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EURASIAN ECONOMIC COMMISSION
BOARD

DECISION

July 24, 2018 **No. 123** city of Moscow

On Criteria for inclusion of several modifications of the medical product relating to one type of the medical product in accordance with the medical product nomenclature applied in the Eurasian Economic Union in one registration certificate

In accordance with paragraph 2 of Article 3, paragraphs 2 and 4 of Article 4 of the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Medical Equipment) within the Eurasian Economic Union dated December 23, 2014 and paragraph 14 of the Rules for Registration and Examination of Safety, Quality and Efficacy of Medical Products approved by Decision No. 46 of the Council of the Eurasian Economic Commission dated February 12, 2016, and in accordance with paragraph 21 of the list of acts of the Eurasian Economic Commission on regulation of common markets for drugs and medical products within the Eurasian Economic Union for 2017 - 2019 (Annex to Instruction No. 15 of the Council of the Eurasian Economic Commission dated May 17, 2017), the Board of the Eurasian Economic Commission **decided**:

1. To approve the attached Criteria for inclusion of several modifications of the medical product relating to one type of the medical product in accordance with the medical product nomenclature applied in the Eurasian Economic Union in one registration certificate.

2. This Decision shall enter into force after 30 calendar days have elapsed from the date of its official publication.

Chairman of the Board of the Eurasian Economic Commission — T. Sargsyan

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APPROVED
by Decision No. 123 of the Board of
the Eurasian Economic Commission
dated July 24, 2018

CRITERIA
for inclusion of several modifications of the medical product relating to one type of the medical product in accordance with the medical product nomenclature applied in the Eurasian Economic Union in one registration certificate

1. This document establishes the criteria for inclusion of several modifications of the medical product relating to one type of the medical product in accordance with the medical product nomenclature applied in the Eurasian Economic Union in one registration certificate.

2. For the purposes of this document, the concepts defined by the Rules for Keeping Medical Product Nomenclature approved by Decision No. 177 of the Board of the Eurasian Economic Commission dated December 29, 2015, the Rules for Clinical and Clinical Laboratory Trials (Studies) of Medical Products approved by Decision No. 29 of the Council of the Eurasian Economic Commission dated February 12, 2016, and the Rules for Registration and Examination of Safety, Quality and Efficacy of Medical Products approved by Decision No. 46 of the Council of the Eurasian Economic Commission dated February 12, 2016.

3. Inclusion of several modifications of the medical product relating to one type of the medical product in accordance with the medical product nomenclature applied in the Eurasian Economic Union in one registration certificate is possible provided that these modifications comply with all of the following criteria:

a) modifications of a medical product are manufactured by one manufacturer of the medical product according to the same technical documentation;

b) modifications of the medical product belong to the same class of the potential risk of use;

c) presence and (or) quantitative content of the same clinically (diagnostically) significant analyte (analytes) in a biological sample (for medical products for in vitro diagnostics);

d) modifications of the medical product have different configurations that do not affect the principle of operation and functionality, which allows to ensure expansion or specialization of their use for medical purposes (if applicable);

e) modifications of the medical product have various technical parameters (for example, wavelength of radiation, size of light field, resolution, etc.), which do not affect the principle of operation and functionality (if applicable);

f) modifications of the medical product form a dimension range (for example, they have different sizes (dimensional, linear, volumetric, etc.), shape, color coding, etc.) or they are a group of a medical product version (for example, stationary mobile unit (device, system, complex, etc.) with a wall and (or) floor mounting, etc.) (if applicable). At the same time, a group of a medical product version is understood as products in respect of which one group drawing of parts and (or) one group specification is made.

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