Circulation
of the Medical Devices in Russian Federation

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Федеральная служба по надзору в сфере здравоохранения

Definition of Medical Device in Russian Federation

The Federal Law No. 323-FZ dated 21.11.2011
“The basis of health protection in the Russian Federation“
Article 38. Medical devices.

Medical devices are

any instrument, apparatus, appliances, equipment, materials and other devices used for medical purposes alone or in combination with each other as well as with other accessories required for use of these devices for their purpose, including special software and designed by the manufacturer for the prevention, diagnosis, treatment and rehabilitation of diseases, monitoring the state of the human body, for medical research, rehabilitation, replacement, changes of anatomical structure or physiological functions, prevention or termination of pregnancy, which function is not implemented by pharmacological, immunological, genetic or metabolic effects on the human body. Medical devices may be recognized as interchangeable if they are comparable in functionality, quality and technical characteristics and can replace each other.

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Classification of Medical Device in Russian Federation

The Federal Law No. 323-FZ dated 21.11.2011
“The basis of health protection in the Russian Federation“
Point 2. Article 38.

Medical devices are divided

on classes

depending on the degree of the potential risk of the application of medical devices

on types

depending on the nomenclature classification of medical devices

Nomenclature classification of medical devices is approved by the authorized federal agency

The order of the Ministry of Health of the Russian Federation
Dated 06.06.2012 No.4n
“Adoption of the Nomenclature classification of medical devices”

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The Order of the Ministry of Health of the Russian Federation No.4n Dated 06.06.2012 "Adoption of the Nomenclature classification of medical devices" (as revised in the Order of the Ministry of Health of the Russian Federation No.557n Dated 25.09.2014)

Came into force on 06 January 2015

Classes of medical device

Class 3	medical devices with high degree of risk
Class 2b	medical devices with increased degree of risk
Class 2a	medical devices with average degree of risk
Class 1	medical devices with low degree of risk

The rules of classification were separately established for the **in vitro diagnosis** medical devices, according to the recommendations of the Group for Global Harmonization of medical devices (GHTF/SG1/N045:2008).

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Structure of the type of medical device

- Identification unique entry number
- Name of type of medical device
- Description of the type of medical device

Classification attributes of the type of medical device, according to the purpose of medical device

- Application area
- Invasiveness
- Sterility
- Exploitation aspects
- Frequency of use (one time or multiple use)
- Structural specifics

The nomenclature classification of medical devices by types can be found on the official Roszdravnadzor site *www.roszdravnadzor.ru* in the section «Electronic services»

Федеральная служба по надзору в сфере здравоохранения

Circulation of Medical Devices

The Federal Law No. 323-FZ dated 21.11.2011
“The basis of health protection in the Russian Federation“
Point 3. Article 38.

Circulation of medical devices includes:

Technical testing	Import to the territory of the Russian Federation	Sales
Toxicity testing	Export from the territory of the Russian Federation	Installation
Clinical trials	Confirmation of compliance	Calibration
Official registration	State control	Application
Production	Storage	Repair
Manufacturing	Transportation	Utilization and disposal

Exploitation, including maintenance, required by regulatory, technical and (or) exploitation manufacturer’s documentation

Expertise of quality, effectiveness and safety of medical devices

Федеральная служба по надзору в сфере здравоохранения

The Scheme of Circulation of Medical Devices on the Territory of the Russian Federation

Medical devices imports
for the purpose of state registration

State registration of the medical devices

Permission of the circulation of the medical devices
(getting registration certification)

State control of the circulation of medical devices

Федеральная служба по надзору в сфере здравоохранения

Laws Regulating Registration of Medical Devices in the Russian Federation

Federal Law **No. 323-FZ dated 21.11.2011**
“The basics of health protection of the citizens of the Russian Federation”

Russian Government order **No. 323 dated 30.06.2004**
“Adoption of the statues of the Federal Service for Surveillance in Healthcare”

Russian Government order **No. 1416 dated 27.12.2012**
“Adoption of rules for state registration of medical devices”

Roszdravnadzor’s order **No. 3371 dated 06.05.2019**
“Adoption of administrative regulation of the Federal Service for Surveillance in Healthcare provision of state services of the state registration of medical devices”

Ministry’s of Health order **No. 7n dated 15.06.2012**
“Approval of the procedures for imports of medical devices into the Russian Federation for the purposes of state registration”

Федеральная служба по надзору в сфере здравоохранения

The scheme of issuing permission for import of medical devices for the purpose of registration

Company-applicant

Company's application to the expert organization for the purpose of:

1. To conclude the agreement for conducting testing (technical, toxicity etc.)
2. To determine the necessary quantity of medical devices for the testing

Expert organization

Submission of documents to Roszdravnadzor

I. Application
- Medical device name, including components, quantity, manufacturing number, lot, batch number, production dates, expiry and (or) exploitation dates
- Purpose of medical device
- Applicant's information
- Organization's information, where the testings to be conducted

II. Copies of the agreements for necessary testings (studies) with the required number of medical devices

III. Copy of the document, confirming powers of the manufacturing representative.

Roszdravnadzor's decision

Permission for import of medical device for the purpose of registration

Notification of permission denial for import of medical device for the purpose of registration

Федеральная служба по надзору в сфере здравоохранения

The Scheme of State Registration of Medical Devices in the Russian Federation

Preparation of documents

Testing of medical devices :
- ✓ technical
- ✓ toxicological
- ✓ for the purposes of type approval of measuring instruments (if necessary)

Preparation of documents for state registration of medical devices

Registration of medical devices (Stage I)

The review of documents

Elimination of violations (if necessary)

Stage I
examination of the quality, effectiveness and safety of medical devices

Request additional materials and information

Permission to conduct clinical trials

Refusal in state registration

Preparation of documents

Clinical trials of medical devices
(suspension of state registration of medical devices)

Registration of medical devices (Stage II)

Renewal of state registration

The review of documents

Stage II
examination of the quality, effectiveness and safety of medical devices

Request additional materials and information

The decision on the state registration

Refusal in state registration

Федеральная служба по надзору в сфере здравоохранения

Algorithm of Registration procedure (for the MD class I and IVD) in Russian Federation

Russian Government order **No. 1416 dated 27.12.2012** "Adoption of rules for state registration of medical devices"
(as revised in the Russian Government order **No. 633 Dated 31.05.2018**)

Came into force on 13 June 2018

Pre-registration procedure

In-country Testing of medical devices at Russian Authorized Labs :

- ✓ Technical tests
- ✓ Toxicological test
- ✓ Metrological tests (if necessary)

In country Clinical trials of medical devices at Russian Authorized Hospitals

The Registration dossier forming in Russian (application, check-list, test reports, report of clinical trials)

Registration of medical devices

Renewal of state registration

The review of documents

Stage II
Expertise of the quality, effectiveness and safety of medical devices

Request additional materials and information

The decision on the state registration

Refusal in state registration

Федеральная служба по надзору в сфере здравоохранения

Algorithm of Registration procedure (because of COVID-19) in Russian Federation

Russian Government order **No. 1416 dated 27.12.2012** "Adoption of rules for state registration of medical devices"
(as revised in the Russian Government order **No. 299 Dated 18.03.2020**)

Came into force on 19 March 2020

Registration of medical devices

Technical and operational documentation of medical device
Photos of medical device
Power of attorney for an authorized representative of an manufacturer
All documents must be certified in the country of origin in the prescribed manner

Not more 150 days

Confirmation of registration

In-country Testing of medical devices at Federal State Budgetary Institution "All-Russian Scientific-research and Test Institute for Medical Engineering" of Roszdravnadzor:

- ✓ Technical tests
- ✓ Toxicological test

In country Clinical trials of medical devices at Russian Authorized Hospitals

Renewal of state registration

The review of documents

Expertise of the quality, effectiveness and safety of medical devices

Request additional materials and information

The decision on the state registration

Refusal in state registration

Федеральная служба по надзору в сфере здравоохранения

Algorithm of Registration procedure (because of COVID-19) in Russian Federation

Russian Government order **No. 430 dated 03.04.2020** “About features of the circulation of medical devices, including state registration of a series (batch) of a medical device”

Came into force on 06 April 2020

Preparation of documents

Operational documentation of medical device
Photos of medical device
Documents confirming that the series (batch) of the medical device belongs to the applicant on legal grounds
Technical tests according to the standard program
Toxicological tests according to the standard program
Clinical trials according to the standard program
All documents must be certified by the applicant

Registration of medical devices

Expertise of the quality, effectiveness and safety of medical devices

Request additional materials and information

The decision on the state registration of a series (batch) of medical devices

Refusal in state registration

Validity of the registration certificate – 01.01.2021

Single-use medical devices registered in the country of origin are not subject to registration in Russian Federation

Федеральная служба по надзору в сфере здравоохранения

Circulation of Medical Devices in Eurasian Economic Union

On January 1, 2015

The Treaty on Eurasian Economic Union entered into force

Федеральная служба по надзору в сфере здравоохранения

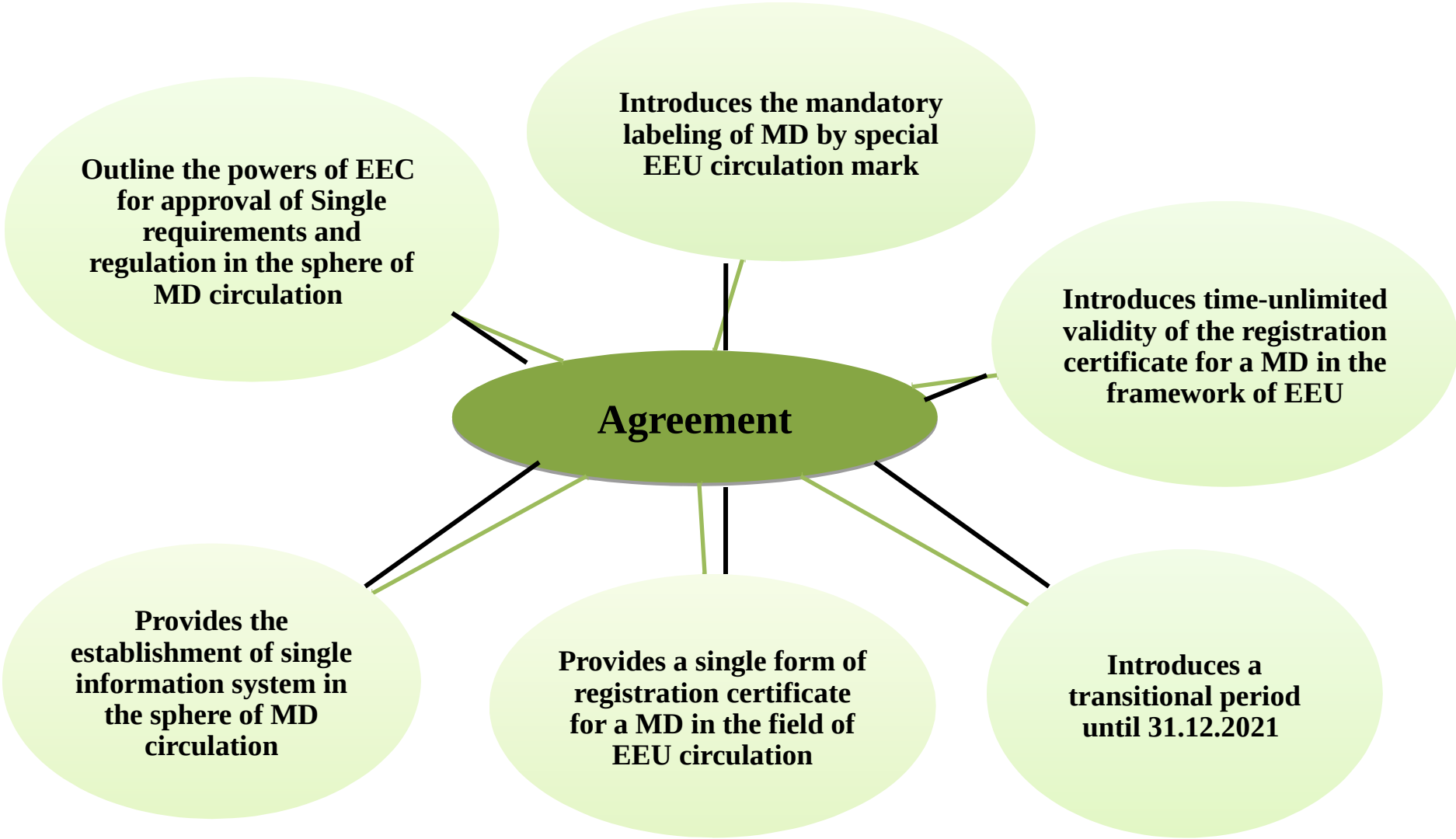
The Main Principles in Eurasian Economic Union

An agreement “On Single principles and rules of MD circulation” in the framework of EEU from 23.12.2014

Single rules of pre-market approval procedure, classification, conducting trials for registration purposes, single requirements of safety and efficiency except requirements for implementation, maintaining and evaluation of MD QMS

Федеральная служба по надзору в сфере здравоохранения

An Agreement “On Single principles and rules of MD circulation” in the framework of Eurasian Economic Union from 23.12.2014



Федеральная служба по надзору в сфере здравоохранения

Transitional provisions in the EEC acts in the sphere of circulation of medical device

Transitional period until 31.12.2021

- **registration of MD by the manufacturer (authorized representative) may be carried out in accordance with the Rules either in accordance with the legislation of a member state of the Eurasian economic union**

- **medical devices, registered in accordance with the legislation of a member state of the Eurasian economic Union, are circulated only on the territory of that state**

- **the documents confirming the fact of registration of MD and issued by the regulation authority of a member state of the Eurasian economic Union in the field of healthcare in accordance with the laws of this state, are valid until the end of their validity period, but not later than 31 December 2021**

Федеральная служба по надзору в сфере здравоохранения

Documents, developed in the Framework of Eurasian Economic Union

1. The rules of pre-market approval procedure of MD.

2. The procedure for application by RA of Member States of the Eurasian economic union measures on suspension or prohibition of use of MD that are hazardous to life and (or) human health, substandard, counterfeit or falsified MD and withdrawal them from circulation on the territory of the Union.

3. On a special mark of MD circulation on the market of the Eurasian economic Union.

4. General requirements for safety and performance of MD, requirements for labeling and user manuals.

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6. The rules of conducting of researches (trials) on evaluation biological compatibility of MD.

Федеральная служба по надзору в сфере здравоохранения

Documents, developed in the Framework of Eurasian Economic Union

7. The rules of conducting of clinical and clinical-laboratory trials (researches) of MD.

8. The requirements for implementation, maintaining and evaluation of MD QMS depending on potential risk of application.

9. The list of MD being a subject to assignment to measuring devices while providing State registration.

10. The order of formation and conducting of information system in the sphere of MD circulation.

11. The rules of classification of MD depending on potential risk of application.

12. The rules on MD nomenclature.

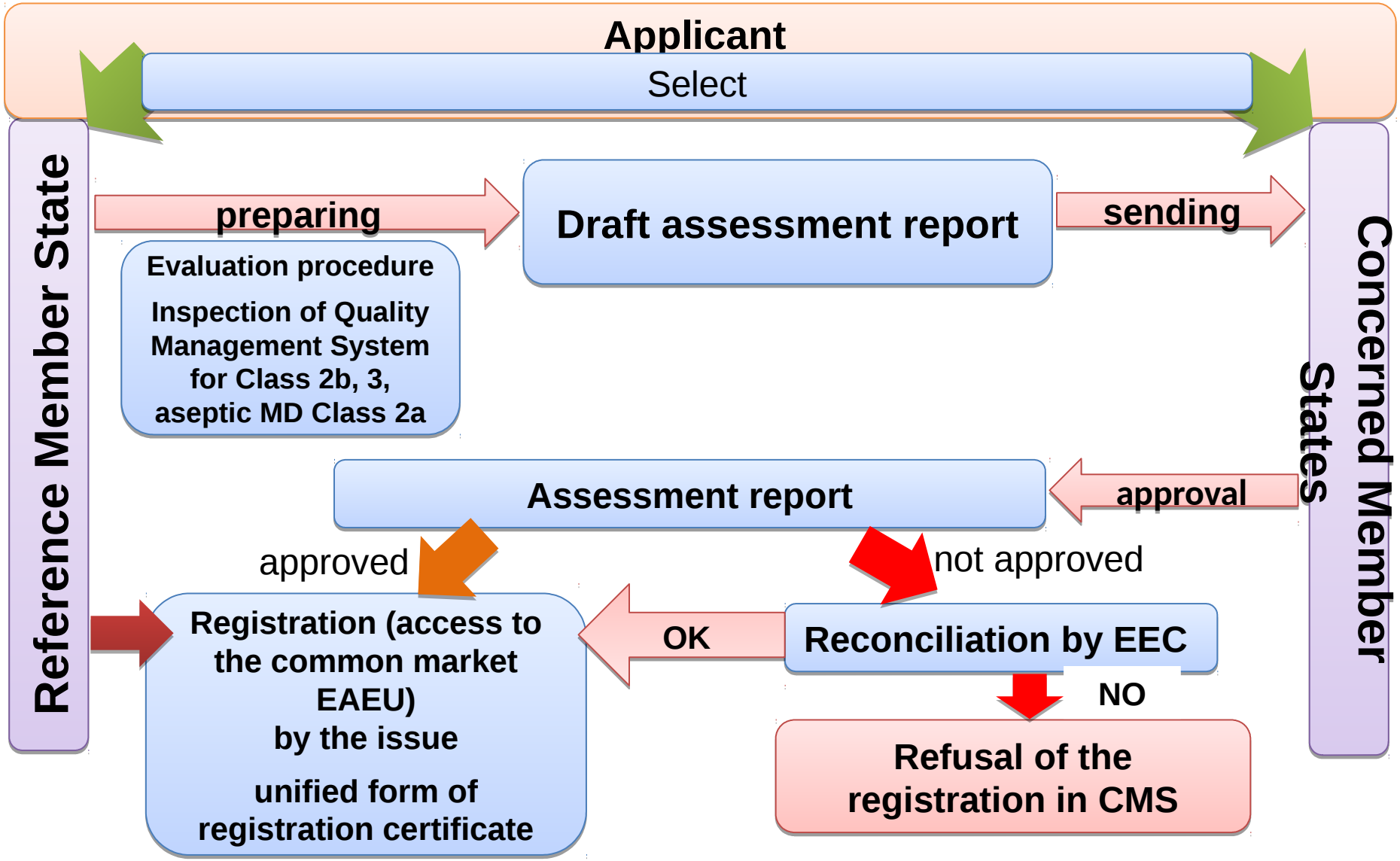
13. The rules of monitoring of safety and performance of MD.

Documents, developed in the Framework of Eurasian Economic Union

1. **The procedure for the formation of the list of standards as a result of which, on a voluntary basis, ensures compliance of the medical devices with general safety and efficiency requirements**
2. **The list of standards as a result of which, on a voluntary basis, ensures compliance of the medical devices with general safety and efficiency requirements**
3. **About the criteria distinction elements of MD that are components of MD in order to its registration**
4. **About the criteria for inclusion several modification of MD related to one type of MD in accordance with the MD nomenclature of EEU in one registration certificate**
5. **About the criteria for classifying products to MD**
6. **Guidelines for carrying out of expertise of safety, quality and efficiency of MD registration dossier**
7. **Guidelines for content and structure of MD registration dossier documents**
8. **Requirements for organizations having the right to carry out inspection of the production of MD on compliance the requirements for implementation, maintaining and evaluation of MD QMS depending on potential risk of application**

Федеральная служба по надзору в сфере здравоохранения

Authorization procedure



Thank you for your attention!

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