



Withdrawal and destruction of improper medical devices: new rules

31 August 2022

News

On 1 September 2022, rules for the withdrawal from circulation and destruction of falsified, defective and counterfeit medical devices will come into force, as per [Russian Government Decree No. 145 dated 10 February 2022*](#).

Previously, the withdrawal of such medical devices was out of the regulatory landscape, and the destruction procedure was only described in general terms.

The withdrawal of falsified, defective and counterfeit medical devices from circulation implies that their owner ensures that the devices are stored in such a way that they cannot be used, operated, sold, installed, commissioned, maintained or repaired.

Falsified and defective medical devices can be withdrawn from circulation and destroyed by decision of:

- their owner;
- the Federal Service for Surveillance in Healthcare ("**Roszdraznadzor**"); or
- a court.

In the case of counterfeit medical devices, this decision can only be taken by a court.

The decision of Roszdraznadzor to withdraw and destroy medical devices can be challenged either by filing a claim with a court or as an administrative recourse (i.e. by filing a complaint to Roszdraznadzor itself). The latter means of challenging the decision is available to the owner of medical devices and their manufacturer.

If the owner withdraws and destroys the falsified or defective medical devices at its own initiative, the owner must do the following:

- Obtain confirmation that the medical devices are falsified or defective.

It is not specified what would constitute sufficient confirmation, but it is likely that the results of an expert examination would be accepted as such.

- Notify the medical devices' manufacturer and Roszdraznadzor of the decision to withdraw and destroy the medical devices.

- Wait until 60 business days have elapsed from the date of the previous step. There are two stages of possible communication between the medical devices' owner and their manufacturer within the specified period:
 - the medical devices' manufacturer may submit its objections to their owner and Roszdraznadzor concerning the decision taken by the medical devices' owner; and
 - upon receipt of objections, the medical devices' owner may submit its reasoned position or reverse the decision to withdraw and destroy the medical devices. In the latter case, the medical devices' manufacturer and Roszdraznadzor will have to be informed additionally.

Formally, the decision of the medical devices' owner to withdraw and destroy the medical devices can be executed only after 60 business days from the date of notification of the manufacturer and Roszdraznadzor (even if there are no objections from the manufacturer). However, in case of obvious falsification or defectiveness of the medical devices, Roszdraznadzor may decide on withdrawal and destruction within a shorter period of time.

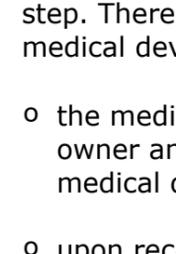
Once the medical devices have been destroyed, Roszdraznadzor must be notified within five business days.

We recommend that companies in the medical device industry bring their internal documents (standard operating procedures, policies, etc.) governing the processes for responding to the detection and disposal of improper products in line with the new regulations.

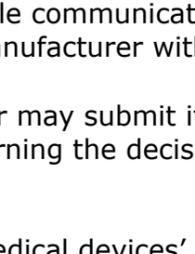
* *In Russian*

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Upcoming event

15.09.2022
10:00 - 12:00
Moscow time

Hybrid event (in Russian)
Artificial intelligence technology in the pharmaceutical industry: Global trends and legal aspects

SEAMLESS Legal and Semantic Hub joint event

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