



IMDRF International Medical
Device Regulators Forum

**NEW ASPECTS IN MD
REGULATIONS
IN THE RUSSIAN FEDERATION**

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IMDRF International Medical Device Regulators Forum

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



Federal Law from 31.12.2014 № 532-FZ

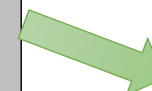
Violation of rules of implementation

Implementation (marketing) unregistered/counterfeit/ substandard medical devices in a large amount



**Criminal
prosecution**

The sale of counterfeit/substandard medical products not on a large scale or counterfeit in any size



Administrative penalty

Other offences in the sphere of implementation of medical devices (including the implementation of unregistered medical devices not on a large scale)





Federal Law from 31.12.2014 № 532-FZ

Violation of rules of manufacturing

The manufacture of medical devices on a large scale without a license, if such license is required

The manufacture of counterfeit/substandard/ unregistered medical devices in larger size

The manufacture of counterfeit/substandard/ unregistered medical devices not on a large scale

The manufacture of medical devices not on a large scale without a license, if such license is required;
Other offences in the sphere of manufacture of medical devices (including the manufacturing of unregistered/counterfeit medical devices in a large size)

**Criminal
prosecution**

**Administrative
penalty**



Federal Law from 31.12.2014 № 532-FZ

Violations of the rules of entry on the territory of Russian Federation

The importation into the territory of the Russia of counterfeit/ substandard, as well as importation for the purpose of sale of unregistered medical products in larger size



**Criminal
prosecution**

The import into the territory of the Russia falsified/ counterfeit/ substandard medical products in a large amount



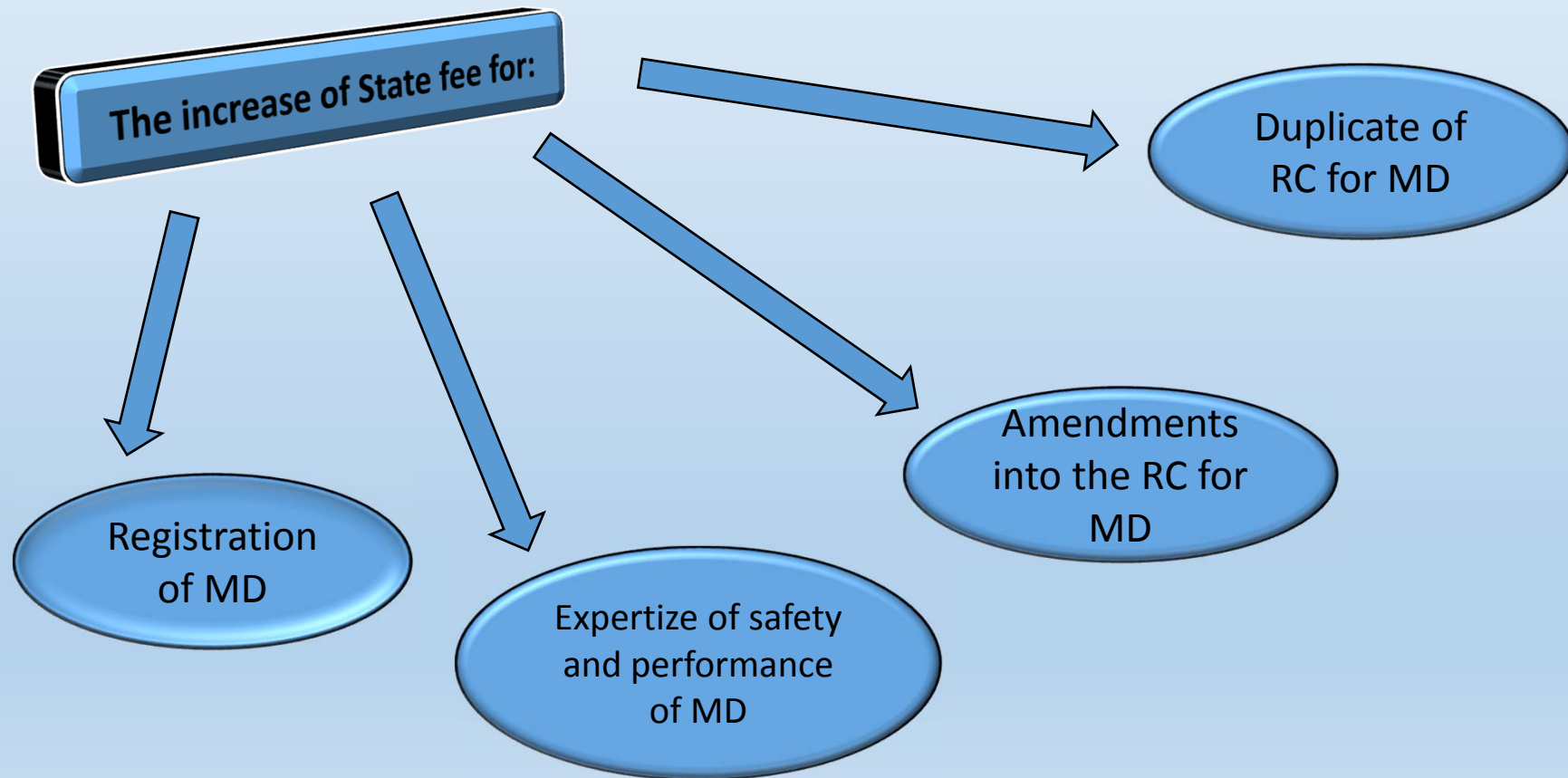
**Administrative
penalty**

Other offences in the sphere of import into the territory of the Russian Federation (including the importation for sale on the territory of the Russian Federation of unregistered medical devices not in large size)





Entered into force a Federal Law from 01.01.2015 № 221-FZ
«On amendments into the Tax code»





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THANK YOU