



Федеральная служба  
по надзору в сфере  
здравоохранения

**Federal Service for Surveillance in Healthcare**

# **Regulation of Circulation of the Medical Devices in Russian Federation**

# Definition of Medical Device in Russian Federation

**The Law 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.

# Classification of Medical Device in Russian Federation

**The Law 323-FZ dated 21.11.2011  
“The basis of health protection in the Russian Federation“  
Point 2. Article 38.**

## on classes

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

Medical devices  
are divided

## 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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*Came into force on 06 January 2015*

**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.rozdravnadzor.ru](http://www.rozdravnadzor.ru) in the section «Electronic services»

# Circulation of Medical Devices

**The Law 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



# 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



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# 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 statutes 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”

Ministry's of Health order **No. 737n** dated **14.10.2013**

“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”

# 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



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# The Counseling Procedures Related to the State Registration of Medical Devices

## **Order of Roszdravnadzor No. 6478 dated 19.07.2017**

“About approval of order of the implementation of counseling procedures related to the state registration of medical devices by Federal State Budgetary Institution “Russian Scientific and Research Institute for Medical Engineering” of Roszdravnadzor and Federal State Budgetary Institution “Center of monitoring and clinic-economic expertise” of Roszdravnadzor “

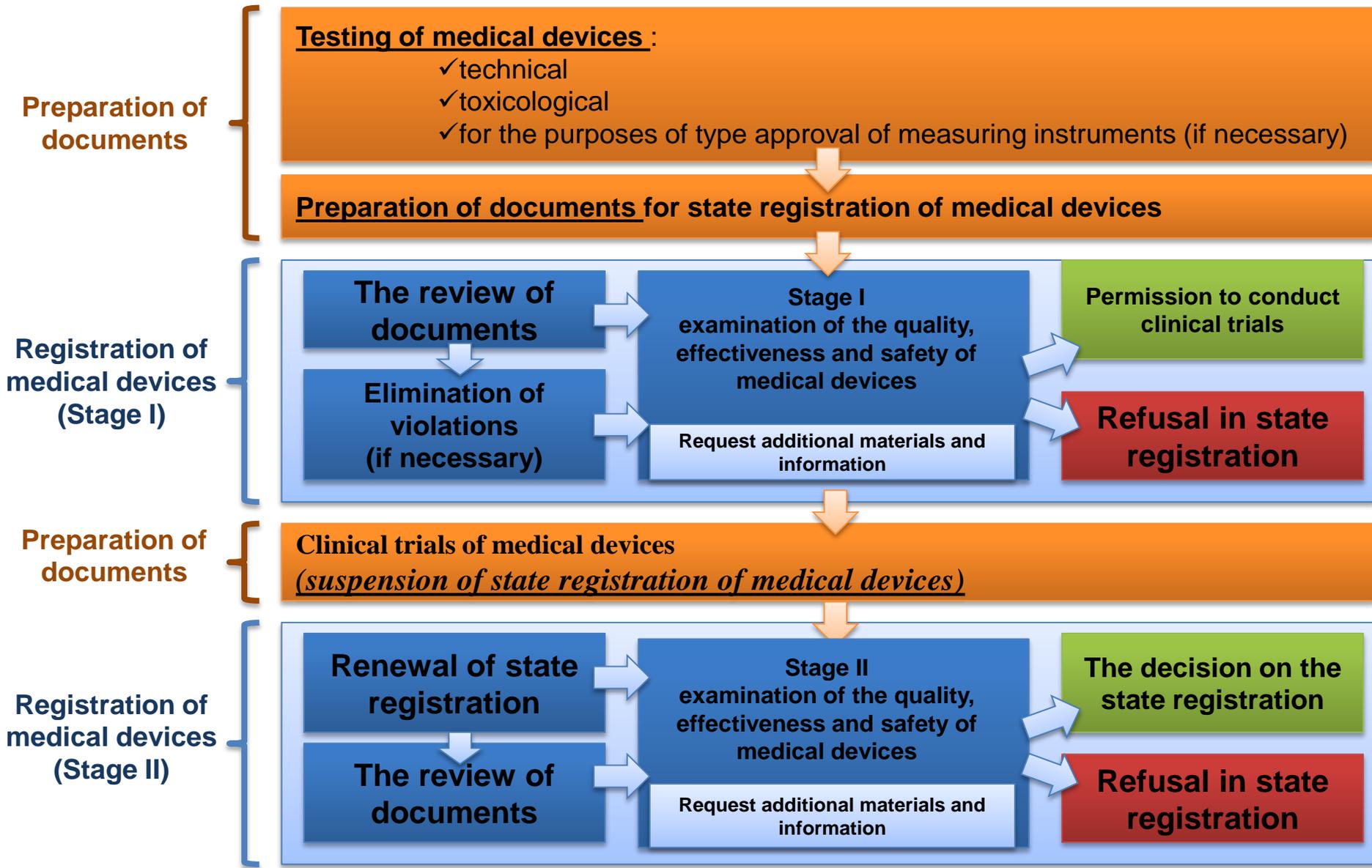
*Entered into force on 10.09.2017*

## **The main provisions**

- Opportunity of implementation of counseling procedures related to the state registration of medical devices by two subordinated Institutions of Roszdravnadzor;
- Forms of counseling: oral, written;
- Term of counseling: 20 working days from the date of enter into an agreement



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



# The Scheme of State Registration of Medical Devices (class 1) in the Russian Federation

## 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 (Stage II)

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

# Requirements to the Content of Technical and Operational Documentation of Medical Device's Manufacturer

## **Order of the Ministry of Health No. 11n dated 19.01.2017**

«About approval of requirements to the content of technical and operational documentation of medical device's manufacturer»

*Entered into force on 24.03.2017*

### The main provisions

- **Obligatory requirements to technical and operational documentation of medical devices.**
- **Define requirements to technical and operational documentation of IVD medical devices.**

# Technical Documentation

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

## Point 4.

### Technical documentation –

documents governing the design of medical products, establishing technical requirements and containing data for its development, production, use, operation, maintenance, repair, recycling or disposal.

### Technical and safety requirements consist of:

- the requirements of purpose characterizing the properties of products and determining its basic functions;
- requirements for the composition and structure;
- chemical, fractional, concentration of impurities, components and etc, physical-chemical, mechanical and other properties (strength, hardness, heat resistance, durability, etc.);
- requirements that determine characteristics such as geometry, biological, electromagnetic, electrical, metrology, strength;
- software requirements.

**Manufacturer develops technical and / or operational documentation,  
in accordance with which the medical device is handled**

## Remarks to the Manufacturer's Documentation

No data for describing the design of medical device

No data for technical requirements for medical device

No data for the development and production of medical device

No data for the application of medical device

No data for the operation of medical device

No data for maintenance and repair of medical device

No data for the disposal or recycle of medical device



# Operational Documentation

Russian Government order **No. 1416 dated 27.12.2012**  
“Adoption of rules for state registration of medical devices”  
**Point 4.**

## Operational documentation –

documents intended to familiarize the user with the design of a medical device, subject to the terms and rules of operation (intended use, maintenance, repair, storage and transportation), the values of the basic parameters guaranteed by the manufacturer, characteristics (properties) of the medical device, warranty, as well as information on its disposal or destruction.

## Operational documents must contain:

- description and operation of the product:
- purpose, basic characteristics necessary for the study and proper technical operation of the product, product composition, structure and operation, measuring instruments, tools, accessories, labeling, packing;
- information on the use of the product for its intended purpose:
- product name, purpose, field of application, conditions of use;
- maintenance requirements;
- routine repairs;
- storage conditions;
- conditions of transportation;
- methods and ways of utilization or disposal.

## Remarks to the Manufacturer's Operation Documentation

No data for users about the design of medical device

No data, subject to the terms and rules of operation (intended use, maintenance, repair, storage and transportation)

No data about the manufacturer guaranteed values of the basic parameters, characteristics (properties) of medical device

No warranties

No data on disposal or utilization



# Requirements for Technical Tests to be Submitted to Roszdravnadzor for the Purpose of State Registration of Medical Devices

Providing a testing laboratory with already prepared for submission to the Roszdravnadzor technical and operational documents, otherwise the documents might not match protocols

Providing a testing laboratory with all possible versions of medical devices for the selection (if the model has several versions)

Always consider that during technical tests by some certain standards and after the receipt of the registration certificate some medical devices are to be supported by mandatory certificates of conformity or by declarations of conformity

Providing a testing laboratory with all the necessary non-standard testing tools

## Remarks to the Protocols of Technical Tests

Technical testing protocols shall confirm the medical devices compliance to the regulatory requirements, technical and operational documentation of the producer:

The functional parameters and characteristics confirmed by the manufacturer were not tested (or not fully tested)

Lack of programs and methods of technical tests, if characteristics of quality or safety are verified, for which there is no existing standard methods

The functional parameters and characteristics confirmed by the manufacturer were not tested (or not fully tested)

Discrepancy between the results of tests and measurements, the characteristics of which are stated by the manufacturer or that are inherent to this type of medical device

Lack of numeric values of the measurement results, including the safety verification, and the only output is the conclusion on the conformity which is insufficient for expert to conduct analysis



# Clinical Trials of Medical Devices

## Basics:

Permission to conduct clinical trials (Roszdravnadzor), the conclusion about the ethical validity of the CT (Ethics Council of the Russian Ministry of Health)

## Clinical trials are conducted in the form of:

Trials involving human subjects (patients)

Clinical evaluation and analysis of clinical data

Order of the Ministry of Health of the Russian Federation No.300n dated 16.05.2013 "Approval of the requirements for medical institutions conducting clinical trials of medical devices and procedures of establishing compliance of medical institutions with these requirements"



# Legal Acts Regulating the Conduct of Clinical Trials in the Form of Studies

The order of the Ministry of Health of the Russian Federation No. 2n dated 09.01.2014 "Approval of the conformity assessment procedure for medical devices in the form of technical testing, toxicological studies, clinical trials for the purpose of state registration of medical devices" (came into force on 4 May 2014)

Testing of medical devices involving human are conducted in the following cases:

a new type of medical device

the use of new, complex and (or) unique and (or) special methods of prevention, diagnosis and treatment of diseases and conditions, as well as the use of new and complex medical technologies

if during the analysis and evaluation of clinical data the efficacy and safety of a medical device are not confirmed

In other cases, clinical trials of medical devices are conducted in the form of analysis and evaluation of clinical data.



# Documents to be Submitted in Roszdravnadzor after an Assessment of Compliance of the Medical Device in the Form of Clinical Trials

The results assessment act of clinical trials of a medical device with the following applications:

approved program of clinical trials of the medical device;

protocols of clinical trial or the results of the evaluation and data analysis, including graphics, images, extracts from medical records, tabulated, statistically processed material;

detailed data on the use of medical devices in medical practice, results of long-term observation (if any);

user documentation for the medical device (instructions for medical application) for clinical trials of physiotherapy devices, reagents (sets) for the diagnosis (in vitro), medical devices intended for the prevention, diagnosis, treatment of diseases at home.

If the original documents are in foreign language, they are provided with a certified translation into Russian.

All documents must be certified by an organization which conducted clinical trials



# Amendments to the Registration Certificate

(PP. 37-39 Russian Government Order No. 1416 Dated 27.12.2012  
“Adoption of Rules for State Registration of Medical Devices”)

Amendments are made in cases referred to in point 37 of the Rules, namely:

**a)** changes in the applicant’s information including information:

the reorganization of the legal entity;  
change of the company (other entity) change of its name (full and (if available) abbreviated, including brand name), address (location); change of surname, name and (if available) middle name, residential address of an individual entrepreneur, details of the document proving his identity;

**b)** change of the address (location of the manufacturing site) of medical device;

**c)** change of the name of the medical device (if the properties and characteristics that affect the quality, efficacy and safety of medical device were not changed)

**d)** the change of the legal entity in whose name a registration certificate may be issued, including the information:

about reorganization of the legal entity;  
change of the company (other entity) about the change of its name (full and (if available) abbreviated, including brand name), address (location);

**e)** indication of the type of medical device according to the nomenclature classification of medical devices (in case of its absence).



# Amendments to the Registration Documentation (P. 55 Russian Government Order No. 1416 Dated 27.12.2012 “Adoption of Rules for State Registration of Medical Devices”)

- Changes in technical documentation
- Changes in the operational documentation on medical device manufacturer, including instructions for use, or the manual of the medical device

If these changes do not cause changes in the properties and characteristics that affect the quality, efficacy and safety of medical device, or improve the properties and characteristics without the change of functional purpose and (or) the principle of medical device



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## Amendments to the Registration Documentation (P. 52 Russian Government Order No. 1416 Dated 27.12.2012 “Adoption of Rules for State Registration of Medical Devices”)

In case of loss of the registration certificate or it's damage Roszdravnadzor shall issue a **duplicate** registration certificate on a form marked "duplicate" and "the original registration certificate is recognized as invalid."

Please note that there are cases when during the procedure of amending the registration certificate the applicant does not have the original registration certificate, in such cases, you must first obtain a duplicate, and after receiving it, the amendment procedure may be initiate.



# State Register of Medical Devices and Organizations (Individual Entrepreneurs), Engaged in the Production and Manufacturing of Medical Devices

(the Government Order No. 615 Dated 19.06.2012)

Since **01.07.2012** Roszdravnadzor enters in the State Register the information contained in a set of registration documents for newly registered medical device:

Medical device name

Registration number and date

Class of potential risk

Code of the National Classification of products

Name and address of the applicant organization

Name and address of the manufacturing organization

Type of medical device



# Regulations on Licensing Activities for the Production and Maintenance (Except Cases when Maintenance is Carried Out to Satisfy Legal Entity's or Individual Entrepreneur's Own Needs) of Medical Equipment

The Federal Law **No. 99-FZ** dated **04.05.2011** "Licensing of certain activities"

The order of the Government of the Russian Federation **No. 469** dated **03.06.2013**  
*"Approval of the statements of licensing of the production and maintenance of medical equipment (except cases when maintenance is carried out to satisfy legal entity's or individual entrepreneur's own needs)"*

**Licensing activities for the production and maintenance (except cases when maintenance is carried out to satisfy legal entity's or individual entrepreneur's own needs) of medical equipment include:**

<b>In part of production of medical equipment:</b>	<b>In part of maintenance</b> (except cases when maintenance is carried out to satisfy legal entity's or individual entrepreneur's own needs) <b>of medical equipment:</b>
➤ production of medical equipment	➤ installation and adjustment of medical equipment
➤ production of customized medical equipment for individual patients, which are prescribed by health workers and special requirements for its intended purpose are applied and which is intended solely for the personal use of the particular patient	➤ Control of technical condition of medical equipment
	➤ periodic and routine maintenance of medical equipment
	➤ repairs of medical equipment



## State Control of the Circulation of Medical Devices

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

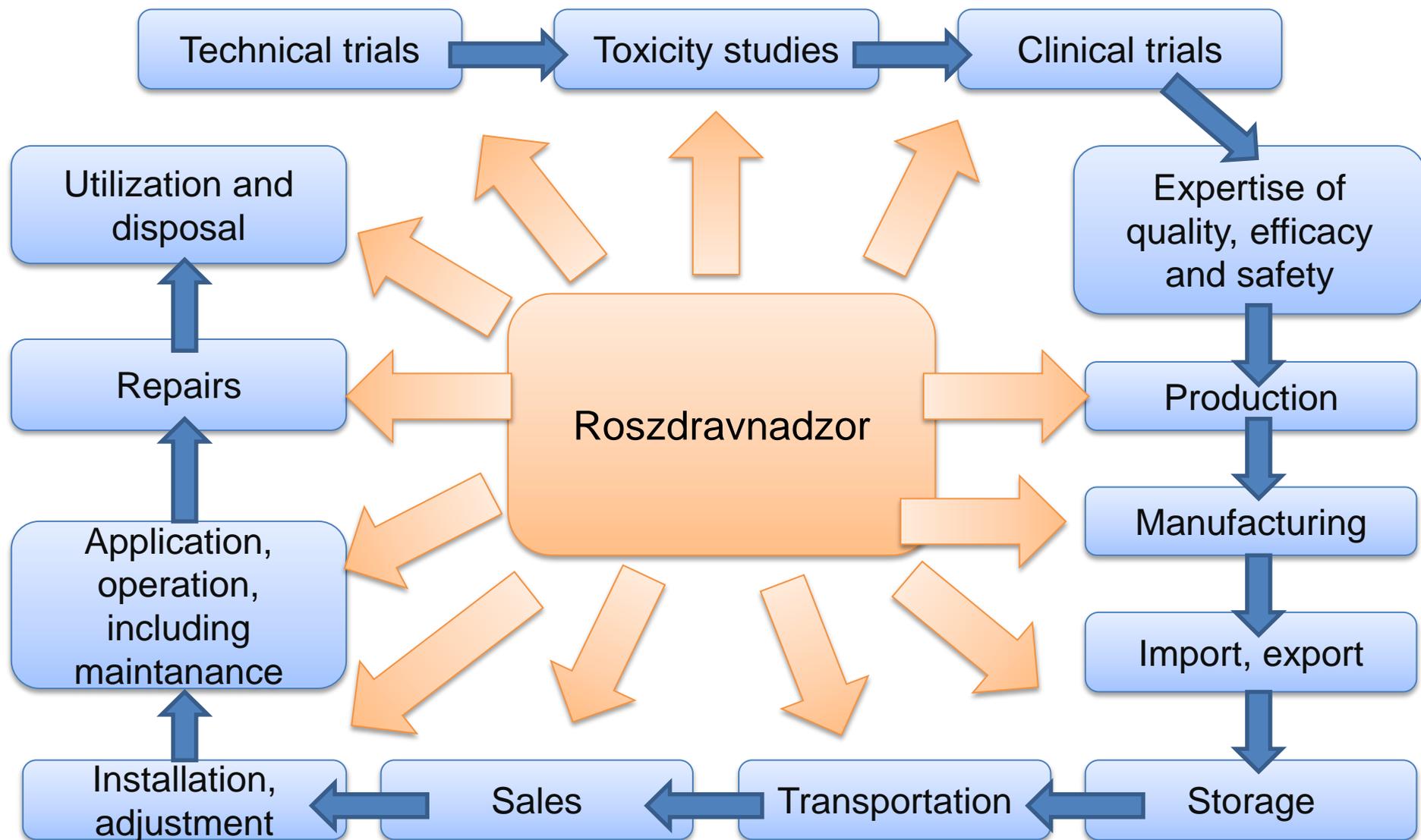
Ministry of Health of the Russian Federation **No. 196n** dated **05.04.2013** “The Administrative Regulations of the Federal Service for Surveillance of Healthcare for the implementation of the state functions of control of medical devices”

Russian Government order **No. 970** dated **27.11.2012** “Statements on state control of circulation of medical devices”



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# Stages of Circulation of Medical Devices





# Methods of State Control of Circulation of Medical Devices

**Audits of the subject's** of circulation of medical devices compliance with the rules of medical devices circulation approved by the Russian Ministry of Health

**Permissions for imports** of medical devices for the purposes of state registration (Ministry of Health order No. 7n dated от 06.06.2012)

**Monitoring of safety of medical devices**



# Control of the Circulation of Medical Devices Using the Risk-oriented Approach

**There are 9 criteria of risk category classification of organization  
accordance with kinds of their activity**

Manufacturers of medical devices and authorized representatives of the  
manufacturer of medical devices

## **Organizations of carrying out**

Installation, adjustment, maintenance,  
repairs of medical devices

Application of medical devices and  
clinical trials (for medical organizations)

Import, export of medical devices

Sales of medical devices

Transportation of medical devices

Utilization and disposal of medical  
devices

Technical trials and toxicity studies

Storage of medical devices



# Referring Organizations of Carrying Out Their Activity in the Sphere of Medical Devices to Categories of Risk for 2018

Category of risk	Frequency of inspections	Quantity of organizations
Significant risk	1 time in 3 years	312 (0,26%)
Average risk	not more than 1 time in 5 years	925 (0,79%)
Moderate risk	not more than 1 time in 6 years	3709 (3,15%)
Low risk	-	112 846 (95,80%)

Quantity of organizations of carrying out their activity in the sphere of medical devices – **117 792**



# The List of Mandatory Requirements in the Sphere of Circulation of Medical Devices

The list of legal acts and their separate parts (provisions) containing mandatory requirements compliance with which is assessed during inspections (**Order of Roszdravnadzor No.4043 dated 27.04.2017**)

Federal laws

2

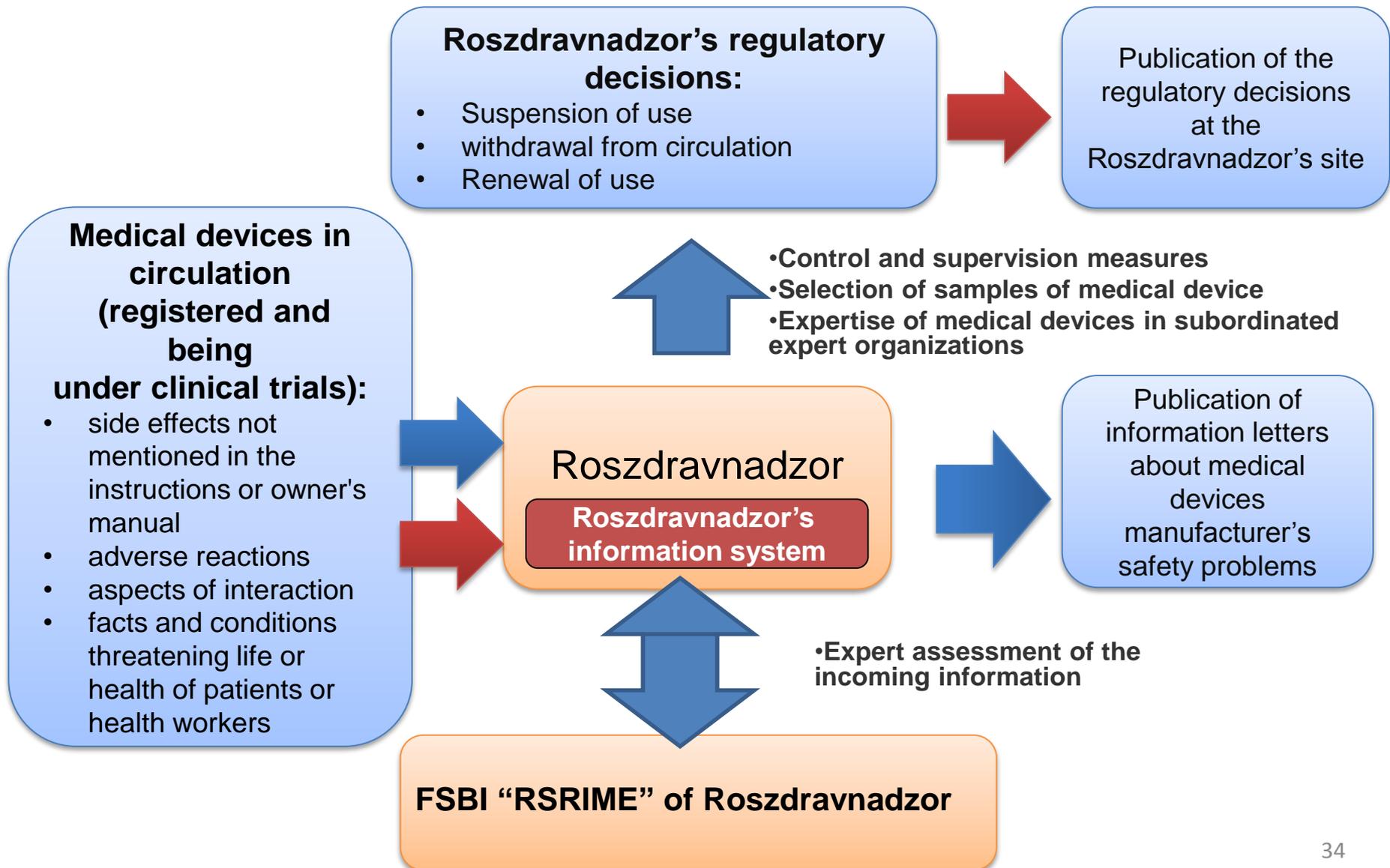
Decrees of the President of the Russian Federation,  
Regulations and Orders of the Government of Russian  
Federation

7

Legal acts of federal executive bodies

11

# Scheme of Organization of Safety Monitoring of Medical Devices





# The Causes of Health Injury when Using Medical Devices Identified during the Monitoring of Safety

1. **Allergic reactions** (*contact lenses disinfectant solutions, surgical gloves, sterile underwear sets, alcohol wipes*)
2. **Violation of the sterility of sterile medical devices** (*catheters*)
3. **Measurement errors due to quality defects** (*glucometers, ophthalmic equipment*)
4. **Destruction when using** (*gypsum splints, devices for osteosynthesis*)
5. **Violation of fixation** (*sticking plasters*)
6. **Failure** (*heart pacemakers*)
7. **Inflammatory reaction to the implant** (*hyaluronic acid solutions for intra-articular injection, intraocular lenses*)
8. **Dislocation of the implant** (*for osteosynthesis devices, intrauterine devices, stents*)
9. **Loss of sealing of devices** (*connectors, catheters, endotracheal tubes cuffs*)
10. **Inability to use due to defects** (*syringes, needles, catheters*)
11. **Fire** (*electrocoagulator*)

# Functions of Roszdravnadzor's Subordinate Expert Organizations

- Expertise of quality, efficiency and safety of medical devices:
  - for the purposes of registration of medical devices
  - within the framework of control measures
  
- Conducting technical testing of medical devices
  
- Toxicological studies
  
- Monitoring the quality, effectiveness and safety of medical devices



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# Federal State Budgetary Institution “Russian Scientific and Research Institute for Medical Engineering” of Roszdravnadzor



Testing laboratory of medical supplies and tools

Technical tests laboratory of medical devices

Testing laboratory of mobile complexes for  
medical purposes

Testing laboratory of instruments and equipment  
for functional diagnostics and physiotherapy

Testing laboratory of medical devices software

Testing laboratory of instruments and apparatus  
for radiation diagnosis and therapy

Testing laboratory of electromagnetic compatibility  
of medical equipment

Testing laboratory of instruments and apparatus  
for medical laboratory tests

Department of toxicology testing and research  
materials and medical devices

Laboratory of microbiological researching in  
medical devices





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**Resolution of the Government of the Russian Federation  
№ 1037 Dated 15.08.1997 "On Measures to Ensure the Availability of Information in  
Russian on the Imported Non-food Items into the Territory of the Russian Federation"**

Information on medical devices must contain the following information in Russian:

- Name of product;
- Name of the country, the company - manufacturer (company name may be indicated by Latin letters);
- Purpose (area of application), the main features and characteristics;
- Terms and conditions of effective and safe use;
- Other information about the goods in accordance with the legislation of the Russian Federation, the requirements of state standards for certain types of non-food items and the rules for their sale.



# Responsibility for Violation of the Rules for Medical Devices

## Administrative Liability

Article of the Administrative Code	Corpus delicti	Liability
<p><b>6.28</b> Violation of the rules in the field of circulation of medical devices</p>	<p>Violations of the rules in the field of medical devices, if they do not contain evidence of a criminal offense</p>	<p>Administrative fine:  <u>For citizens</u> – from <b>2 000 to 4 000 rub</b>  <u>For officials</u> - from <b>5 000 to 10 000 rub</b>  <u>For legal entities</u> - from <b>30 000 to 50 000 rub</b></p>
<p><b>6.33</b> Counterfeit, falsified, substandard and unregistered medicines, medical devices and trafficking of counterfeit dietary supplements</p>	<ol style="list-style-type: none"> <li>1. Production, sales or import into the Russian Federation falsified medical devices or sales or import to the Russian Federation of counterfeit medical products, if these actions do not contain evidence of a criminal offense</li> <li>2. Sale or import to the Russian Federation of substandard medical products, production, sale or import into the Russian Federation of unregistered medicines, if these actions do not contain evidence of a criminal offense</li> </ol>	<p>Administrative fine:  <u>For citizens</u> - from <b>70 000 to 100 000 rubl</b>;  <u>For officials</u> - from <b>100 000 to 600 000 rub</b>  <u>For individual entrepreneurs</u> from <b>100 000 to 600 000 rub</b> or administrative suspension up to 90 days  <u>For legal entities</u> - from <b>1 000 000 to 5 000 000 rub</b> or administrative suspension up to 90 days</p>



# Responsibility for Violation of the Rules for Medical Devices

## Criminal Liability

Article of criminal law	Elements of crime	Responsibility
<b>235.1.</b> Illegal production of medicines and medical devices	Production of medical devices without a special permit (license) if such permission (license) is required <i>Note. in this Article large size shall be the value of medicines or medical devices exceeding one hundred thousand of rubles.</i>	<p>1. Imprisonment for a period of 3 to 5 years with a fine <b>from 500 000 to 2 000 000 rubles</b> or a fine in the amount of salary or other income for a period of 6 months to 2 years or without it</p> <p>2. The same violations, if they were:</p> <ul style="list-style-type: none"><li>a) committed by a group of persons by prior agreement or an organized group;</li><li>b) made in relation to the goods, works or services intended for children under the age of six years;</li><li>c) In case of serious injury or death caused by negligence</li></ul> <p>Are fined in the amount of <b>100 000 to 500 000</b> or in the amount of salary or other income for the period from <b>1 year to 3 years</b> or public service for up to <b>5 years</b>, or imprisonment for up to <b>6 years</b> with a fine of up to <b>500,000 rubles</b> or in the amount of salary or other income for a period of up to <b>3 years</b> or without it</p>



# Responsibility for Violation of the Rules for Medical Devices

## Criminal Liability

Article of criminal law	Elements of crime	Responsibility
<b>238.1.</b> Circulation of counterfeit, substandard and unregistered medicines, medical devices and counterfeit dietary supplements	Production, sale or import to the Russian Federation of counterfeit medical devices, or sale or import to the Russian Federation of substandard medical devices, or illegal manufacture, sale or import to the Russian Federation for the purpose of sale of unregistered medical devices, committed on a large scale.	<p>1. Fine of up to <b>300,000</b> rubles or of salary or other income for a period of <b>2</b> years, or compulsory works for up to <b>360</b> hours or personal restraint for up to <b>2</b> years or community service for up to <b>2</b> years or imprisonment for the same term.</p> <p>2. The same violations, if they were:</p> <ul style="list-style-type: none"><li>a) committed by a group of persons by prior agreement or an organized group;</li><li>b) made in relation to the goods, works or services intended for children under the age of six years;</li><li>c) In case of serious injury or death caused by negligence</li></ul> <p>are punished with a fine of <b>100 000 up to 500 000</b> rubles or in the amount of salary or other income for the period <b>from 1 year to 3 years</b> or public service for up to <b>5 years</b>, or imprisonment for up to <b>6 years</b> with a fine of up to <b>500,000 rubles</b> or in the amount of salary or other income for a period of up to <b>3 years</b> or without it</p> <p>3. Violations caused by negligence which led to the death of two or more persons –</p> <p>obligational works for up to <b>5</b> years or imprisonment for up to <b>10</b> years</p>



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# Results of State Control of the Circulation of Medical Devices

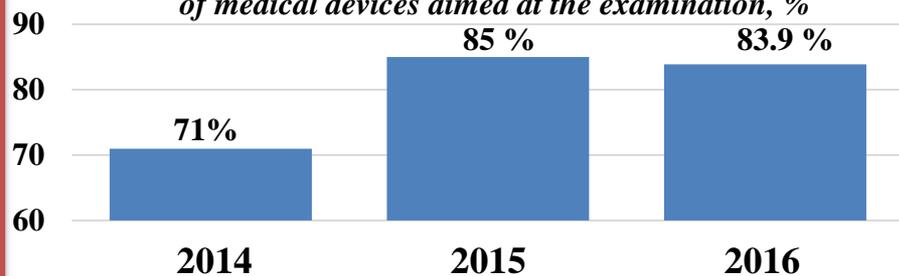
## *The Results of Control Activities in 2014-2016*

Year	2014	2015	2016
Quantity of planned and unplanned control activities	5501	6221	5672
Quantity of identified violations	2855	2982	3674
The sum of imposed fines under articles 6.28 and 6.33 of the Administrative Code	16,3 million rubles	18,9 million rubles	25 million rubles

*The number of items of medical devices, information about which is available on the official website of Roszdravnadzor*

Year	2014	2015	2016
Unregistered medical device	644	388	337
Poor-quality medical device	24	31	135
Manufacturer recall	56	31	116
Retirement		6	15
Falsified medical device		6	20
About new safety data of medical device			102

*The ratio of medical devices which do not comply with the requirements of the examination, the total number of medical devices aimed at the examination, %*



Structure of identified unregistered medical devices by application area	2015	2016
Medical devices for therapy	25%	22%
Medical devices for diagnostic	9%	11%
Consumables for intensive care	12%	10%
Medical furniture	7%	10%
Medical devices for the treatment and prevention	11%	9%
Equipment for disinfection	5%	9%
Dressings	4%	6%
In vitro reagents sets and culture medium	2%	5%
Medical clothing and remedies	10%	3%
Medical devices for dentistry	5%	2%
Medical devices for rehabilitation	3%	2%
Medical devices for ophthalmology	8%	1%



# International Organizations Cooperating with Roszdravnadzor

## Federal Service on Surveillance in Healthcare

**Working Group of  
Enforcement Officers  
of the Head of  
Medicines Agencies  
(HMA WGEO)  
(as observers)**

**Pharmaceutical  
Inspection Co-  
operation  
Scheme (PIC/S)  
(as observers)**

**Organization of the  
Black Sea Economic  
Cooperation (BSEC)  
(as a member of  
World Health  
Organization (WHO)  
(cooperation))**

**The international  
Conference on  
Harmonization of  
Technical Requirements  
for Registration of  
Pharmaceuticals for  
Human Use (ICH)  
(as observers)**

**International Medical  
Device Regulation  
Forum (IMDRF)  
(as a member of the  
Global Medical Device  
Nomenclature Agency  
(GMDN) (cooperation))**



## International Activities of Roszdravnadzor with Regulatory Agencies in Other Countries

- **The Ministry of health of the Republic of Belarus**
- **National center for expertise of drugs, medical devices and medical equipment of the Ministry of health and social development of the Republic of Kazakhstan**
- **China Food and Drug Administration (CFDA)**
- **The National Institutes for Food and Drug Control, China (NIFDC)**
- **Central Drugs Standard Control Organization, Republic of India (CDSCO)**
- **Medicines and Medical Devices Agency of Serbia**
- **European Directorate for Quality of Medicines & HealthCare of the Council of Europe (EDQM)**
- **European Medicines Agency (EMA)**
- **State Service for the Drug Quality Control, Ukraine**
- **The state expert center of the Ministry of health of Ukraine**
- **Food and Drug Administration (US FDA)**
- **U.S. Pharmacopoeia Convention (USP)**
- **Pharmaceuticals and Medical Devices Agency, Japan (PMDA)**



Федеральная служба  
по надзору в сфере  
здравоохранения

## Federal Service for Surveillance in Healthcare

**Thank you for your attention!**