

**THE EURASIAN ECONOMIC COMMISSION**

**THE COUNCIL**

**DECISION**

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| May 19, 2022 | **No. 84** | Bishkek |

**On amending the Rules for Marketing Authorization and Expert Examination of Medical Device Security, Quality and Efficiency**



In accordance with Paragraph 2, Article 31 of the Treaty on the Eurasian Economic Union dated May 29, 2014, Paragraphs 2 and 4, Article 4 of the Agreement on Unified Principles and Rules for the Circulation of Medical Devices (Medical Accessories and Medical Equipment) within the Eurasian Economic Union dated December 23, 2014, Paragraph 92 of Annex 1 to the Rules of Procedure of the Eurasian Economic Commission approved by Decision No. 98 of the Supreme Eurasian Economic Council dated December 23, 2014, the Eurasian Economic Commission's Council **decided**:

1. To revise the second indent of paragraph 1 of the Rules for Marketing Authorization and Expert Examination of Medical Device Security, Quality and Efficiency approved by Decision No. 46 of the Eurasian Economic Commission's Council dated February 12, 2016 to be read as follows:

“The requirements of these Rules may not apply to medical devices the marketing of which is regulated by the legislation of the Union Member States (hereinafter referred to as the Member States) and which are intended for use under conditions of military operations, the emergence, liquidation and prevention of accidents, the threat of the spread of epidemic diseases, hazardous to others, prevention, diagnosis and treatment of diseases and lesions resulting from exposure to adverse chemical, biological, radiation factors, and in the event of threat of absence or absence of medical devices on the markets of the Member States in the context of restrictive economic measures introduced in relation to at least one of the Member States. Non-application of the requirements of these Rules is allowed only during the validity of the above conditions.".

2. This Decision shall come into effect after 10 calendar days have elapsed from the date of its official publication.

**Members of the Eurasian Economic Commission's Council:**

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| **For the Republic of Armenia** | **For the Republic of Belarus** | **For the Republic of Kazakhstan** | **For the Kyrgyz Republic** | **For the Russian  Federation** |
| **M. Grigoryan** | **I. Petrishenko** | **B. Sultanov** | **A. Kozhoshev** | **A. Overchuk** |