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July 13, 2016

Medical Device Registration Process in Russia

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Regulatory affairs for medical devices. Scope.

Regulatory documentation:

Federal Law #210-FZ 27/07/2010 (Providing of public services).

Federal Law #323- FZ 21/11/2011 (Bases of national healthcare safety).

Order of RF Government #1416 from 27/12/2012 (Registration rules for Medical products) with changes + order 4n with changes

Order of RF Government #19 17/01/2002 (About "tax-free" for medical products).

Federal law #532 from 31/12/2014 + Order of Russian Government #6 from 05/01/2015 (circulation of medical products – both of them)

For sale, customs clearance and use:

- Registration certificate (strict requirement)
- Declaration of conformity (GOST R) – if applicable
- CU TR #20 (EMC) - if applicable

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| Regulatory affairs for medical devices. Scope.

1.Registration process:

Purpose of use as medical device is confirmed by registration process. Registration certificate will be given after registration procedure.

Responsible State Body:
Federal Service on surveillance in healthcare (ROSZDRAVNADZOR)
www.roszdravnadzor.ru

Who controls circulation of MP in Russia.

Declaration process:

GOST R and CU TR includes standards for safety, electrical safety, electromagnetic compatibility and other applicable requirements. Declaration of conformity issued strictly after registration

.

Responsible Body: certification body accredited by ROSACCREDITACIA

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|Medical Product. Description.

Regulation of Federal Service ROSDRAVNADZOR

In-scope Regulations

In Scope

«Medical product» means any instrument, apparatus, appliance, software, material or other article used for medical purposes, alone or in combination with each other and with other accessories necessary for the application of these products to the destination, including special software and designed by the manufacturer

- to prevent , diagnosis, treatment and rehabilitation of diseases, monitoring of the human body for medical research, restoration, replacement, modification of anatomical structures or physiological functions of the body, prevent, or abortion,
- which does not achieve its principal intended action … by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

Out of Scope

- Beauty products
- Products for individual use (for one patient)
- Pharmaceuticals

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| Classification rules for medical devices.

- ❖ **Risk class. 1, 2a, 2b and 3 risk class – mainly the same classification rules as in MDD 93/42/EEC**
- ❖ **Nomenclature code. 6-digit classification on the base on product type (order #4n)**
- ❖ **OKP classification. Main classification code in Russia – the base of tax-free system and national regulation, medical products classification is only a part of all product classification scheme**

! For medical products (MP) with 1 risk class – FAST TRACK of registration process is applicable

| Circulation of medical products (1)

Federal Law #532 from 31/12/2014 main ideas:

- Sales, manufacturing and import\export of non-registered and falsified medical products are prohibited by law with punishment
- Punishment could be from 500 000 Russian Rubles penalty until criminal penalty
- As you know – ROSZDRAVNADZOR lists non-registered products in "register of non-registered medical products". Circulation of these products is prohibited.

| Circulation of medical products (2)

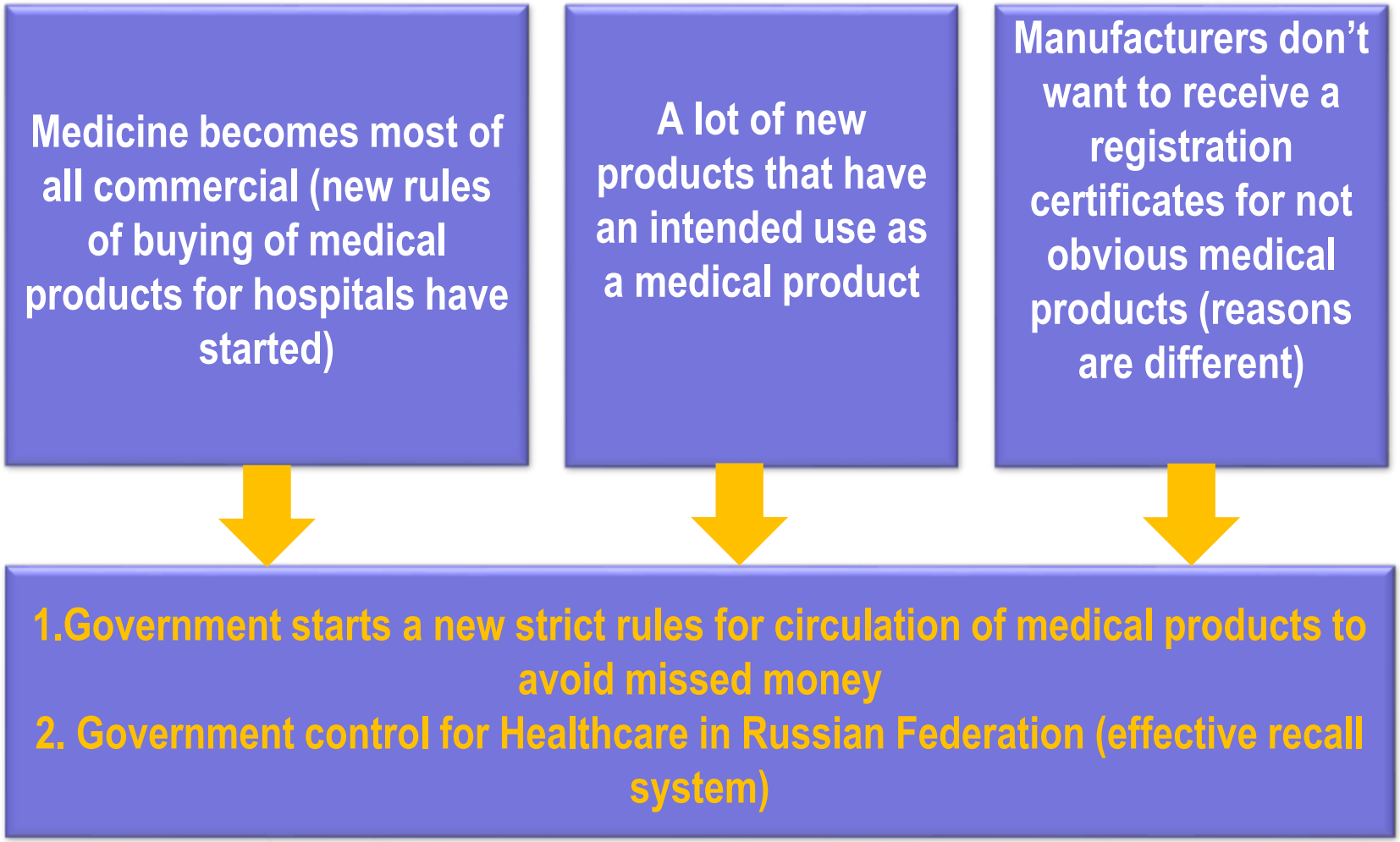
Order of Russian Government #6 from 05/01/2015 main ideas:

- **Sales of medical products must be provided only in fixed places**
- **Sales are prohibited from home, from studying and working places, in the streets and so on.**

| Changes in classification.

- 6-digit classification on the base on GMDN classification – manufacturer can use GMDN code (5-digit) during registration process in Russia
- Classification in Russia is different from GMDN classification (difference is in some medical products types)
- ROSZDRAVNADZOR (department of Ministry of Health) announced that classification codes of registered medical products will be changed by government people automatically
- ROSZDRAVNADZOR announced that changes in classification rules would not cause a negative results of registration process

| Idea of new changes.



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| Most applicable cases.

Changes in registration process first of all cause:

- ❑ **Registration process for all products that have an intended use like a medical (frequent cases):**
  - ✓ **Smartphone gadgets (heart rate and temperature)**
  - ✓ **Beauty products (solarium, devices for muscle stimulation)**
  - ✓ **Medical devices for telemedicine**

- ❑ **Changes in classification – another way for product separation in different registration certificates**
  - ✓ **There is no clear definition between active and non-active devices, sterile and non sterile, single use and non-single use**
  - ✓ **manufacturer can clear understand classification system and use international codes**

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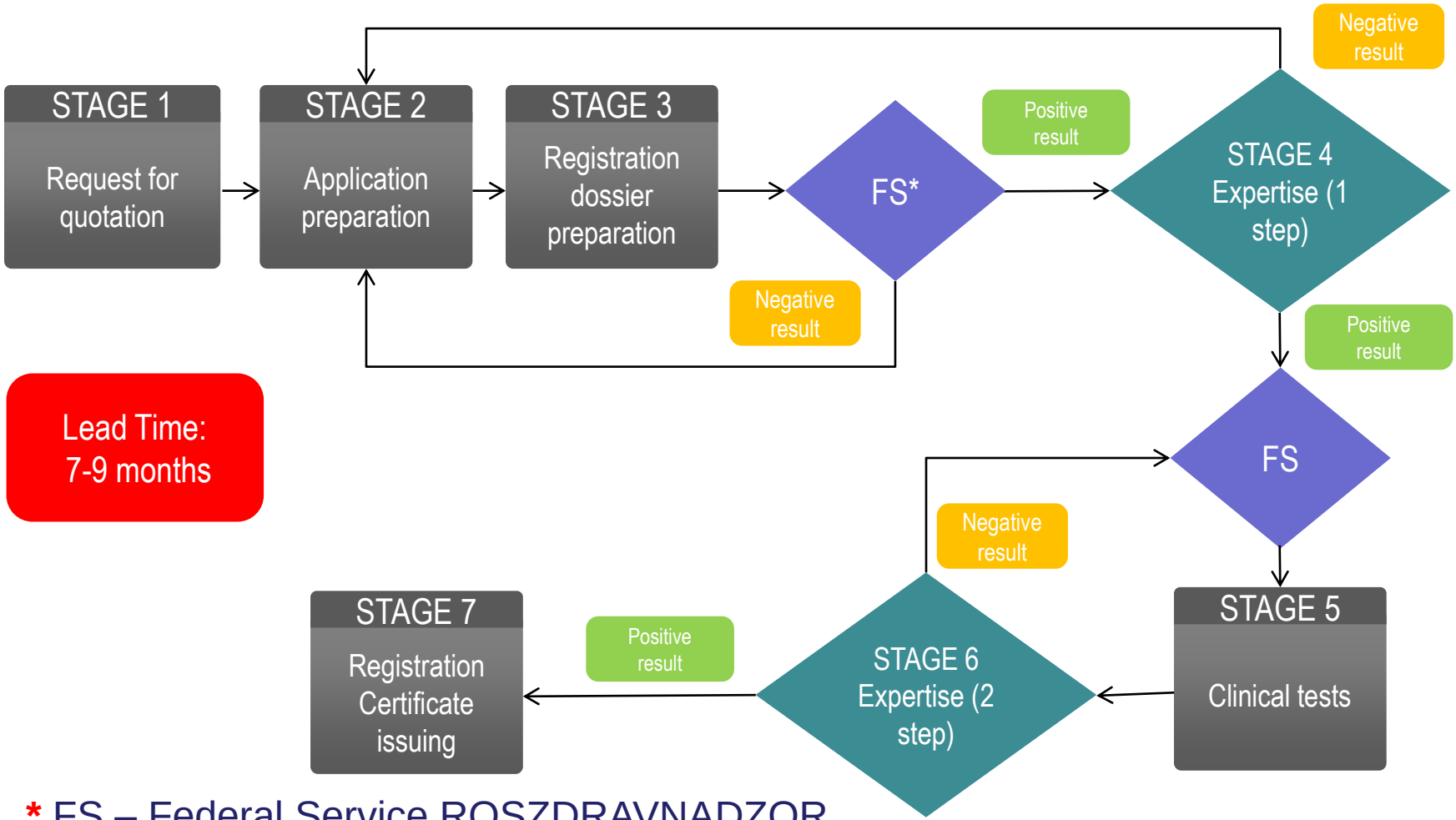
| Regulatory processes for medical products

Manufacturer has no registration certificate for this product. Manufacturer has old form of registration certificate with expiry date. Manufacturer wants to add product in current registration certificate.	→ Registration process
Manufacturer wants to change a holder of registration certificate. Manufacturer wants to add factory site. Manufacturer changed company name.	→ Changing of registration certificate
Manufacturer lost a registration certificate or it was damage.	→ Duplicate of registration certificate

* FS – Federal Service ROSZDRAVNADZOR

| Registration basic procedure –for 2a, 2b,3 risk class MP



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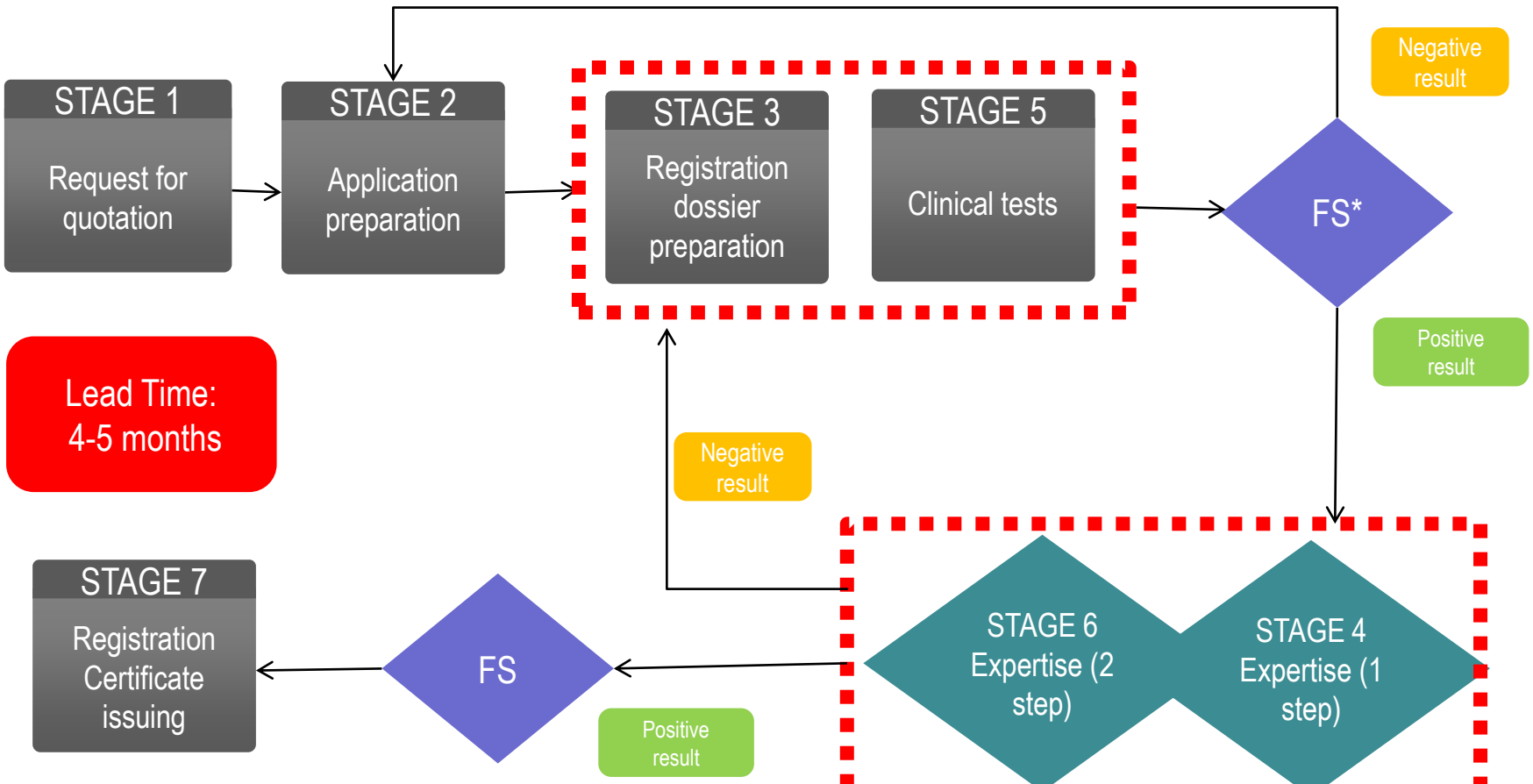
| Registration basic procedure – 1 risk class MP.



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| Regulatory affairs – Certification process

Type of procedure depends on medical product OKP
(according to order of RF government #982 from 01/12/2009)

Mandatory	Voluntary
Declaration	Certification
Declaration of Conformity	Certificate of Compliance
	
3 years validity Local Holder required	3 years validity Manufacturer application allowed

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Questions?

THANK YOU FOR ATTENDING!

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