REQUIREMENTS HAVE BEEN ADOPTED FOR THE CONTENTS OF THE MANUFACTURER'S TECHNICAL AND OPERATING DOCUMENTATION IN THE REGISTRATION DOSSIER OF A MEDICAL DEVICE

For the attention of Russian and foreign developers and manufacturers of medical devices

Pepeliaev Group advises that a new legal regulation has been adopted for the state registration of medical devices

On 19 January 2017, the Russian Healthcare Ministry adopted the corresponding Order No. 11n 'On adopting the requirements for the content of the manufacturer's technical and operating documentation for a medical device' ('Order No. 11n'), which establishes special requirements for the specified documentation within the registration dossier (the 'Requirements').
Starting from 24 March 2017 all the manufacturers of medical devices must comply with the new rules when filing with the Federal Service for Surveillance in Healthcare applications for state registration of medical devices.

Only a few exceptions from the new procedure have been determined:

- for medical devices made pursuant to patients' individual orders, when such medical devices are subject to special requirements with respect to the medical professionals to be assigned to them and are intended solely for personal use by a certain patient;
- for medical devices intended for use within an international medical cluster.

The key points of the regulation

Now the manufacturer's or its authorised representative's technical documentation within the registration dossier must be in line with the list provided in section II of the Requirements ('Requirements for the content of the manufacturer's technical documentation for a medical device'), such list including 20 names.

The requirements for the content of the operating documentation of the manufacturer of a medical device or of its authorised representative are specified in clause 21 of section III of the Requirements ('Requirements to the content of the manufacturer's operating documentation for a medical device'). There is a special note that the specified documentation must be provided to the customer for information purposes in full in the form of a printed document and may be posted on the Internet or placed on a screen which is part of the medical device itself. A shortened version (provided that this volume of information is enough for a medical device to be used safely for its intended purpose) is allowed only with respect to medical devices of potential risk classes 1 and 2a .

Each relevant section of the Requirements contains an individual list of additional information regarding the technical and operating documentation necessary for the registration of medical devices for in vitro diagnostics.

What to think about and what to do

Participants in the medical devices market, especially manufacturers, should familiarise themselves in advance with the requirements in effect and should take account of the new regulation when they file the relevant registration documents with Roszdravnadzor.

Help from your adviser

Pepeliaev Group's lawyers are ready to provide comprehensive legal support regarding registration actions in accordance with the new rules of Order No. 11n as well as regarding other issues of regulating the circulation of medical devices on the Russian market.

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