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International Medical  
Device Regulators Forum

# **NEW ASPECTS IN MEDICAL DEVICES REGULATION IN RUSSIAN FEDERATION**

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## Order of Roszdravnadzor No. 10449 dated 20.12.2017

“About approval of forms of checklists (lists of control questions) used by Federal Service on Surveillance in Healthcare and its regional offices at carrying out of scheduled checks at realization of the state control of the circulation of medical devices“

**Entered into force on  
06.02.2018**

## **7 checklists (lists of control questions) contain compliance with mandatory requirements for:**

- Technical tests and toxicity studies
- Clinical trials
- Application of medical devices in medical organizations
- Circulation of medical devices by manufacturers/ authorized representative of the manufacturer
- Installation, adjustment, maintenance, repairs of medical devices
- Transportation of medical devices
- Storage or/and sales of medical devices



**The Checklists (Lists of Control Questions) Used by Federal Service on Surveillance in Healthcare and its Regional Offices at Carrying out of Scheduled Checks at Realization of the State Control of the Circulation of Medical Devices contain following main questions:**

Presence in organization at the moment of scheduled check unregistered, poor-quality, falsified and counterfeit medical devices

Necessary documents for the implementation of activities

Monitoring of medical devices safety



**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 of Armenia, the Republic of Belarus, the Republic of Kazakhstan,  
the Kyrgyz Republic and the Russian Federation





## Documents Developed in the Framework of Eurasian Economic Union

The requirements for implementation, maintaining and evaluation of MD QMS depending on potential risk of application (Decision of the Council of the Eurasian Economic Commission No. 106 dated 10.11.2017)

**Entered into force on  
16.03.2018**

## The main provisions

- Manufacturer must introduce MD QMS before pre-market approval (for sterile MD 2a, MD 2b and 3 classes of potential risk of application)
- Evaluation of MD QMS is carried out from 16.03.2019 (for sterile MD 2a, MD 2b and 3 classes of potential risk of application)
- Evaluation of MD QMS is carried out by the inspecting organization in the form of production inspection
- The period of scheduled inspection is 1 time every 3 years



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**Thank you for your attention!**

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