NEW ASPECTS IN MEDICAL DEVICES REGULATION IN RUSSIAN FEDERATION

- 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.
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"

- 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.

Entered into force on 01.09.2021
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"

- 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

Entered into force on 01.09.2021
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
Thank you for your attention!