MEDICAL DEVICES CIRCULATION IN RUSSIA

State registration. Regulation. Eurasian Economic Union.

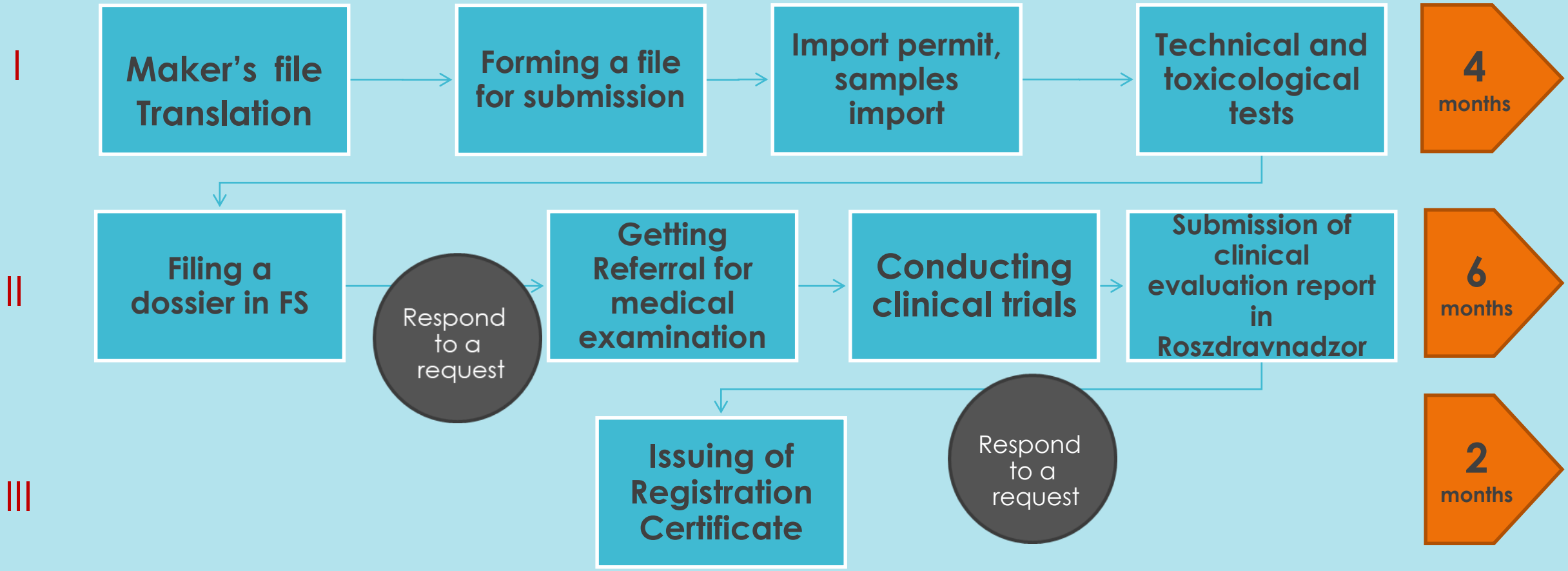
CONTENT

- **Confirmation of compliance of medical devices in RUSSIAN FEDERATION**
- **Circulation of medical devices in Russia**
- **Eurasian Economic Union. Single market.**

CONFIRMATION OF COMPLIANCE OF MEDICAL DEVICES IN RUSSIA

Registration Certificate(RC)	+	**Declaration of Conformity(DC)**
The main document		Issued after registration
No expiry date		Valid for 1,2,3 years
1 device – 1 RC		1 importer – 1 DC

REGISTRATION OF MEDICAL DEVICES IN RUSSIA



REGISTRATION DOSSIER

Document	Kind of legalization
1. Power of Attorney	Apostille/ Consulate legalization
2. ISO 13:485	Apostille/ Consulate legalization
3. CE certificate, CE declaration or national document confirming compliance of the device to the international standards	Apostille/ Consulate legalization
4. Technical File (STED format)	Notary public
5. Exploitation File	Notary public
6. Photos	-----
7. Trade Mark registration certificate	Apostille / Consulate legalization
8. Clinical Evaluation data	Notary public

POWER OF ATTORNEY AND AUTHORIZED REPRESENTATIVE COMPANY

- Power of Attorney is made in strict accordance with recommended form and gives the entrusted company right of authorized representative company (ARC)

- It is impossible to register the product without an authorized representative company.

TRADE MARK CERTIFICATE

If you use the mark ®, it is necessary to provide confirming certificate

You can use your brand name without ® if you do not have such a certificate for Russia

РОССИЙСКАЯ ФЕДЕРАЦИЯ

СВИДЕТЕЛЬСТВО

на товарный знак (знак обслуживания)

№ 603346

REG MED

Правообладатель: *Стенина Инна Анатольевна, 119607, Москва, ул. Раменки, 9, корп. 3, кв. 505 (RU)*

Заявка № **2015743258**

Приоритет товарного знака **29 декабря 2015 г.**

Зарегистрировано в Государственном реестре товарных знаков и знаков обслуживания Российской Федерации ***27 января 2017 г.***

Срок действия регистрации истекает ***29 декабря 2025 г.***

Руководитель Федеральной службы по интеллектуальной собственности

Г.П. Ивлиев

CONSULTING COMPANY FUNCTIONS

+ Initial evaluation
+ Assessment, translation, finalizing of dossier
+ Professional regulator relations

+ Trials monitoring
+ Assessment and finalizing of tests reports
+ Customs clearance of the samples

+ Paying the bills of expert and research organizations and state fees

Regular reporting to the customer

SINGLE MARKET OF MEDICAL DEVICES IN EAEU

EAEU – Eurasian Economic Union

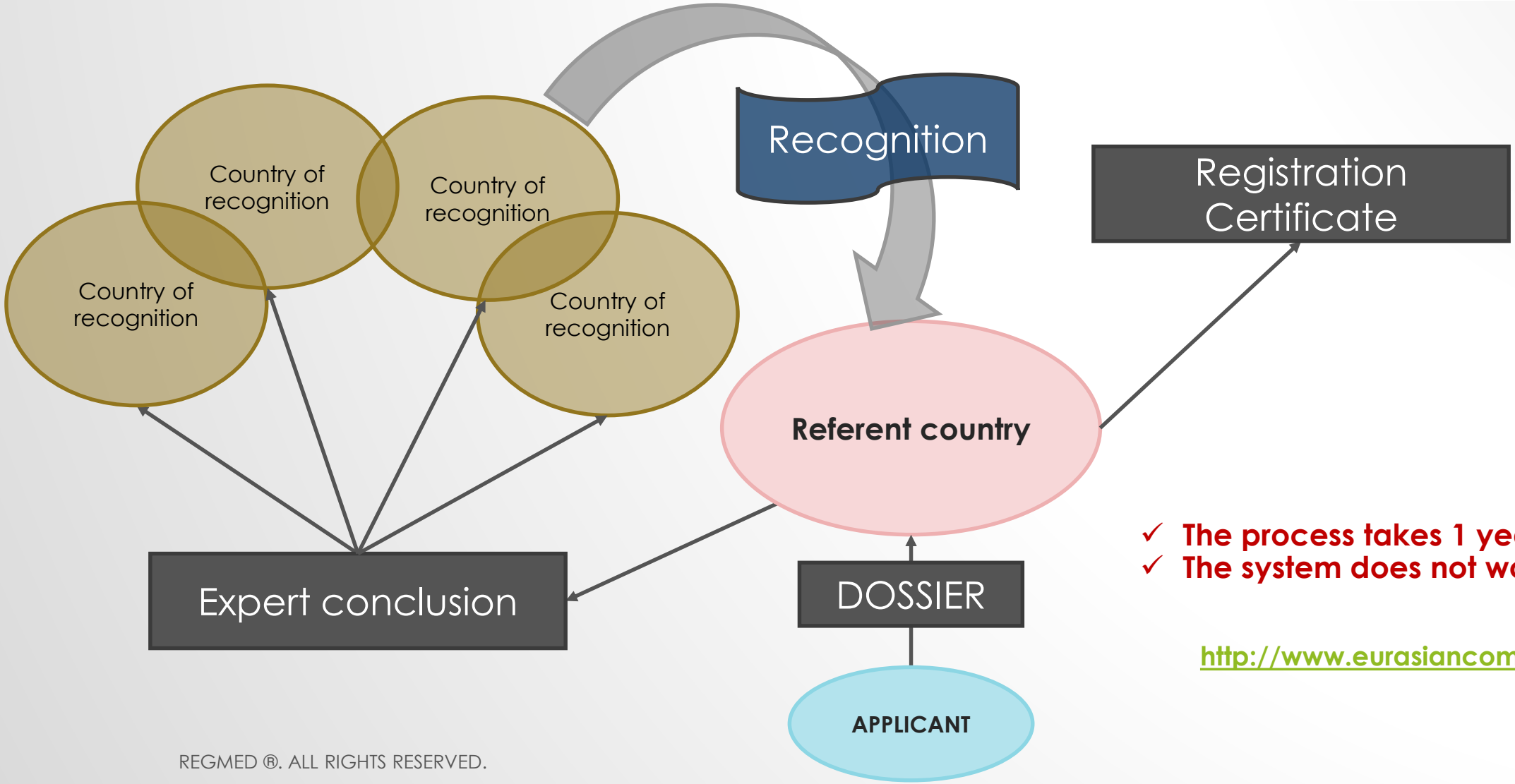
Russia Kazakhstan Belarus Armenia Kirgyzstan

SINGLE MARKET OF MEDICAL DEVICES IN EAEU

- It is declared that single EAEU market was started in May 2017
- In fact EAEU market of medical devices does not exists. National registration certificates are not valid on the territories of other countries.
- The procedure of single registration is described in the documents of Eurasian economic commission ***www.eurasiancommission.org***

National Registration Certificates are valid till 31.12.2021in accordance with the Eurasian Economic Commission Decision № 46 от 12.02.2016

SINGLE REGISTRATION IN EAEU



- ✓ **The process takes 1 year**
- ✓ **The system does not work on 05/12/2018**

http://www.eurasiancommission.org/

AUTHORIZED REPRESENTATIVE COMPANY

IN RUSSIA

FUNCTIONS
OF AUTHORIZED REPRESENTATIVE COMPANY
AFTER THE PRODUCT IS APPROVED AND REGISTERED

Interaction with consumers

Interaction with supervisory authorities

Informing the manufacturer about novellas in legislation

Contacts of ARC are on labels, in state registry, in manual

Only the ARC can implement variations in registration dossier

Information is prepared by RegMed prof. company

Contact information

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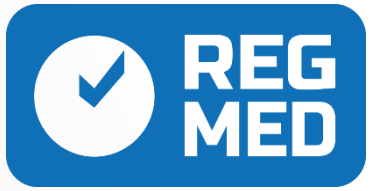
Thank you for your attention!



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