Basic Eurasian Economic Union legislation

There are about fifty distinct rules regulating the medical device registration in the Eurasian Economic Union. We have highlighted 16 important documents that are must-to-know to better understand the new system. They are as follows:

Level 1	1. Treaty on the Eurasian Economic Union (EAEU) 2. Agreement on Common Principles and Rules for circulation of Medical Products (medical products and medical equipment) in the Eurasian Economic Union
Level 2	3. EAEU Commission Decision **№46** "On Rules of Registration and Safety, Quality and Efficacy Evaluation of Medical Devices" 4. EAEU Commission Decision **№27** "On Approval of General Safety and Performance Requirements for medical devices, requirements for their labeling and operational documentation" 5. EAEU Commission Decision **№28** "On Approval of Medical Devices Technical Testing Rules" 6. EAEU Commission Decision **№29** "On Approval of Medical Devices Clinical and Clinical Laboratory Trials (Studies) Rules" 7. EAEU Commission Decision **№38** "On Approval of Medical Devices Testing for Biological Action Evaluation Rules" 8. EAEU Commission Decision **№42** "On Approval of the List of Medical Devices to be classified as Measuring Instruments" 9. EAEU Collegium (Board) Decision **№173** "On Approval of the Classification Rules of Medical Devices, depending on their potential Risk of Use" 10. EAEU Collegium (Board) Decision **№46** "On the Medical Devices Nomenclature in the Eurasian Economic Union" 11. EAEU Collegium (Board) Decision **№116** "On the Differentiation Criteria of Medical Device Elements for the Purpose of its Registration" 12. EAEU Collegium (Board) Decision **№123** "On the Criteria for the inclusion in one registration certificate of several modifications of a medical device related to one type of medical device in accordance with the nomenclature of medical devices used in the Eurasian Economic Union"

Level 3	13. EAEU Collegium (Board) Recommendation **№14** "On Methodological Recommendations for the Examination of the Safety, Quality and Effectiveness of Medical Devices for their registration in the Eurasian Economic Union" 14. EAEU Collegium (Board) Recommendation **№17** "On the List of Standards, as a result of the application of which, on a voluntary basis, compliance with the General Safety and Performance requirements of medical devices, the requirements for their labeling and operational documentation for them is fully or partially ensured" 15. EAEU Collegium (Board) Recommendation **№25** "On the Criteria for classifying products as Medical Devices in the Eurasian Economic Union" 16. EAEU Collegium (Board) Recommendation **№29** "On Methodological Recommendations on the Content and Structure of the Medical Device Registration Dossier documents"