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EURASIAN ECONOMIC COMMISSION
BOARD

RECOMMENDATION

September 04, 2017 **No. 16** city of Moscow

On Procedure for formation of the list of standards the application of which, on a voluntary basis, fully or partially ensures compliance of medical products with the General Requirements for Safety and Efficacy of Medical Products, Requirements for Their Marking and Operational Documentation on Them

In accordance with paragraph 2 of Article 3, paragraph 4 of Article 4 and paragraph 4 of Article 7 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 in accordance with paragraph 110 of the General Requirements for Safety and Efficacy of Medical Products, Requirements for Their Marking and Operational Documentation on Them approved by Decision No. 27 of the Council of the Eurasian Economic Commission dated February 12, 2016, the Board of the Eurasian Economic Commission

recommends to the Member States of the Eurasian Economic Union to apply, from the date of publication of this Recommendation on the official website of the Eurasian Economic Union, the Procedure according to the Annex when forming a list of standards the application of which, on a voluntary basis, fully or partially ensures compliance of medical products with the General Requirements for Safety and Efficacy of Medical Products and Requirements for Their Marking and Operational Documentation on Them.

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

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ANNEX
to Recommendation No. 16 of the Board of
the Eurasian Economic Commission
dated September 4, 2017

On Procedure for formation of the list of standards the use of which, on a voluntary basis, fully or partially ensures compliance of medical products with the General Requirements for Safety and Efficacy of Medical Products, Requirements for Their Marking and Operational Documentation on Them

1. This Procedure has been developed on the basis of paragraph 2 of Article 3, paragraph 4 of Article 4 and paragraph 4 of Article 7 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 in accordance with paragraph 110 of the General Requirements for Safety and Efficacy of Medical Products, Requirements for Their Marking and Operational Documentation on Them approved by Decision No. 27 of the Council of the Eurasian Economic Commission dated February 12, 2016 (hereinafter referred to as the General Requirements) in order to form a list of standards, the application of which on a voluntary basis fully or partially ensures compliance of medical products with the General Requirements (hereinafter referred to as the List) and the procedure for introduction of changes thereto.

2. The compliance of medical products with the General Requirements is ensured by meeting requirements, established directly by the specified document or requirements of listed standards.

3. The list is developed in the form according to Annex No. 1.

4. The list is formed by inclusion of standards into it taking into account the following priorities:

a) interstate standards, developed on the basis of actual versions of international and (or) regional standards;

b) national (state) standards of the member-states of the Eurasian Economic Union (hereinafter referred to as the member-states), developed on the basis of actual versions of international and (or) regional standards. If there are several national (regional) standards, developed on the basis of the actual version of the international and (or) regional standard, they are put in the list;

c) interstate standards, developed not on the basis of international and (or) regional standards;

d) national (state) standards of the Member States, developed on the basis of international and (or) regional standards.

5. Prior to the development of standards specified in paragraph 4 of this Procedure, containing the rules and methods of tests (studies) and measurements necessary to confirm the compliance of medical products with the General Requirements, the list may include methods of tests (studies) and measurements, validated and approved in accordance with the legislation of the Member State.

6. In case if national (state) standards of the Member States and (or) methods of tests (studies) and measurements for the specified standards and (or) methods are put, the period to which it is necessary to adopt and put interstate standards for the relevant standardization facility in the list is specified in the list column “Date of termination of the standard application”, if necessary.

Authorized authorities of the Member States which register medical products (hereinafter referred to as the authorized authorities) submit proposals on development of relevant interstate standards to the authorized standardizing bodies of the Member States.

7. The authorized authorities send proposals to the Eurasian Economic Commission (hereinafter referred to as the Commission) for inclusion of the standards in the list in the form provided for in Annex 1 to the General Requirements, as well as results of the analysis of compliance of such standards with the objectives of the General Requirements in the form according to Annex No. 2.

8. When preparing proposals for inclusion of standards in the list and introduction of changes to it, the authorized authority:

a) make an analysis of standards to determine the possibility that their use ensures compliance of the medical product with the General Requirements, particularly taking into account recommendations of the International Medical Device Regulators Forum (IMDRF);

b) make an analysis of the international experience in the application of standards to ensure safety and efficacy of medical products;

c) selects the standards most appropriate to the objectives of the General Requirements. Compliance with the provisions of the General Requirements can be ensured by application on a voluntary basis of the

requirements of the standard in whole or one or more sections, paragraphs, subparagraphs of the standard.

9. The Commission sends proposals received from the authorized authority to other authorized authorities within 5 working days from the date of their receipt.

10. In case of disagreement with the proposals received, the authorized authorities send their comments to the Commission within 30 working days from the date of receipt (with justification). In the absence of comments of the authorized authority in the specified period, such proposals are deemed as agreed upon.

The specified comments of the authorized authorities are discussed at the meeting of the working group on the formation of common approaches to the regulation of the circulation of medical products within the Eurasian Economic Union. The decision on whether to put the standard in the list or to exclude it is adopted by consensus. Based on this decision, the issue of introduction of changes to the list is considered at the meeting of the Board of the Commission in accordance with the established procedure.

11. When a national (state) standard of the Member State, developed on the basis of the international and (or) regional standards is put in the list, the designations of such international and (or) regional standards, as well as the degree of harmonization of the national (state) standard of the Member State with the specified standard are additionally indicated.

International or regional standards are applied after they are accepted as interstate or national (state) standards.

12. Changes to the list are introduced in the manner prescribed for inclusion of the standard into the list or its exclusion in the following case:

a) non-compliance of the standard with the objectives of the General Requirements;

b) standard cancellation;

c) replacement of the standard in the old version with the standard in the current version.

13. If, instead of the standard contained in the list, a new standard is included, for the application of which a transition period is required, during which both the replaced and replacing standards can be applied, the relevant information is listed.

If, instead of the methodology of tests (studies) and measurements contained in the list, a standard is included that requires a transitional period during which both the replaced method of tests (studies) and measurements and the standard replacing it can be applied, the relevant information is provided in the list.

14. Interstate standards approved from the effective date of this Procedure are put in the list provided that all Member States adhere to them.

15. The authorized standardizing bodies of the Member States inform the Commission of the termination of interstate and national (state) standards in their territory from those included in the list.

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ANNEX No. 1
to the Procedure for formation of the list of standards
the application of which, on a voluntary basis, fully or partially ensures
compliance of medical products with the General Requirements for Safety and
Efficacy of Medical Products, Requirements for Their Marking and Operational
Documentation on Them

(form)

L I S T
of standards, the application of which, on a voluntary basis,
fully or partially ensures compliance of medical products
with the General Requirements for the safety and efficacy of medical products,
requirements for their marking and operational documentation on them

Item No.	Standard designation	Standard name	Date of start of standard application	Date of the end of standard application	Applied structural elements of the standard	Paragraph of the General Requirements
1	2	3	4	5	6	7
I. Standards applied for medical products (except for in vitro diagnostics) II. Standards applied for medical products for in vitro diagnostics						

Notes: 1. Dates of the start and end of the application of the standard are indicated in columns 4 and 5 in order to ensure the compliance of medical product with the General Requirements for Safety and Efficacy of Medical Products, Requirements for Their Marking and Operational Documentation on Them, approved by Decision No. 27 of the Council of the Eurasian Economic Commission dated February 12, 2016 (hereinafter referred to as the General Requirements).

2. The used structural elements of the standard are indicated in column 6, if not all structural elements of the standard provide a presumption of conformity of medical products to the General Requirements.

3. The relevant paragraph of the General Requirements, which is fulfilled when applying the structural element of the standard indicated in column 6, is indicated in column 7.

ANNEX No. 2
to the Procedure for formation of the list of standards
the application of which, on a voluntary basis, fully or partially ensures
compliance of medical products with the General Requirements for Safety and
Efficacy of Medical Products, Requirements for Their Marking and Operational
Documentation on Them

FORM
of presentation of results of the analysis of compliance of the standard with the objectives of the General Requirements for the safety and efficacy of medical products, requirements for their marking and operational documentation on them

Item No.	Standard designation	Standard name	Date of standard enactment (cancellation)	Conformity of the current version of the international or regional standard (for standards adopted on the basis of international and (or) regional standards) to the objectives of the General Requirements	Information on the application of the relevant international or regional standard for regulatory purposes at the international or regional level (for standards adopted on the basis of international and (or) regional standards)	Information on the provision of the standard with methods of tests (studies) (if necessary)
1	2	3	4	5	6	7