Administration in the sphere of circulation of medical devices
Starting from January 1st 2013
In accordance with Art. 38 / Federal law № 323:

Pre-market approval and post-market surveillance of medical devices

- State registration of medical devices
- Issuance of import permits for medical devices for the purpose of state registration
- Control over the entire life cycle of medical devices
- Monitoring of safety of medical devices
- Licensing the manufacturing of medical devices
Regulation of the Circulation of MD

In accordance with the Federal law «On the fundamental principles of healthcare in the Russian Federation»

RESOLUTIONS OF THE GOVERNMENT OF THE RUSSIAN FEDERATION

27.12.2012 № 1416
19.06.2012 № 615
26.09.2012 № 970
The scheme of registration (I level)

**APPLICANT** (documents for the state registration of MD)

- Checking the Package of documents
- Technical and toxicological tests (Independent laboratory)

**Ministry of Health Roszdravnadzor**
- A positive conclusion - the direction to clinical trials
- A negative conclusion - the refusal of state registration of the MD

**Conclusion of expert organization**

**Expert organization**

determine the possibility (impossibility) of clinical trials
The scheme of registration of MD (2 level)

Applicant (clinical trial)

Renewal of state registration

A positive conclusion - a decision on the state registration

A negative conclusion - the refusal of state registration of the MD

Conclusion from expert organization

Expert organization

Ministry of Health Roszdravnadzor

examination of the completeness and the results of technical tests and clinical studies

A positive conclusion - a decision on the state registration

A negative conclusion - the refusal of state registration of the MD

Conclusion from expert organization

Expert organization