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EURASIAN ECONOMIC COMMISSION
COUNCIL

DECISION

November 10, 2017 **No. 106** city of Moscow

On Requirements to the implementation, Maintenance and Evaluation of Medical Product Management System Depending on the Potential Risk of Their Use

In accordance with paragraph 2 of Article 31 of the Treaty on the Eurasian Economic Union dated May 29, 2014, paragraph 1 of Article 6 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, paragraph 107 of Annex No. 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, and in order to implement Decision No. 109 of the Supreme Eurasian Economic Council dated December 23, 2014 "On Implementation of the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Medical Equipment) within the Eurasian Economic Union", the Council of the Eurasian Economic Commission **decided:**

1. To approve the attached Requirements to the implementation, maintenance and evaluation of medical product quality management system depending on the potential risk of their use (hereinafter referred to as the Requirements).

2. To establish that:

a) within 12 months from the effective date of this Decision:

the quality management system of the manufacturer of a medical product is not evaluated for compliance with the Requirements;

when submitting an application for registration of a medical product of class 2a (for medical products released in sterilized form), 2b or 3 of the potential risk of use, the registration dossier includes documents confirming that the manufacturer of the medical product has production conditions claimed for the registration of the medical product complying with the requirements of the legislation of a Member State of the Eurasian Economic Union, to the authorized authority of which the specified application is submitted (if there are such requirements), and copies of certificates of compliance of the quality management system with the requirements of GOST ISO 13485, "Medical products. Quality management systems. System requirements for regulatory purposes" or the corresponding national (state) or international standard, as well as copies of reports on previous inspections for compliance with ISO 13485 (if any);

b) manufacturers of medical products registered within 12 months from the effective date of this Decision in accordance with 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 should confirm implementation of a quality management system by the unplanned production inspection in accordance with the Requirements within 2 years from the date of the medical product registration;

c) indents 3 and 4 of paragraph 3 of the Requirements come into force from the effective date of the provisions on introduction of relevant changes to 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. The state authority of a Member State of the Eurasian Economic Union, authorized to implement and (or) coordinate activities in the field of circulation of medical products in the territory of this state, gives inspecting organizations to inspect manufacturers of medical

products in accordance with the requirements for such organizations, approved by the Eurasian Economic Commission.

4. This Decision shall enter into force after 10 calendar days have elapsed from the date of its official publication.

Members of the Council of the Eurasian Economic Commission:

For the Republic of Armenia	**For the Republic of Belarus**	**For the Republic of Kazakhstan**	**For the Kyrgyz Republic**	**For the Russian Federation**
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V. Gabrielyan	**V. Matyushevskiy**	**A. Mamin**	**T. Abdygulov**	**I. Shuvalov**

APPROVED
by Decision No. 106 of the Council of
the Eurasian Economic Commission
dated November 10, 2017

REQUIREMENTS
to the implementation, maintenance and evaluation of medical product quality management system depending on the potential risk of their use

I. General provisions

1. These Requirements are developed in accordance with paragraph 2 of Article 31 of the Treaty on the Eurasian Economic Union dated May 29, 2014 and paragraph 1 of Article 6 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 establish within the Eurasian Economic Union (hereinafter referred to as the Union) requirements to the implementation, maintenance and evaluation of medical product quality management system depending on the potential risk of their use.

2. For the purposes of these Requirements the concepts are used having the following meanings:

"production inspection" - assessment of production conditions and quality management system of the manufacturer of the medical product for compliance with these Requirements;

"inspecting organization" – an authorized authority or organization (organizations) authorized by the authorized authority of the Member State of the Union to conduct production inspections;

"corrective action" - an action taken by the manufacturer of medical products to eliminate the cause of the detected non-compliance or undesirable event;

"correction" – an action taken to eliminate the detected non-compliance;

"critical supplier" - a supplier products or services of which have a direct impact on safety and efficacy of the medical product;

"poor-quality medical product" - a medical product which does not meet the general requirements for safety and efficacy of medical products, requirements for their marking, technical and operational documentation for them, and cannot be used for the intended purpose determined by the manufacturer in a safe manner;

"evaluation of the medical product quality management system" - confirmation of the implementation, maintenance and efficacy of the functioning of the medical product quality management system to ensure compliance of the General Requirements for Safety and Efficacy of Medical Products, Requirements for Their Marking, Technical and Operational Documentation for Them, approved by Decision No. 27 of the Council of the Eurasian Economic Commission dated February 12, 2016;

"after-sales monitoring" - a system for collection and analysis of the data of a medical product manufacturer on the use of medical products, tracking and identification of side effects of medical products during their operation;

"preventive action" - an action taken to eliminate the cause of a potential non-conformity or potentially undesired situation;

"production site" - a territorially separate complex designed for performance of the entire process of medical product manufacture or its specific stages;

"medical product quality management system" – an organizational structure, functions, procedures, processes and resources necessary for coordinated activities for administration and management of an organization that manufactures medical products in relation to quality;

“authorized authority” – a state authority of a Member State of the Union authorized to carry out and (or) coordinate activities in the field of circulation of medical products in the territory of that state;

“production conditions”- infrastructure and production environment necessary to ensure compliance of the manufactured medical products with the General Requirements for Safety and Efficacy of Medical Products, Requirements for Their Marking, Technical and Operational Documentation for Them, approved by Decision No. 27 of the Council of the Eurasian Economic Commission dated February 12, 2016.

II. Requirements to medical product quality management system depending on the potential risk of use

3. Manufacturers of medical products (except for manufacturers of medical products of class 1 of the potential risk of use and non-sterile medical products of class 2a of the potential risk of use) are obliged to introduce a medical product quality management system depending on the class of the potential risk of their use.

Manufacturers of medical products of class 1 of the potential risk of use and non-sterile medical products of class 2a of the potential risk of use have the right to introduce and maintain a medical product quality management system.

In case if manufacturers of medical products of class 1 of the potential risk of use and non-sterile medical products of class 2a of the potential risk of use were assessed against the medical product quality management system, including design and development processes in accordance with these Requirements, then during the period of validity of the opinion contained in the report of results of production inspection, introduction of changes to the registration dossier of such medical products is carried out without examination of safety, quality and efficacy post factum notification.

The manufacturer of the medical product notifies the authorized authority, issued the registration certificate of the medical product, of the introduction of the relevant changes in the form in accordance with Annex No. 7 to 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.

4. Manufacturers of medical products of class 2a and 2b of the potential risk of use (for medical products manufactured in a sterile form) prior to submission of documents for registration of medical products are obliged to implement a medical product quality management system (except for implementation of design and development processes).

5. Manufacturers of medical products of class 3 of the potential risk of use prior to submission of documents for registration of medical products are obliged to implement the medical product quality management system, including design and development processes.

6. Medical product quality management system should ensure compliance of medical products released into circulation within the Union with applicable General Requirements for Safety and Efficacy of Medical Products, Requirements for Their Marking, Technical and Operational Documentation for 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 for Safety and Efficacy).

7. To implement a medical product quality management system, the manufacturer of medical products is obliged:

a) to develop documented requirements for risk management at all stages of the life cycle of medical products;

b) to determine processes necessary for the effective functioning of the medical product quality management system (hereinafter referred to as the processes), and use of processes in the organization which manufactures medical products;

c) to determine the sequence and relationship of processes;

d) to determine criteria and methods necessary to ensure effectiveness, both during implementation of processes and management of processes;

e) to ensure availability of production conditions, resources and information required to support processes and monitor processes;

f) to monitor, measure (where applicable) and analyze processes;

g) to take measures necessary to achieve the planned results and maintain effectiveness of processes.

8. All elements of the medical product quality management system (organizational structure, methods and description of processes) should be documented and maintained in the current state.

The documentation of the medical product quality management system is made on paper, and in case if the legislation of a Member State of the Union (hereinafter referred to as the Member State) provides for the possibility to execute the specified documentation electronically – in electronic format. Such documentation is submitted in Russian or with the authentic translation into Russian certified by the manufacturer in the manner established by the legislation of the Member State.

9. The documentation of the medical product quality management system should also contain a description of:

a) requirements for technical characteristics of the medical product, standards or individual sections (paragraphs, subparagraphs) of the standards to be applied, and, in case if the relevant standards are not applied, of the methods which will be used to guarantee that the General Requirements for Safety and Efficacy applicable to the manufactured medical products will be met;

b) methods and depth of control of a third party in case if the development, production and (or) final check are performed by a third party;

c) processes of production, quality control and assurance of medical product quality, processes and systematic measures that will be used to control quality and assure quality of the medical product, including processes of corrective and preventive actions;

d) documents of record of indicators of the medical product quality (reports on internal checks, inspections, test results and other documents);

e) means to control achievement of the required quality of the medical product and effective functioning of the medical product quality system;

f) plans, procedures and documents of feedback from consumers (including monitoring of safety and efficacy of the medical product at the after-sales stage).

10. Manufacturers of medical products that have the medical product quality management system in accordance with these Requirements should maintain it in the current state and ensure its effectiveness.

III. Requirements for evaluation of the medical product quality management system

11. The inspecting organizations assess the medical product quality management system in the form of production inspection.

12. The costs associated with the production inspection as part of the assessment of the medical product quality management system are borne by the manufacturer of the medical product on the basis of a contract concluded with the inspecting organization. The tariffs for carrying out of the production inspection are established in accordance with the legislation of Member States.

The standard duration of the production inspection is calculated according to the rules in accordance with Annex No. 1.

13. The inspecting organization should not be interested in the results of the production inspection.

The inspecting organization, its management and employees involved in the production inspection should not take part in activities that can affect the independence of their judgments or their impartiality with regard to the results of production inspection, they also should not be developers, manufacturers, suppliers of medical products, should not perform maintenance (repair) of medical products which they evaluate, or should not be authorized representatives of the developer, manufacturer, supplier of medical products, persons performing maintenance (repair) of medical products.

14. The inspecting organization is obliged to document processes that cover:

a) processing of the request for the production inspection received from the manufacturer of the medical product;

b) planning, conduction and drawing up of a report of the production inspection;

c) the terms of the contract to carry out the production inspection, concluded with the manufacturer of the medical product or his authorized representative;

d) determination of production sites that will be subject to the production inspection;

e) execution of reports with an opinion on compliance or non-compliance of the medical product quality management system with these Requirements;

f) control over corrective actions to eliminate inconsistencies identified during the production inspection;

g) allocation of responsibilities and powers of the inspection team members when inspecting production (taking into account their competence) and, if necessary, involvement of external experts.

15. The inspecting organization is obliged to develop and implement procedures for the initial determination of the competence of inspectors when assigning them to positions and continuously maintenance of its level.

Inspectors should have a diploma of higher education with a specialization in medicine, science or engineering, at least a 3-year experience in the field of assessment of safety, quality and efficacy of medical products and (or) state control over the circulation of medical products, and should know:

production processes and technologies that are used by manufacturers of medical products;

requirements for safety and efficacy of medical products, technologies and risks of their medical application;

standards of the medical product quality management system and the medical product risk management system;

fundamentals of the theory of probability and statistics (including methods to determine levels of confidence in a representative sample and regression analysis).

The competence of the inspectors specified in the third and fourth indents of this paragraph should be confirmed for the subgroups of medical products listed in accordance with Annex No. 2. The inspecting organization should document areas of competence of its inspectors. Records on areas of competence of the inspectors should be kept up to date and taken into account when appointing inspectors to inspect production of relevant medical products.

The inspecting organization should check a professional level of the inspectors in order to confirm their competence by qualification and subsequent re-qualification at least once every 3 years.

16. The inspecting organization should implement a documented procedure to ensure confidentiality of information which is a trade secret and obtained during inspections, taking into account the possibility of involvement of external experts and participation of inspectors (experts) from authorized authorities.

The confidentiality agreement concluded between the inspecting organization and the manufacturer of medical products should contain provisions providing for the possibility to submit materials to the authorized authority based on the results of the inspection, as well as to any other authorized authorities between which there are confidentiality agreements.

17. The inspecting organization for at least 10 years should maintain in working condition and keep records of inspections and other activities for all manufacturers of medical products that have submitted applications for production inspection and (or) who passed the production inspection, which should include:

a) information on the application and reports on the results of the production inspection;

b) a contract for the production inspection;

c) justification of the duration of the production inspection;

d) control over implementation of corrective actions based on the results of inspections;

e) records of complaints and appeals, as well as subsequent corrective actions;

f) documents confirming competence of inspectors and external experts.

18. Authorization of inspecting organizations to conduct inspections of manufacturers of medical products, except for cases when inspecting organizations are authorized authorities, is carried out by the authorized authority for each subgroup of medical products according to the list in accordance with Annex No. 2 to these Requirements based on the assessment of their compliance with these Requirements.

The authorized authority is entitled to determine the number of inspecting organizations to inspect production at the request of manufacturers of medical products and (or) in accordance with schedules of the production inspection within a period not exceeding 3 months from the date when the manufacturer of the medical product submits the complete set of documents, including documents of payment of the production inspection.

The list of inspecting organizations is posted on the websites of authorized authorities in the information and telecommunications network Internet (hereinafter referred to as the Internet) and is also published on information portal of the Union.

Within 3 working days from the date of introduction of changes to the information contained in the list of inspecting organizations, authorized authorities place the relevant information on their official websites in the Internet and submit it to the Eurasian Economic Commission using the integrated information system of the Union.

19. The authorized authority perform an audit of inspecting organizations for compliance with these Requirements at least once every 2 years except for cases when the inspecting organizations are authorized authorities. Authorized authorities should post schedules of the audit of inspecting organizations that should be available to inspecting organizations and authorized authorities on their official websites in the Internet, not later than 3 months prior to the start of the audit.

In case if the inspecting organization is an authorized authority, control over its activities is carried out in the manner established by the legislation of the Member State.

Powers of the inspecting organization can be withdrawn by the authorized authority, if, based on results of the audit, it will be established that the inspecting organization does not comply with these Requirements.

The authorized authorities are entitled to send their representatives to participate in the audit of the inspecting organization as inspectors (experts) at their own expense, except for cases where the inspecting organizations are authorized authorities. Based on the results of the audit, the inspector (expert) is entitled to submit written comments and suggestions to the authorized authority conducting the audit.

20. Authorized authorities, within the framework of coordination of works in the field of inspection administration, development of mutual expert evaluation mechanisms, are entitled to send their inspectors (experts) to participate in the production inspection at their own expense within the framework of the assessment of the medical product quality management system. The manufacturer of the medical product is obliged to ensure the access of the members of the inspection (expert) team to the inspection facilities.

21. Reports on the results of the production inspection are sent by the inspecting organization to the authorized authority for inclusion in the registration dossier by registered mail with a

notice of delivery or in the form of an electronic document with a digital signature within 15 working days from the date of completion of the production inspection.

22. The inspecting organization conducting the production inspection should not make a favorable opinion if the medical product quality management system does not comply with these Requirements or is not maintained in the current state.

An integral assessment of the significance of inconsistencies in the medical product quality management system identified during the production inspection of these products is carried out in accordance with Annex No. 3.

Inconsistencies identified based on the results of the production inspection should be eliminated by the manufacturer of the medical product during the production inspection or within a period not exceeding 30 working days from the date of completion of the production inspection.

23. In case if the manufacturer of a medical product does not agree with a negative opinion or identified inconsistencies, he sends a complaint to the inspecting organization within 30 working days from the date when the inspecting organization receives a copy of the report of the results of the production inspection. The inspecting organization is obliged to consider this complaint and to send a response within 15 working days from the date of its receipt. In case of failure to reach an agreement, the manufacturer of the medical product can lodge a complaint to the court at the location of the inspecting organization or to the authorized authority which gave powers to the organization to assess medical product quality management systems. If the manufacturer of the medical product does not agree with the decision of the authorized authority, he is entitled to appeal against this decision in the court at the location of the authorized authority.

If the manufacturer of the medical product does not eliminate or violates the deadlines to eliminate comments, the inspecting organization informs the authorized authority which gives powers to the organization to conduct an assessment of the medical product quality management systems.

Until the manufacturer of the medical product eliminates the comments contained in the report of the results of the production inspection, the authorized authority is entitled to suspend the release of the medical product into circulation in the territory of the Member State in accordance with the legislation of that state. In this case, the authorized authority informs the authorized authorities of other Member States of the suspension of the release of the medical product into circulation in the territory of the Member State using the integrated information system of the Union.

24. During the production inspection, an assessment of the medical product quality management system for the following processes is conducted:

processes of design and development, if they are included in the quality management system of the manufacturer of the medical product;

processes of management of documents and records;

production and final check processes;

processes of corrective and preventive actions;

processes related to the consumer.

If the manufacturer of the medical product has implemented a medical product quality management system in accordance with the requirements of standards equivalent to the international standard ISO 13485, then the evidence of compliance of the quality management system with the requirements of these standards (certificate of compliance, reports on the audit of the medical product quality management system) ensure its compliance with these Requirements in a part of processes and procedures associated with functioning of the medical product quality management system. In this case, the inspection is limited by verification of carrying out of requirements related to processes of the design, development, production and final check of the medical product and consumer-related processes (in the part of after-sales monitoring).

25. Evaluation of processes of the design and development of the medical product quality management system includes:

a) confirmation of the existence of design and development procedures (including risk management);

b) analysis of documents describing the design procedure and covering a model range of medical products;

c) confirmation, that design and development procedures have been established and applied , based on chosen records on the design of the medical product;

d) confirmation that the input data on the design process has been developed taking into account the designation of the medical product and relevant provisions of General Requirements for Safety and Efficacy;

e) analysis of specifications for medical products in order to confirm that the output data of the design of the medical product ensuring safety and efficacy of the medical product when it is used for its intended purpose has been determined;

e) confirmation that risk management activities have been identified and implemented, risk acceptance criteria have been established and are appropriate, any residual risk has been assessed and, if necessary, disclosed to the consumer in accordance with the General Requirements for Safety and Efficacy.

26. Evaluation of processes of management of documentation and records of the medical product quality management system includes:

a) confirmation that procedures for identification, storage and removal (destruction) of documents and records (including change management) have been developed;

b) confirmation of the availability of documents required for the organization to ensure planning, implementation of production processes and their management;

c) confirmation that the documentation for the medical product includes:

evidence of compliance of medical products with requirements (including requirements of applicable standards);

description of medical products, including instructions for use, materials and specifications;

summary documentation on verification and validation of projects (including data of clinical trials (studies) in accordance with 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);

marking of medical products;

risk management documents.

27. Evaluation of production processes and final check of medical products includes:

a) analysis of production processes to produce serial products (including production conditions);

b) evaluation of sterilization processes (for medical products released in a sterile form), including:

determination that sterilization processes were documented, records of the parameters of the sterilization process for each sterilized batch of medical products are maintained;

determination that a sterilization process was validated;

determination that a sterilization process is carried out in accordance with the established parameters;

c) confirmation that production processes are monitored and controlled and operate within the established limits, as well as confirmation of provision of the necessary level of control of products and (or) services of critical suppliers;

d) confirmation of identification and traceability of medical products and processes of their production, as well as their compliance with the established requirements;

e) confirmation that the activities on the final check of medical products ensures the compliance of medical products with the established requirements and have been documented.

28. Evaluation of the processes of corrective and preventive actions of the medical product quality management system includes:

a) confirmation that corrective and preventive action procedures have been developed;

b) confirmation that the controls prevent distribution of medical products, quality of which does not comply with the General Requirements for Safety and Efficacy of medical products;

c) confirmation that corrective and preventive actions are effective;

d) confirmation that the manufacturer of the medical product developed an effective procedure for issuance and application of notices for medical product safety in accordance with the Rules for the Monitoring of Safety, Quality and Efficacy of Medical Products approved by Decision No. 174 of the Board of the Eurasian Economic Commission dated December 22, 2015 (hereinafter referred to as the Rules for the Monitoring of Safety, Quality and Efficacy of Medical Products).

29. Evaluation of consumer-related processes of the medical product quality management system includes:

a) confirmation that the manufacturer of the medical product took measures necessary to establish communication with consumers in order to take necessary corrective and preventive actions, has a system for collection and analysis of data on safety and efficacy of medical products at the after-sales stage and maintain it in the current state, and also sends to the authorized authority reports on the results of after-sales monitoring of safety and efficacy of medical products in accordance with the Rules for the Monitoring of Safety, Quality and Efficacy of Medical Products;

b) confirmation that the feedback from the consumer is analyzed by the manufacturer of the medical product during processes of product life-cycle and is used to re-evaluate the risk and, if necessary, to update the risk management activities.

30. The medical product quality management system is evaluated in the form of the initial, periodic (planned) and unplanned production inspection.

31. The initial production inspection is carried out during the procedure of the medical product registration within the Union.

32. When carrying out the initial production inspection, the inspecting organization inspects production of all production sites declared by the manufacturer of medical products.

If medical products belonging to several groups (subgroups) of medical products according to the list in accordance with Annex No. 2 to these Requirements depending on the class of the potential risk of their use are manufactured at the same production site, production inspection within one inspection can cover several groups (subgroups) of medical products in accordance with production sites declared by the manufacturer of medical products.

33. Based on the results of the initial production inspection, the inspecting organization prepares a report in accordance with Annex No. 4. The specified report is valid for 3 years from the date of its issue.

34. The results of the production inspection are distributed to a group (subgroup) of medical products according to the list in accordance with Annex No. 2 to these Requirements, depending on the class of the potential risk of use of manufactured medical products. For medical products of class 1 and 2a of the potential risk of use, the results of the production inspection are applicable to groups of medical products. For medical products of class 2b and 3 of the potential risk of use, the results of production inspection are applicable to subgroups of medical products.

When submitting an application for registration of new names of medical products manufactured at the production site, which was inspected previously for medical products of the same group or subgroup according to the list in accordance with Annex No. 2 to these Requirements, the applicant together with the documents of the registration dossier submits a copy of the report of the results of production inspection, conducted not earlier than 3 years prior to the day of submission of the application for the medical product registration.

35. Periodic (planned) production inspection is carried out once every 3 years.

The manufacturer of the medical product is entitled to apply to any inspecting organization with a request to conduct periodic (planned) production inspection within 6 months before the end of the validity period of the report of the results of the previous production inspection with submission of the following documents:

an application for production inspection with indication of medical products and their groups (subgroups) according to the list in accordance with Annex No. 2 to these Requirements and production sites included in the inspection area;

a certificate of the actual number of employees involved in the processes of the evaluated medical product quality management system;

technical files for medical products in accordance with Annex No. 3 to 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 (for medical products for in vitro diagnostics - technical file that complies with the requirements of Annex No. 5). Technical files are submitted in Russian in electronic form in a searchable format;

a copy of the report of the results of the last production inspection (if any);

a copy of the report of the results of the last audit of the medical product quality management system (if any) performed by the certification authority (for certified quality management systems).

If the periodic (planned) production inspection is carried out by the inspecting organization of the wrong Member State the authorized authority of which registered the medical product, reports of the results of the periodic (planned) production inspection are sent by the authorized authority, the inspecting organization of which conducted periodic (planned) production inspection, to the authorized authority that registered the medical product, for inclusion into the registration dossier. Reports of the results of the periodic (planned) production inspection are sent by registered mail with a notice of delivery or transmitted in the form of an electronic document with a digital signature within 15 working days from the date of completion of the periodic (planned) production inspection.

36. The inspecting organization performs analysis of the submitted documents within 10 working days from the date of submission of the application for periodic (planned) production inspection by the manufacturer of the medical product. If the inspecting organization decided to conduct a periodic (planned) production inspection, it conclude an appropriate contract with the manufacturer of the medical product.

If a negative decision is taken, the inspecting organization notifies the manufacturer of the medical product in writing of the refusal to conduct periodic (planned) production inspection (with indication of reasons).

The grounds for refusal to conduct periodic (planned) production inspection are:

non-compliance of the presented set of documents with the list of documents specified in paragraph 35 of these Requirements;

non-compliance of technical files with the established requirements;

the inspecting organization has no authority to inspect the declared groups (subgroups) of medical products.

The schedule of periodic (planned) production inspection is posted on official websites of authorized authorities on the Internet, and also published on the information portal of the Union.

Authorized authorities submit relevant information to the Eurasian Economic Commission using the integrated information system of the Union.

37. During the periodic (planned) production inspection, the following is assessed:

a) maintenance of compliance of the medical product quality management system with these Requirements;

b) effectiveness of the medical product quality management system in ensuring compliance of the medical products released into circulation within the Union with the General Requirements for Safety and Efficacy applicable to them.

38. The periodic (planned) production inspection is carried out at the production sites chosen by the inspecting organization in accordance with subparagraph “d” of paragraph 14 of these Requirements by the example of representative medical products for each group or subgroup of the manufactured medical products, depending on the class of the potential risk of their use according to the list in accordance with Annex No. 2 to these Requirements through the analysis of documents and records which arose from the implementation of the relevant documented processes and (or) operating procedures of the medical product quality management system, as applied to these medical products. For medical products of classes 1 and 2a of the potential risk of use, a representative sample of medical products is selected from the group of medical products according to the list in accordance with Annex No. 2 to these Requirements, for medical products of classes 2b and 3 of potential risk of use - from a subgroup of medical products according to the list in accordance with Annex No. 2 to these Requirements.

The criteria for selection of representative medical products is the novelty of technical solutions, designations, production technologies, taking into account the results of previous inspections. The justification of selection of representative medical products should be included in the report of the results of the production inspection.

In case of periodic (planned) and unplanned production inspection, the inspecting organization collects samples of medical products (implantable, invasive, and medical products for in vitro diagnostics) of class 3 of the potential risk of use in order to confirm compliance of their characteristics with data of the technical file providing safe use of such medical products. Medical products are selected according to one model (version) from each subgroup of the manufactured medical products in accordance with Annex No. 2 to these Requirements in the amount necessary for the relevant tests. The criterion for selection of representative medical products is the commonality of technical solutions, prescriptions and (or) technologies for this subgroup of the manufactured medical products. In the absence of these samples, a subgroup of medical products is excluded from the scope of inspection.

The inspecting organization carries out necessary tests of the specified samples of medical products or, if the inspecting organization has no accreditation to carry out appropriate type of tests, within 3 working days from the date of sampling, it sends a notice to the relevant organizations entered in the unified register of authorized organizations entitled to conduct tests (studies) of medical products for the purpose of their registration.

The inspecting organization submits the results of tests of the collected samples of medical products to the authorized authority within 5 working days from the date of registration of the corresponding protocol of studies (tests). In case of non-confirmation of the compliance of the characteristics of the collected samples of the medical product with the data of the technical file providing its safe use, the inspecting organization suspends the report of the results of the production inspection. Prior to elimination of the identified inconsistencies by the manufacturer of the medical product, the authorized authority is entitled to suspend the release of the medical product into circulation in the territory of the Member State in accordance with the legislation of this state, and also informs the authorized authorities of other Member States about the suspension of the release of the medical product into circulation in the territory of the Member State using the integrated information system of the Union.

39. Based on the results of the periodic (planned) production inspection, the inspecting organization draws up a report in accordance with Annex No. 6. The specified report is valid for 3 years from the date of its issue.

40. The manufacturer of medical products is entitled to apply to the inspecting organization for the unplanned production inspection for the following purposes:

a) introduction of changes to the list of production sites, list of groups (subgroups) of medical products subject to the report of the results of the inspection;

b) confirmation of elimination of violations based on the results of the production inspection;

c) confirmation of elimination of reasons that led to the release of poor-quality medical products, by inclusion of a report of the unplanned inspection in the final report of corrective

actions in the form in accordance with Annex No. 2 to the Rules for the Monitoring of Safety, Quality and Efficacy of Medical Products;

d) confirmation of introduction of the medical product quality management system by the manufacturer (in case if this quality management system was not assessed for compliance with these Requirements).

41. Based on the results of the unplanned production inspection for the purposes specified in subparagraphs “a” – “c” of paragraph 40 of these Requirements, the inspecting organization draws up a report in accordance with Annex No. 7 for the purposes specified in subparagraph “d” of paragraph 40 of these Requirements in the form in accordance with Annex No. 4 to these Requirements. The specified report is valid for 3 years from the date of its issue. The planned inspection is carried out within at most 3 years from the date of issue of the specified report.

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Eurasian Economic Commission. For documents

ANNEX No. 1
to the Requirements to the implementation,
maintenance and evaluation of the medical
product quality management system depending on
the potential risk of their use

RULES
for calculation of standard duration
of the production inspection

1. The standard duration of the production inspection is calculated during determination of the cost of the production inspection regardless of the actual duration of the production inspection.

2. The standard duration of the production inspection is calculated in man-days on the basis of an 8-hour working day. The standard duration of the production inspection includes the time spent outside the inspected organization and spent on the analysis of documentation and planning of the production inspection, as well as the time spent directly in the inspected organization and spent on preparation of reports.

If the facilities of production inspection are located in another city in relation to the inspecting organization, the regulatory duration of the production inspection is increased by 2 man-days for each inspection facility.

3. The actual number of employees of the inspected organization participating in the processes within the evaluated quality management system is used as a basis to calculate the standard duration of the production inspection. The number of part-time employees is taken into account by its conversion into an equivalent number of full-time employees.

4. The standard duration of the production inspection, depending on the actual number of employees of the inspection facility, is given in the table.

Table

Actual number of employees (men)	Standard duration of the initial production inspection (man-days)	Standard duration of the periodic (planned) production inspection (man-days)
5-49	6	4
50-99	7	5
100-199	8	6
200 - 499	9	7
500-999	10	8
1,000- 1,999	11	9
2,000 – 4,999	12	10
more than 5,000	13	11

ANNEX No. 2
to the Requirements to the implementation, maintenance and evaluation of the medical product quality management system depending on the potential risk of their use

LIST
of groups and subgroups of medical products

Group of medical products	Subgroup of medical products (for classes 2b and 3 of the potential risk of use)
1. Inactive medical products (except for medical products for in vitro diagnostics)	1.1. Inactive cardiovascular implants
	1.2. Inactive orthopedic implants
	1.3. Inactive implants of soft tissues
	1.4. Inactive functional implants
	1.5. Inactive dental implants and dental materials
	1.6. Inactive medical products for injections, infusions, blood transfusion and dialysis
	1.7. Inactive ophthalmic medical products
	1.8. Inactive orthopedic medical products and medical products for rehabilitation
	1.9. Medical products for contraception
	1.10. Medical instruments
	1.11. Inactive medical products for disinfection, hygienic treatment and sterilization of medical products
	1.12. Suture materials, dressing and other medical products for wound healing
	1.13. Inactive medical products, not included in subgroups 1.l – 1.12
2. Active non-implantable medical products (except for products for in vitro diagnostics)	2.1. Medical products for control of physiological parameters
	2.2. Medical products for imaging, using ionization radiation
	2.3. Medical products for imaging, not using ionization radiation
	2.4. Medical products for X-ray therapy, using ionization radiation
	2.5. Medical products for X-ray therapy not using ionization radiation
	2.6. Medical products for lithotripsy
	2.7. Active medical products for artificial circulation, intravenous infusion and plasmapheresis
	2.8. Active anesthesia-respiratory, hyperbaric medical products and medical products for respiratory therapy
	2.9. Active medical products for stimulation and inhibition
	2.10. Active surgical medical products
	2.11. Active ophthalmic medical products
	2.12. Active dental medical products
	2.13. Active medical products for disinfection and

Group of medical products	Subgroup of medical products (for classes 2b and 3 of the potential risk of use)
	sterilization of medical products
	2.14. Active medical products for rehabilitation and active prostheses
	2.15. Active medical products for positioning and transportation of patients
	2.16. Independent medical software
	2.17. Active medical products for extracorporeal fertilization and artificial fertilization
	2.18. Active medical products, not included in subgroups 2.1 - 2.17
3. Active implantable medical products	3.1. Active implantable medical products for stimulation and inhibition
	3.2. Active implantable medical products for administration of drug and other substances
	3.3. Active implantable medical products, supporting, substituting or replacing body functions
	3.4. Radioactive implants for interstitial radiotherapy
	3.5. Active implantable medical products not included in subgroups 3.1 - 3.4
4. Medical products for in vitro diagnostics	4.1. Reagents, reagent kits, calibration and control materials
	4.2. Devices and equipment for in vitro diagnostics
	4.3. Independent medical software for in vitro diagnostics
	4.4. Other medical products for in vitro diagnostics not included in subgroups 4.1 - 4.3

ANNEX No. 3
to the Requirements to the implementation,
maintenance and evaluation of the medical
product quality management system depending on
the potential risk of their use

INTEGRAL ESTIMATION
of the degree of significance of non-conformities of
the quality management system identified during the production inspection
to Requirements to the implementation, maintenance and evaluation of
the medical product quality management system depending on
the potential risk of use

I. Classification of non-conformities

Classification of non-conformities in the quality management system identified during the production inspection to Requirements to the implementation, maintenance and evaluation of the medical product quality management system depending on the potential risk of their use (hereinafter referred to as non-conformity) is carried out in 2 stages:

I stage - use of the classification matrix to provide a preliminary assessment of the degree of significance of non-conformities;

II stage - use of raising scores to determine the final assessment of the degree of significance of non-conformities.

Multiple cases of non-conformity to one requirement are considered as one non-conformity.

II. Classification matrix

According to the classification matrix, all identified non-conformities are divided into 4 groups.

Each group is characterized by a quantitative value of the degree of significance of the non-conformity for safety, efficacy and quality of the medical product:

Effect of the non-conformity on safety, efficacy and quality of the medical product	direct	3	4
	indirect	1	2
		for the first time	repeatedly
		Non-conformity frequency	

The classification matrix reflects the effect of the non-conformity on safety, efficacy and quality of the medical product, as well as frequency of the identified non-conformity.

The effect of the non-conformity on safety, efficacy and quality of the medical product is considered indirect if it affects requirements related to the functioning of the medical product quality management system and direct if it relates to requirements related to the design, development, production and final check of the medical product.

The term “for the first time” means that a specific non-conformity was not identified in the last 2 cases of production inspection, during which the same processes were checked within the quality management system at the inspected site.

The term “repeatedly” means that a specific non-conformity was identified in one of the last 2 cases of production inspection, during which the same processes were checked within the quality management system at the inspected site.

III. Raising scores

The quantitative value of the degree of non-conformity obtained at stage I is specified at stage II by using raising scores accrued for the following non-conformities:

absence of documented procedures related to the design, development, production and final check of the medical product, as well as after-sales monitoring required to ensure safety and efficacy of the medical product;

release of a poor-quality medical product into circulation during the reporting period. In case if the manufacturer of a medical product conducted the unplanned production inspection in order to confirm the elimination of the causes that led to the release of a poor-quality product, no raising score is accrued.

In this case, 1 score is accrued to the estimation obtained at stage I for each non-conformity.

IV. Form of presentation of results of the integral estimation of the degree of significance of non-conformities

Results of the integral estimation of the degree of significance of non-conformities are presented in the form of a table:

Item No.	Non-conformity	Gradation of the non-conformity			
		Stage I, score	Stage II in absence of documented processes, score	Stage II, during release of a poor-quality product, score	Total score on the non-conformity
1					
2					

Total score: _____

The inspecting organization should not make a positive opinion on compliance of the manufacturer of the medical product with these Requirements, if one or more violations were evaluated as 5 or 6 scores or more than two violations are evaluated as 4 scores.

ANNEX No. 4
to the Requirements to the implementation, maintenance and evaluation of the medical product quality management system depending on the potential risk of their use

(form)

REPORT
on the results of initial production inspection

1	Report number	
2	Organization, performed production inspection (full and abbreviated (if any) name of a juridical person (including a corporate name), legal organizational form and address (location))	
3	Information on a medical product manufacturer:	
3.1	Full and abbreviated (if any) name of a juridical person (including a corporate name), legal organizational form and address (location), contact information	
3.2	Organizational structure and cooperation with juridical persons in the framework of the medical product quality management system	
3.3	List of production sites (with indication of their addresses and manufactured medical products, approximate number of employees, involving in processes within the evaluated quality management system, as well as contact information)	
3.4	List of manufactured medical products designed for circulation within the Eurasian Economic Union	
3.5	List of groups (subgroups) of medical products in respect of which the production is inspected according to the application of the manufacturer of the medical product (with indication of the information on the inclusion (non-inclusion) of design and development processes in the field of production inspection)	
3.6	List of critical suppliers (with indication of addresses, supplied products and rendered services as well as contact information)	
4	Information on production inspection	
4.1	Dates of production inspection, including dates of on-site production inspection of each inspected facility	
4.2	Composition of the inspection team (with indication of functions of team members, as well as information on involved interpreters and on the inspectors (experts), if any)	
4.3	Production inspection plan	
5	Results of production inspection (for each inspected facility)	
5.1	General description of the inspected activities and (or) technical processes	
5.2	Surnames, names, patronymics (if any) and positions of respondents	

5.3	Names of medical products chosen for inspection as representative samples, as well as justification of this choice	
5.4	Types and number of documents and records checked	
5.5	List of identified non-conformities of the medical product quality management system to Requirements to the implementation, maintenance and evaluation of the medical product quality management system, depending on the potential risk of their use	
5.6	Information on non-conformities eliminated during the production inspection, as well as on time periods of corrective actions in respect of non-rectified non-conformities and forms of confirmation of such actions (presentation of supporting documentation or on-site verification)	
6	Conclusions:	
6.1	Statement of conformity (non-conformity) of the medical product quality management system to requirements of its implementation (with indication of information on inclusion (non-inclusion) in the scope of production inspection of processes of design and development for inspected groups (subgroups) of medical products)	
7.	Surnames, names, patronymics (if any) and positions of inspectors	
8.	Signatures, seal (if any)	

ANNEX No. 5
to the Requirements to the implementation,
maintenance and evaluation of the medical
product quality management system depending on
the potential risk of their use

REQUIREMENTS
to the contents of the technical file for the medical product
for in vitro diagnostics

I. General requirements to the technical file for
the medical product for in vitro diagnostics

1. A technical file should contain the following information on the medical product for in vitro diagnostics:

a) product name;

b) product type in accordance with the nomenclature of medical products used within the Eurasian Economic Union;

c) class of the potential risk of use and applicable classification rules in accordance with the Rules for Classification of Medical Products Depending on the Potential Risk of Their Use approved by Decision No. 173 of the Board of the Eurasian Economic Commission dated December 22, 2015;

d) product designation, including (if applicable):

target analyte description, including indication of the qualitative, semi-quantitative or quantitative form of determination;

functional purpose;

specific pathology, condition or risk factor for detection, determination or differentiation of which the product is designed;

type of the sample analyzed;

potential users.

e) description of the analytical method principle or product operating principle;

f) description of components, including a list of possible versions of the considered product;

g) description of accessories, other products (including medical ones) that are intended to be used in combination with the product;

h) description of materials for collection and transportation of samples or description (characteristics) of materials recommended for this purpose;

i) for analytical equipment - technical specifications.

2. In case of use of information on similar or previous versions of the medical product for in vitro diagnostics in order to prove its compliance with the General Requirements for Safety and Efficacy of medical products, requirements for their marking and operational documentation for 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 for Safety and Efficacy), the technical file should contain a brief description of:

a) previous modifications of the product considered (if any);

b) similar modifications of medical products being in circulation within the Eurasian Economic Union and in international markets.

II. Supporting information

3. The technical file should contain:

a) data on marking of the medical product for in vitro diagnostics and its package;

b) instruction for use (operational documentation) of the medical products for in vitro diagnostics (if any).

III. Data on compliance with the General Requirements for Safety and Efficacy

4. The technical file should include a control list of compliance with the General Requirements for Safety and Efficacy according to Annex No. 2 to the General Requirements for Safety and Efficacy.

IV. Results of analysis and risk management

5. The technical file should contain a brief list of risks identified during the analysis of risks and description of ways to manage these risks in order to reduce them to the accepted level.

V. Design and development of the medical product for in vitro diagnostics

6. The technical file should contain the information on the main stages of the design of the concerned medical product for in vitro diagnostics. This information can be presented in the form of a flowchart of processes.

VI. Production processes

7. The technical file should contain information on production processes including on production, assembly, final tests of the medical product for in vitro diagnostics and final package of the finished medical product for in vitro diagnostics. This information can be presented in the form of a flowchart of processes.

VII. Production sites

8. The technical file should contain data on production sites on which the concerned medical product for in vitro diagnostics is produced. If there are certificates of quality management system and equivalent documents in respect of these sites, then their copies are attached to the technical file.

VIII. Verification and validation activities

9. The technical file should contain the following information and documents on verification, which were used to prove conformation of the medical product for in vitro diagnostics to the General Requirements for Safety and Efficacy:

a) list of standards used by the manufacturer of the medical product;

b) results of tests in testing laboratories (centers);

c) results of laboratory and (or) factory tests;

d) declarations of conformity to standards from the list of standards, the application of which, on a voluntary basis, fully or partially ensures the compliance of the medical product for in vitro diagnostics with the General Requirements for Safety and Efficacy;

e) declarations of conformity to standards that are not included in the list specified in subparagraph “d” of this paragraph (with justification of their use);

f) review of published literature sources with regard to the considered medical product for in vitro diagnostics or similar medical products;

g) clinical evidence of efficacy and safety of the medical product for in vitro diagnostics.

10. The technical file should contain the following information on the analytical performance of the medical product for in vitro diagnostics (if applicable):

a) analytical sensitivity (detection threshold);

b) analytical specificity;

c) correctness of definitions;

d) variable error;

e) data on metrological traceability of values of calibrators and control materials;

f) data on the analytical range (linearity range - for linear analytical systems), as well as description of methods to determine characteristics;

g) data on the definition of a “cut-off”, including description of details of the method to determine characteristics;

h) population (demographic) aspects of the use of the medical product for in vitro diagnostics.

11. The technical file should contain information on the scientific validity of the analyte (if applicable).

12. The technical file should contain information on the clinical efficacy of the medical product for in vitro diagnostics, including (if applicable) data on diagnostic sensitivity and diagnostic specificity.

13. The technical file should contain data on stability of the medical product for in vitro diagnostics.

14. If the medical product for in vitro diagnostics is released in a sterile form, a sterilization method is described, including a report of the sterilization process validation.

15. The technical file should include a summary of the results of the verification and validation activities of the software performed in the manufacturing organization.

ANNEX No. 6
to the Requirements to the implementation, maintenance and evaluation of the medical product quality management system depending on the potential risk of their use

(form)

REPORT
on the results of periodic (planned) production inspection

1	Report number	
2	Organization, performed production inspection (full and abbreviated (if any) name of a juridical person (including a corporate name), legal organizational form and address (location))	
3	Information on a medical product manufacturer:	
3.1	Full and abbreviated (if any) name of a juridical person (including a corporate name), legal organizational form and address (location), contact information	
3.2	Organizational structure and cooperation with juridical persons in the framework of the medical product quality management system	
3.3	List of production sites (with indication of their addresses and manufactured medical products, approximate number of employees, involving in processes within the evaluated quality management system, as well as contact information)	
3.4	List of manufactured medical products designed for circulation within the Eurasian Economic Union	
3.5	List of groups (subgroups) of medical products according to the previously issued statement of conformity (with indication of the information on inclusion (non-inclusion) of processes of design and development into the area of the production inspection)	
3.6	List of critical suppliers (with indication of addresses, supplied products and rendered services as well as contact information)	
4	Information on production inspection	
4.1	Dates of production inspection, including dates of on-site production inspection of each inspected facility	
4.2	Composition of the inspection team (with indication of functions of team members, as well as information on involved interpreters and on the inspectors (experts), if any)	
4.3	Production inspection plan	
5	Results of production inspection (for each inspected facility)	
5.1	General description of the inspected activities and (or) technical processes	
5.2	Surnames, names, patronymics (if any) and positions of respondents	
5.3	Names of medical products chosen for inspection as	

	representative samples, as well as justification of this choice	
5.4	Types and number of documents and records checked	
5.5	List of identified non-conformities of the medical product quality management system to Requirements to the implementation, maintenance and evaluation of the medical product quality management system, depending on the potential risk of their use	
5.6	Information on non-conformities eliminated during the production inspection, as well as on time periods of corrective actions in respect of non-rectified non-conformities and forms of confirmation of such actions (presentation of supporting documentation or on-site verification)	
5.7	Information on previously detected non-conformities and results of corrective and (or) preventive actions	
6	Conclusions:	
6.1	Statement of conformity (non-conformity) of the medical product quality management system to requirements of its maintenance in actual state	
7.	Surnames, names, patronymics (if any) and positions of inspectors	
8.	Signatures, seal (if any)	

ANNEX No. 7
to the Requirements to the implementation, maintenance and evaluation of the medical product quality management system depending on the potential risk of their use

(form)

REPORT
on the results of unplanned production inspection

1	Report number	
2	Organization, performed production inspection (full and abbreviated (if any) name of a juridical person (including a corporate name), legal organizational form and address (location))	
3	Information on a medical product manufacturer:	
3.1	Full and abbreviated (if any) name of a juridical person (including a corporate name), legal organizational form and address (location), contact information	
3.2	Organizational structure and cooperation with juridical persons in the framework of the medical product quality management system	
3.3	List of production sites (with indication of their addresses and manufactured medical products, approximate number of employees, involving in processes within the evaluated quality management system, as well as contact information)	
3.4	List of manufactured medical products designed for circulation within the Eurasian Economic Union	
3.5	List of groups (subgroups) of medical products according to the previously issued statement of conformity (with indication of the information on inclusion (non-inclusion) of processes of design and development into the area of the production inspection)	
3.6	List of critical suppliers (with indication of addresses, supplied products and rendered services as well as contact information)	
4	Information on production inspection	
4.1	Dates of production inspection, including dates of on-site production inspection of each inspected facility	
4.2	Composition of the inspection team (with indication of functions of team members, as well as information on involved interpreters and on the inspectors (experts), if any)	
4.3	Production inspection plan	
4.4	Content and scope of production inspection	
5	Results of production inspection (for each inspected facility)	
5.1	General description of the inspected activities and (or) technical processes	
5.2	Surnames, names, patronymics (if any) and positions of respondents	

5.3	Names of medical products chosen for inspection as representative samples, as well as justification of this choice taking into account the purpose of production inspection	
5.4	Types and number of documents and records checked	
5.5	List of identified non-conformities of the medical product quality management system to Requirements to the implementation, maintenance and evaluation of the medical product quality management system, depending on the potential risk of their use	
5.6	Information on non-conformities eliminated during the production inspection, as well as on time periods of corrective actions in respect of non-rectified non-conformities and forms of confirmation of such actions taking into account the purpose of production inspection	
6	Conclusions:	
6.1	Statement of conformity (non-conformity) of the medical product quality management system to requirements of its implementation and maintenance in actual state taking into account the purpose of production inspection	
7.	Surnames, names, patronymics (if any) and positions of inspectors	
8.	Signatures, seal (if any)	