SINGLE MARKET OF MEDICAL DEVICES IN THE EURASIAN ECONOMIC UNION

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Treaty on the Eurasian Economic Union of May 29, 2014 (Articles 31 and 100)  
Came into force on January 1, 2015

Agreement on Common Principles and Rules of Circulation of Medical Devices in the EAEU of December 23, 2014  
Came into force on February 12, 2016

Came into force on April 26, 2016

The single market of medical devices was launched on May 6, 2017  
(main sublaw documents came into force)
POWERS IN THE SPHERE OF CIRCULATION OF MEDICAL DEVICES IN THE EAEU

Establishment of uniform rules and requirements

Implementation of the uniform requirements and rules.

Implementation of state control (surveillance)

Monitoring of safety, quality and efficacy of medical devices

- Eurasian Economic Commission
- Authorized bodies of the Member States
LEGISLATION REGULATING
THE MARKET OF MEDICAL DEVICES: EEC ACTS

26 ACTS OF THE EURASIAN ECONOMIC COMMISSION:
10 EEC Council Decisions,
13 EEC Board Decisions and 3 EEC Recommendations

COMMON ACTS
Marketing authorization and assessment rules ♦ Special mark of MA ♦ MD nomenclature ♦
Registers and information bases♦ Measures for dangerous MDs ♦ Electronic form of the
registration dossier ♦ Regulation on Consultative Committee on MDs

Safety
♦ Common rules for safety, efficacy and labelling
♦ Rules for technical tests of MDs
♦ Classification of MD according to the degree of risk
♦ Rules for conducting biological investigation
♦ List of standards for safety assessment and rules for its formation

Efficacy
Rules for clinical and clinical-laboratory studies
Rules for safety, efficacy and quality monitoring

Quality
List of MDs classified as measuring instruments
Requirements to assessment of QMS of medical devices
<table>
<thead>
<tr>
<th>End of period</th>
<th>Characteristics</th>
<th>Document</th>
</tr>
</thead>
</table>
MARKETING AUTHORIZATION AND ASSESSMENT OF MEDICAL DEVICES

**Abbreviations and symbols:**
- RS – reference state,
- CS – concerned state,
- IS – information system

- Stages of assessment of documents and decision-making
- Positive decision on assessment and MA
- Negative decision on examination and MA
- Time not included in the total time of assessment
- Time included in the total time of assessment

**Overall time for evaluation and granting an MA:**
- Including «stop-times» ≈ 337 working days, without «stop-times» ≈ 114 working days
Decision of the EEC Council of 12.02.2016 № 26
approved the image of a special certification mark of medical devices’ circulation on
the market of the Eurasian Economic Union, as well as the regulation on it
CRITERIA AND CLASSIFICATIONS (3 DOCUMENTS)

- Criteria for inclusion of several modifications of MDs into one MA (EEC Board Decision of 24.07.2018 № 123)
- Criteria for classifying products as medical devices (EEC Board Recommendation of 12.11.2018 № 25)

AUDITING OF QSM (4 DOCUMENTS)

- Requirements for auditing organizations (public discussion of the draft is finished)
- The rules of evaluation and authorization of auditing organizations
- Requirements to the auditors (the draft is under public discussion)
- Guidelines for the requirements of the QMS assessment

ASSESSMENT OF SAFETY, EFFICACY, QUALITY (1 DOCUMENT)

- Guidelines on safety, quality and efficacy auditing (public discussion of the draft is finished)

PREPARATION OF REGISTRATION DOSSIER (1 DOCUMENT)

- Guidelines on the content and structure of the registration dossier (the draft is under public discussion)
### Name of the Common Process

**Included in the List of common processes in the Eurasian Economic Union (EEC Board Decision of April 14, 2015 № 29)**

<table>
<thead>
<tr>
<th>Name of the Common Process</th>
<th>Legislative act</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forming, maintaining and using the Unified register of medical devices with MA in the Eurasian Economic Union</td>
<td>EEC Board Decision of 30.08.2016 № 92</td>
</tr>
<tr>
<td>Forming, maintaining and using the Unified register of authorized bodies of the Eurasian Economic Union, carrying out investigation (tests) of medical devices for their MA</td>
<td>EEC Board Decision of 30.08.2016 № 93</td>
</tr>
<tr>
<td>Forming, maintaining and using the Single information database of monitoring safety, quality and efficacy of medical devices (“MDs-vigilance”)</td>
<td>EEC Board Decision of 30.08.2016 № 94</td>
</tr>
</tbody>
</table>
INFORMATION SYSTEM OF THE UNION: PARTICIPANTS OF THE PROCESS

Stakeholders

- Manufacturers
- Authorized organizations
- Commission staff and authorized bodies
- Consumers

INTEGRATIONAL SEGMENT OF THE COMMISSION

Informational portal of the Union

INTEGRATED SYSTEM

National system of AB of the Member State

NATIONAL SEGMENT OF MEMBER STATE

Applicants

REQUIREMENTS TO THE ELECTRONIC APPLICATION FORM AND DOCUMENTS OF THE REGISTRATION DOSSIER
(Decision of the EEC Board of 30.06.2017 № 78)
http://www.eurasiancommission.org

Access:
Technical regulation →
Technical Regulation and Accreditation Department →
Creation of common markets of medicines and medical products
Hyperlink:
Acts in the sphere of circulation of medical products
Thank you for attention!

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