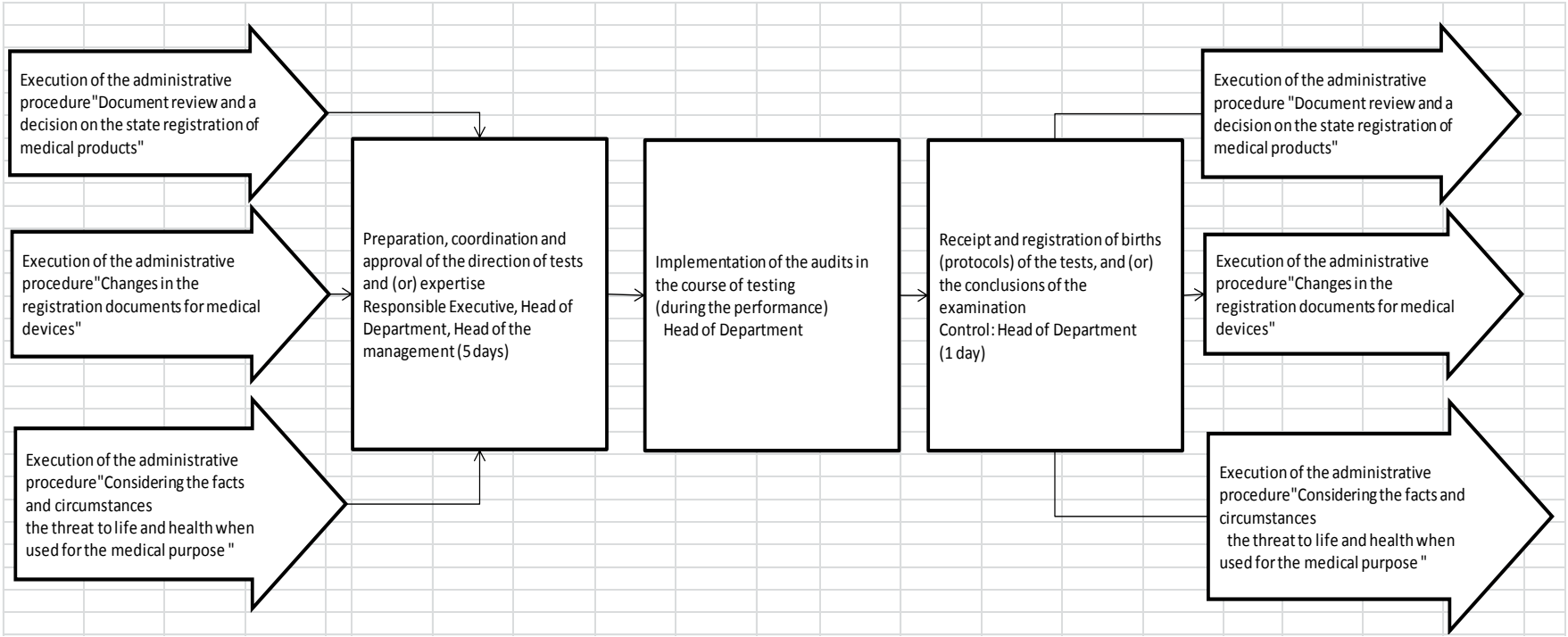
Appendix 6. A block diagram of the administrative procedure "Control of the arrangements for medical and other tests of medical products"

Annex 6 to the Administrative Regulations

A block diagram of the administrative procedure

"Control of the arrangements for medical and other tests of medical products"

Management of registration of medicines and medical equipment



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