

#### **INDRF** International Medical Device Regulators Forum

# NEW ASPECTS IN MEDICAL DEVICES REGULATION IN RUSSIAN FEDERATION

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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



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

There are 9 criterions 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

Import, export of medical devices

Transportation of medical devices

Technical trials and toxicity studies

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

Sales of medical devices

Utilization and disposal of medical devices

Storage of medical devices



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

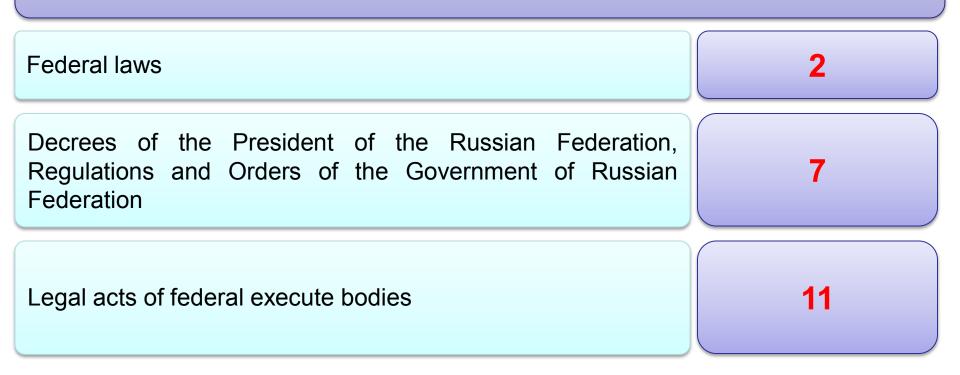
Category of risk	Frequency of inspections	Quantity of organizations
Significant risk	1 time in 3 years	312 (0,26%)
Average risk	not more than 1 time in 5 years	925 (0,79%)
Moderate risk	not more than 1 time in 6 years	3709 (3,15%)
Low risk	_	112 846 (95,80%)

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)





#### Regulation No.1517 dated 30.12.2015

«On state regulation of prices for MD included into the list of MD implanted in the human body while providing medical assistance under the program of state guarantees of free rendering to citizens of medical care»

#### Approved:

The Order of the Government of Russian Federation № 2229-r dated 22.10.2016 (in redaction of the Order of the Government of Russian Federation № 1587-r dated 25.07.2017) «On approval of the list of MD implanted in the human body while providing medical assistance under the program of state guarantees of free rendering to

citizens of medical care»

As of September 15, 2017:

➤agreed on weighted average prices for 32 types of medical devices;

>177 prices of different medical devices are registered

Procurement of medical devices within a program of state guarantees of free rendering to citizens of medical care based on registered prices of medical devices will begin **on January 1, 2018** 



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## **Documents developed in the Framework of Eurasian Economic Union entered into force on the 6<sup>th</sup> of May 2017**

The Eurasian Economic Union the Republic Armenia, the Republic of Belarus, the Republic of Kazakhstan, the Kyrgyz Republic and the Russian Federation

#### 182,7 million people

over 20 million sq. km. 14% of the world's firm land



#### **Documents Developed in the Framework of Eurasian Economic Union**

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 (Recommendation of Collegium of Eurasian Economic Commission No. 16 dated 04.09.2017)

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 (Recommendation of Collegium of Eurasian Economic Commission No. 17 dated 04.09.2017)



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# Thank you for your attention!

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