

**THE EURASIAN ECONOMIC COMMISSION**

**THE COUNCIL**

**DECISION**

|  |  |  |
| --- | --- | --- |
| November 12, 2021 | **No. 131** | Nur-Sultan |

**On amending the Requirements for implementing, maintaining and assessing the quality management system of medical devices depending on the potential risk of their use,**

In accordance with Paragraph 2, Article 31 of the Treaty on the Eurasian Economic Union dated May 29, 2014, Paragraph 1, Article 6 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 107 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 make amendments to the Requirements for implementing, maintaining and assessing the quality management system of medical devices depending on the potential risk of their use approved by Decision No. 106 of the Eurasian Economic Commission's Council dated November 10, 2017 in accordance with the Annex.

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

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **For the Republic ofArmenia** | **For the Republic ofBelarus** | **For the Republic ofKazakhstan** | **For theKyrgyz Republic** | **For the Russian Federation** |
| **M. Grigoryan** | **I. Petrishenko** | **A. Smailov**  | **A. Kozhoshev** | **A. Overchuk** |

ANNEX

to Decision of the Council

of the Eurasian Economic Commission

No. 131 dated November 12, 2021

**AMENDMENTS**

**to be made to the Requirements for implementing, maintaining and assessing the quality management system of medical devices depending on the potential risk of their use.**

1. Add paragraph 42 with the following wording:

42. It is allowed to assess the quality management system of medical devices using means of remote communication (e.g., via videolink). Such assessment shall be performed in accordance with Annex No. 8 in the cases provided for by the indicated Annex.”.

2. Add Annex No. 8 with the following wording:

|  |
| --- |
| "ANNEX No. 8to the Requirements for implementing, maintaining and assessing the quality management system of medical devices, depending on the potential risk of their use. |

**ASSESSMENT**

**of the quality management system of medical devices**

**to be performed using means of remote**

**communication**

1. By decision of the authorized authority, it is allowed to assess the quality management system of medical device using means of remote communication (e.g, via videolink) in accordance with the acts included in the law of the Eurasian Economic Union, in the following cases:

a) risk of emergence, occurrence and liquidation of an emergency and/or the emergence of risk of the epidemic disease spread posing danger to others, diseases and injuries resulting from exposure to adverse chemical, biological, radiation factors;

b) occurrence of force majeure circumstances or circumstances beyond the control of the parties that pose a threat of harm to the life and health of inspectors.

2. Prior to start the assessment of the quality management system of medical device to be performed using means of remote communication, the manufacturer shall confirm the geolocation data (latitude, longitude) of the production site location.

3. To assess the quality management system of medical device to be performed using means of remote communication, the manufacturer shall provide the documents and information specified in the table.

 Table

| Requirements (basis) | At initial inspection | At periodic (scheduled) inspection |  |
| --- | --- | --- | --- |
| 1. Description of the quality management system of medical devices depending on the potential risk of their use in accordance with the Requirements for implementing, maintaining and assessing the quality management system of medical devices depending on the potential risk of their use approved by Decision No. 106 of the Eurasian Economic Commission's Council dated November 10, 2017. . | complete description of the quality management system of medical devices  | summary of changes introduced from the date of the last inspection  |  |
| 2. Availability of manufacturing permit (license) issued by the competent authority (if there are relevant requirements in the legislation) | copies of manufacturing permits (licenses) and amendments made to them  | copies of manufacturing permits (licenses) and amendments made to them(for the last 3 years)  |  |
| 3. Information on employees involved in the processes of the assessed quality management system of medical devices | statement of actual number of employees involved in the processes of the assessed quality management system of medical devices | statement of actual number of employees involved in the processes of the assessed quality management system of medical devices |  |
| 4. Information on medical devices manufactured (planned for manufacture) at the manufacturing site | list of medical devices | list of medical devices |  |
| 5. Availability of technical files for medical devices | technical files soft copies with search option | technical files soft copies with search option |  |
| 6. Availability of report on results of audit of the quality management system of medical devices by the certification body and report on the results of the manufacture inspection, certificate of conformity to ISO 13485 (if available) | copies of report on results of the last audit of the quality management system of medical devices by the certification body and the report on results of the last manufacture inspection (with notarized translation, if necessary), certificate of conformity to ISO 13485 (if available) | copies of report on results of the last audit of the quality management system of medical devices by the certification body and the report on results of the last manufacture inspection (with notarized translation, if necessary), certificate of conformity to ISO 13485 (if available)  |  |
| 7. Requirements for the processes of designing and developing the quality management system for medical devices (potential risk class 3) | the following documents and information regarding medical devices,in relation to which manufacture inspection is carried out:a) details of design and development procedures (including risk management);b) documents describing the design procedure and covering the model range of the medical device;c) medical device design records confirming that design and development procedures are established and applied;d) design process inputs, developed taking into account the purpose of the medical device and the relevant provisions of the General Requirements for Medical Device Safety and Efficiency, the Requirements for their Marking and Operational Documentation approved by Decision No. 27 of the Eurasian Economic Commission's Council dated February 12, 2016 (hereinafter referred to as the General Requirements);e) specifications for medical devices to confirm that the medical device design output data ensuring safety and efficiency of the medical device when used as intended are determined; f) documents confirming that risk management activities are defined and implemented, risk acceptability criteria are established and are appropriate, any residual risk has been assessed and, if necessary, brought to the attention of the consumer in accordance with the General Requirements | documents and records relating to medical devices selected as representative samples  |  |
| 8. Requirements for the documentation and records management processes of the quality management system of medical devices(if evidence of the quality management system conformity to the requirements of standards equivalent to ISO 13485 is not available) | the following documents and information related to medical devices subject to manufacture inspection:a) information on the procedures for identification, storage and deletion (destruction) of documents and records (including change management);b) documents necessary to enable the company to plan, implement and manage manufacturing processes;c) documentation for medical devices, including:evidence of the medical device compliance with requirements (including the requirements of applicable standards); description of medical devices, including instructions for use (operating manuals), materials and specifications; summary documentation for verification and validation of projects (including data from clinical studies (tests) in accordance with the Rules for conducting clinical and clinical laboratory tests (research) of medical devices approved by Decision No. 29 of the Eurasian Economic Commission's Council dated February 12, 2016);labeling of medical devices;risk management documents | documents and records relating to medical devices selected as representative samples |  |
| 9. Requirements for the processes of manufacturing and release control of medical devices | the following documents related to medical devices subject to manufacture inspection;a) documents related to the manufacture processes for manufacturing serial products (including production conditions); b) documents related to the sterilization process (for medical devices manufactured in sterile form), including:confirmation that sterilization processes are documented and records of sterilization process parameters for each sterilized batch of medical devices are maintained;confirmation that the sterilization process is validated;confirmation that the sterilization process is carried out in accordance with the established parameters;c) documents confirming that the manufacturing processes are managed and controlled and operate within the established limits, as well as confirmation of provision of the necessary control level of the critical supplier products and/or services;d) documents confirming identification and traceability of medical devices and their production processes, as well as their compliance with established requirements; e) documents confirming that the activities for the medical device release control ensure the compliance of medical devices with the established requirements and are documented | documents and records relating to medical devices selected as representative samples |  |
| 10. Requirements for the processes of corrective and preventive actions of the quality management system of medical devices(if evidence of the quality management system conformity to the requirements of standards equivalent to ISO 13485 is not available) | the following documents related to medical devices subject to manufacture inspection:a) documents confirming that procedures for corrective and preventive actions have been developed;b) documents confirming that the controls prevent the distribution of medical devices, the quality of which does not meet the requirements for expert assessment of medical devices in the manner prescribed by the General Requirements; c) documents confirming that corrective and preventive actions are effective;d) documents confirming that the manufacturer of the medical device has developed an effective procedure for issuing and applying safety notices for medical devices in accordance with the Rules for Monitoring Medical Device Safety, Quality and Efficiency approved by Decision No. 174 of the Eurasian Economic Commission's Board dated December 22, 2015 | documents and records relating to medical devices selected as representative samples |  |
| 11. Assessment of customer-related processes of the quality management system of medical devices(if evidence of the quality management system conformity to the requirements of standards equivalent to ISO 13485 is not available, otherwise the assessment is carried out in terms of post-sales monitoring) | the following documents related to medical devices subject to manufacture inspection:a) documents confirming that the medical device manufacturer has taken the measures necessary to establish communication with consumers in order to perform the necessary corrective and preventive actions, has a system for collecting and analyzing data on the safety and efficacy of medical devices at the post-sale stage and maintains it up to date and also sends to the authorized authority reports on the results of post-sale monitoring of the safety and efficiency of medical devices in accordance with the Rules for monitoring the safety, quality and efficiency of medical devices;b) documents confirming that the feedback from the consumer is analyzed by the manufacturer of the medical device during the product life cycle processes and used to re-assess the risk, if necessary, to update risk management activities | documents and records relating to medical devices selected as representative samples | ". |

\_\_\_\_\_\_\_\_\_\_\_\_\_