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International Medical  
Device Regulators Forum

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



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**Federal Law No. 128-FZ dated 30.04.2021 "On Amendments to the Federal Law "On the Basics of Public Health Protection in the Russian Federation" and Articles 12 and 22 of the Federal Law "On licensing of certain types of activities"**



- the licensing of the production of medical equipment is canceled since January 1, 2022;
- the possibility of importing unregistered medical devices for providing medical care for the vital indications of a particular patient has been introduced;
- there are provisions providing for the submission by manufacturers and importers of medical devices to Roszdravnadzor of information about each series (batch) put into circulation on the territory of the Russian Federation.



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**The order of the Ministry of Health of the Russian Federation  
No. 386n dated 22.04.2021 "On Amendments to the Order of  
the Ministry of Health of the Russian Federation of 20.03.2020  
No. 206n "On Approval of the Procedure for organizing and  
Conducting an Examination of the Quality, Effectiveness and  
Safety of Medical Devices"**



**Entered into force on  
01.09.2021**

- The requirements for the providing expertise of documentation of software that is a medical device, including software with the use of artificial intelligence technologies, are established.



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**The order of the Ministry of Health of the Russian Federation  
No. 321n dated 09.04.2021 "On approval of the list of  
measuring instruments that meet the requirements for their  
verification provided for in Article 13 of the Federal Law "On  
ensuring the Uniformity of Measurements", technical means  
and equipment necessary for the maintenance of the declared  
groups of medical equipment by classes of potential risk of use"**



**Entered into force on  
01.09.2021**

- **The list of measuring instruments, technical means and equipment necessary for the maintenance of the declared groups of medical devices by classes of potential use has been approved**



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## **Circulation of Medical Devices in Eurasian Economic Union**

**7** medical devices are registered in accordance with the rules for registration of medical devices of the EEU

**Russian Federation has approved amendments to the Agreement of EEU, under which the validity of national registration certificates is extended, from January 1, 2022, the primary registration of medical devices is carried out only under the legislation of the Eurasian Economic Union**



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**Thank you for your attention!**