Draft

**PROTOCOL**

**on making amendments to 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.**

The Member States of the Eurasian Economic Union, hereinafter referred to as the Member States,

following the provisions of the Treaty on the Eurasian Economic Union dated May 29, 2014

have agreed as follows:

Article 1

To amend Article 11 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 to be read as follows:

"Article 11
 Transition Period

On or before December 31, 2021, the application for the medical device expert assessment or authorization may be filed according to the procedure stipulated by the Member State legislation. If the application for the medical device expert assessment or authorization has been filed according to the procedure stipulated by the Member State legislation on or before December 31, 2021, the medical device may be authorized according to the procedure stipulated by the Member State legislation.

A medical device authorized according to the procedure stipulated by the Member State legislation is released to the market within the territory of that Member State until expiry of period of validity of the documents confirming its authorization and shall be traded within the territory or that Member State.

A medical device authorized according to the procedure stipulated by the Member State legislation (except for the medical device, pertaining which an undated document confirming its authorization is issued) may be re-authorized (the document confirming the authorization re-issued) according to the procedure stipulated by the Member State legislation, if the corresponding application is filed on or before December 31, 2026.

The medical device authorization documents may be amended according to the procedure stipulated by the Member State legislation (except for the amendments requiring new authorization in accordance with the procedure stipulated by clause 2, Article 4 of this Agreement), if the corresponding application is filed on or before December 31, 2026."

Article 2

This Protocol shall be temporarily applied by the Member States from January 1, 2022, and for the Member State whose legislation does not provide for the possibility to temporarily apply international treaties this Protocol shall be applied from the date when such a Member State fulfils internal legal procedures required for the entry into force of this Protocol, but not earlier than January 1, 2022.

This Protocol shall become effective on the date when the depositary receives through diplomatic channels the last written notice on fulfilling the internal legal procedures required for the entry into force of this Protocol by the Member States.

Done at Moscow on December 30, 2021 in one original copy in Russian.

The original copy of this Protocol shall be kept by the Eurasian Economic Commission, which, being the Depositary of this Protocol, shall send a certified copy thereof to each Member State.

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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** |