SOFTWARE BEING CLASSIFIED AS MEDICAL DEVICES

For the attention of Russian and foreign software developers, producers, sellers.

Pepeliaev Group advises that the Federal Service on Surveillance in Healthcare (known in Russia by the abbreviation 'Roszdravnadzor') has issued explanations concerning the registration of software as medical devices ('Explanations')[1].

Russian legislation provides for a broad definition of medical devices, which used to create particular difficulties for market players to have a product classified as a medical device. Until recently, Roszdravnadzor had provided no official explanations with respect to software supplied individually. The Explanations, which were issued at the end of 2015, although advisory in nature, are of primary importance for the market.

Thus, according to the regulator, certain types of software are subject to mandatory registration with Roszdravnadzor in compliance with the procedure provided for by Russian legislation. Such software according to the technical and maintenance documents provided by the manufacturer[2] is intended to:

- Manage the work of equipment and monitor how it functions;
- Receive diagnostic data from the equipment, to collect and automatically calculate such data;
- Monitor how the human organism functions and transfer the data received (including by means of wireless technology);
- Calculate the dosage parameters (with respect to radiation exposure, medication, a radiopaque substance, etc.);
- Process the data received from diagnostic medical equipment, and transfer such data to treatment and planning systems;
- Process medical images (in particular in cases when their quality, colour resolution, etc. are changed);
- Build 3D models;
- Connect diagnostic and therapeutic equipment;
- Process digital images (in particular when the data from diagnostic equipment is received in an unchanged form).

Depending on what purpose the manufacturer determines for particular software, it may be classified as a medical device to be used both separately and together with other medical devices.

From now on, the following products may be classified as medical devices: mobile medical applications, including those which may function together with other devices connected to mobile phones/tablet computers, displays/panels, software designed to display and process images, etc.

[1] Informational Letter No. 01i-2358/15 dated 30 December 2015.

[2] See Informational Letter of Roszdravnadzor No. 01-42284/15 dated 22 December 2015.

What to think about and what to do

All good-faith market players should be extremely cautious when producing, importing, and selling software and, in particular, when implementing mobile applications intended for maintaining/monitoring human health and/or for treating a person, as, from now on, supervisory authorities may classify such products as unregistered medical devices. This may entail grave consequences right up to criminal liability.

Moreover, it should be noted that activity relating to the production and maintenance of medical equipment is subject to mandatory licensing[3].

It is recommended that market players take a number of actions to ensure that, in their operations, they comply with the Explanations. In particular, they should:

(1) identify which software may be classified as medical devices, check the quality of the products manufactured, imported and sold as well as ensure that such products are labelled in compliance with the legislation, check and take an inventory of warehouse stock, etc.;

(2) apply to Roszdravnadzor in accordance with the prescribed procedure to have the software registered as a medical device;

(3) check whether the company's activity is in compliance with the licensing requirements of the legislation;

(4) perform an audit with respect to business relationships with counterparties (i.e. the terms and conditions of the contracts in effect, the stock of goods provided (received) under contracts, whether any disputes have been resolved at the pre-trial stage between the parties to a contract and whether any assistance was provided or information exchanged between the parties to a contract).

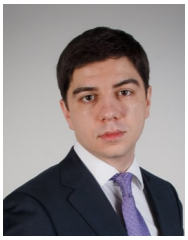
Market players should also monitor explanations and judgements of the regulatory and court authorities on a regular basis.

Help from your adviser

Pepeliaev Group's lawyers are ready to provide comprehensive legal assistance on all matters connected with the circulation of medical devices, in particular on matters relating to the registration of software as medical devices, and on licensing activities with respect to the production and maintenance of medical equipment.

Pepeliaev Group's lawyers have significant experience of drafting recommendations and documents, and of representing companies before regulatory authorities and in court.

Contact details



Sergey Klimenko
Head of Life Sciences Group
T.: +7 (495) 967-00-07
S.Klimenko@pgplaw.ru

[3] Resolution No. 469 of the Russian Government dated 3 June 2013 'On licensing activities relating to the production and maintenance (except for the cases when maintenance is performed for a legal entity's or individual entrepreneur's own needs) of medical equipment'.