New aspects in MD regulations in the Russian Federation

Amiran Preobrazhenskiy
PreobrazhenskiyAV@roszdravnadzor.ru
The Order of the Ministry of Health of the Russian Federation  
No.4n Dated 06.06.2012  
“Adoption of the Nomenclature classification of medical devices”  
(as revised in the Order of the Ministry of Health of the Russian Federation No.557n Dated 25.09.2014)  

**Classes of medical device**

<table>
<thead>
<tr>
<th>Class</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class 3</td>
<td>medical devices with <strong>high</strong> degree of risk</td>
</tr>
<tr>
<td>Class 2b</td>
<td>medical devices with <strong>increased</strong> degree of risk</td>
</tr>
<tr>
<td>Class 2a</td>
<td>medical devices with <strong>average</strong> degree of risk</td>
</tr>
<tr>
<td>Class 1</td>
<td>medical devices with <strong>low</strong> degree of risk</td>
</tr>
</tbody>
</table>

The rules of classification were separately established for the **in vitro diagnosis** medical devices, according to the recommendations of the Group for Global Harmonization of medical devices (GHTF/SG1/N045:2008).
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Came into force on 06 January 2015

Structure of the type of medical device

- Identification unique entry number
- Name of type of medical device
- Description of the type of medical device

Classification attributes of the type of medical device, according to the purpose of medical device

- Application area
- Invasiveness
- Sterility
- Exploitation aspects
- Frequency of use (one time or multiple use)
- Structural specifics

Violation of rules of implementation

Implementation (marketing) unregistered/counterfeit/ substandard medical devices in a large amount

The sale of counterfeit/substandard medical products not on a large scale or counterfeit in any size

Other offences in the sphere of implementation of medical devices (including the implementation of unregistered medical devices not on a large scale)

Criminal prosecution

Administrative penalty

Violation of rules of manufacturing

- The manufacture of medical devices on a large scale without a license, if such license is required
- The manufacture of counterfeit/substandard/ unregistered medical devices in larger size
- The manufacture of counterfeit/substandard/ unregistered medical devices not on a large scale
- The manufacture of medical devices not on a large scale without a license, if such license is required;
  Other offences in the sphere of manufacture of medical devices (including the manufacturing of unregistered/counterfeit medical devices in a large size)

Criminal prosecution

Administrative penalty

Violations of the rules of entry on the territory of Russian Federation

The importation into the territory of the Russia of counterfeit/ substandard, as well as importation for the purpose of sale of unregistered medical products in larger size

Criminal prosecution

The import into the territory of the Russia falsified/ counterfeit/ substandard medical products in a large amount

Administrative penalty

Other offences in the sphere of import into the territory of the Russian Federation (including the importation for sale on the territory of the Russian Federation of unregistered medical devices not in large size)
Entered into force a Federal Law from 01.01.2015 № 221-FZ «On amendments into the Tax code»

The increase of State fee for:
- Registration of MD
- Expertize of safety and performance of MD
- Amendments into the RC for MD
- Duplicate of RC for MD
THANK YOU