

**On approval of the Rules for conducting inspections of medical devices**

***Unofficial translation***

Order of the Minister of Healthcare of the Republic of Kazakhstan dated December 23, 2020, No. ҚР ДСМ-315/2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on December 24, 2020, No. 21898

      Unofficial translation

      In accordance with paragraph 9 of Article 244 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On public health and healthcare system" **I HERBY ORDER:**

      1. To approve the attached Rules for conducting inspections of medical devices.

      2. The Committee for Medical and Pharmaceutical Control of the Ministry of Health of the Republic of Kazakhstan, in accordance with the procedure established by the legislation of the Republic of Kazakhstan, shall ensure:

      1) state registration of this Order with the Ministry of Justice of the Republic of Kazakhstan;

      2) posting this Order on the Internet resource of the Ministry of Health of the Republic of Kazakhstan after its official publication;

      3) within ten working days after the state registration of this Order with the Ministry of Justice of the Republic of Kazakhstan, submission to the Legal Department of the Ministry of Health of the Republic of Kazakhstan information on the implementation of the measures provided for in subparagraphs 1) and 2) of this paragraph.

      3. Control over the execution of this Order shall be entrusted to the supervising Vice-Minister of Healthcare of the Republic of Kazakhstan.

      4. This Order shall come into effect upon the expiration of ten calendar days after the day of its first official publication.

|  |  |
| --- | --- |
| *Minister of Healthcare of the* *Republic of Kazakhstan* | *A. Tsoi* |

|  |  |
| --- | --- |
|  | Approved  by Order of the Minister of Healthcare of the Republic of Kazakhstan dated December 23, 2020 No. ҚР ДСМ-315/2020 |

**The Rules for conducting inspections of medical devices**

**Chapter 1. General Provisions**

      1. These Rules for conducting inspections of medical devices (hereinafter referred to as the Rules) have been developed in accordance with paragraph 9 of Article 244 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On public health and healthcare system" (hereinafter referred to as the Code) and shall determine the procedure for conducting inspections of medical devices in compliance with the requirements for the implementation, maintenance, and assessment of the quality management system for medical devices, depending on the potential risk of their use.

      2. For these Rules, the following terms and definitions shall be applied:

      1) the authorized body in the field of health care (hereinafter referred to as the Authorized body) - the central executive body that carries out management and inter-sectoral coordination in the field of health protection of citizens of the Republic of Kazakhstan, medical and pharmaceutical science, medical and pharmaceutical education, sanitary and epidemiological well-being of the population, circulation of medicines and medical devices, the quality of medical services (assistance);

      2) a state body in the field of circulation of medicines and medical devices (hereinafter referred to as the State body) - a government body that exercises leadership in the field of circulation of medicines and medical devices, control over the circulation of medicines and medical devices;

      3) a state expert organization in the field of circulation of medicines and medical devices (hereinafter referred to as the Expert organization) – an entity of a state monopoly that carries out production and economic activities in the field of health care to ensure the safety, efficiency, and quality of medicines and medical devices;

      4) applicant - a manufacturer (producer) or their representative authorized to submit an application, documents, and materials for an examination of a medical device for registration, re-registration, amendments to the registration dossier, and inspection.

      3. Inspections of medical devices shall be carried out by an expert organization by visiting a medical device manufacturing facility (hereinafter referred to as the Inspection).

      4. Inspection is subject to production sites that carry out both full and incomplete (packaging, filling, and labeling) production cycles of a medical device (hereinafter referred to as the Object of inspection).

      5. Inspection shall be carried out during the period of expertise during state registration, re-registration of medical devices, amendments to the registration dossier of a medical device, as well as within the framework of monitoring the safety, quality, and effectiveness of medical devices in the following forms:

      1) initial inspection:

      when examining medical devices 2a (sterile), 2b, and 3 classes of the potential risk of use by manufacturers who have not previously registered products in the Republic of Kazakhstan or have not previously supplied products from production sites in the Republic of Kazakhstan, carried out in the manner prescribed by paragraph 4 of Article 23 of the Code;

      before, during, or after the completion of clinical trials of medical devices of potential risk classes 3, 2b and implantable medical devices carried out in the manner prescribed by paragraph 6 of Article 238 of the Code.

      2) periodic (planned) inspection of facilities that have undergone initial inspection shall be carried out once every 3 years to confirm the effectiveness of the quality management system in ensuring the compliance of medical devices put into circulation;

      3) unscheduled inspection:

      when examining changes in the registration dossier of a medical device (changes in the list of production sites), carried out in the manner prescribed by paragraph 4 of Article 23 of the Code;

      if necessary, confirmation of the fact of elimination of violations based on the results of a production inspection;

      when conducting investigations related to the safety and effectiveness of a medical device, carried out in the manner prescribed by paragraph 3 of Article 261 of the Code;

      if it is necessary to confirm the fact of eliminating the causes that led to the production of substandard medical devices.

      6. The costs of organizing and conducting an inspection shall be borne by the applicant based on an agreement concluded with an expert organization in accordance with the civil legislation of the Republic of Kazakhstan.

      7. By decision of the expert organization, conducting inspections, except for entities located in the territory of the Republic of Kazakhstan, according to documents using means of remote interaction, via audio or video communication without visiting a production facility in the following cases:

      1) in the event of a threat of occurrence, occurrence, and liquidation of an emergency;

      2) when there is a threat of the spread of the disease, posing a danger to others;

      3) diseases and injuries resulting from exposure to an adverse chemical, biological, radiation factors.

      8. In case of a positive result of the remote inspection, within one year after the removal of the restrictions provided for in paragraph 7 of these Rules, an inspection shall be carried out with a visit to the subject of the inspection.

      9. To carry out the inspection, an inspection team shall be created, consisting of a lead inspector (team head), team members, including inspectors, attracted experts, and trainees in the field of circulation of medicines and medical devices.

      10. The inspection team shall consist of two or more inspectors, including the head of the inspection team.

      The requirements for the size of the inspection team, the level of qualifications of the inspectorate staff, and the experts involved in the work of the inspection team shall be established by the quality system procedures of the inspectorate in accordance with the international quality management system standard (hereinafter referred to as the ISO standard 13485).

      The inspection team shall include experts and trainees (newly recruited specialists to the inspectorate), their status shall be noted in the order of the formation of the inspection team. Trainees shall not participate in the classification of inconsistencies resulting from the inspection.

      If necessary, observers and interpreters shall accompany the inspection team.

      11. When conducting an inspection, inspectors shall not act as consultants, respect the confidentiality of information obtained during the preparation and conduct of an inspection, and also maintain the confidentiality of inspection results.

      12. The duration of an inspection of one site (site) depends on the amount of work performed, the type and complexity of the space (site).

**Chapter 2. Procedure for inspection of medical devices**

      13. To carry out an inspection, an expert organization, in the course of expert work, shall send a notification to the applicant about the need for an inspection of production.

      The duration of the organization and conduct of an inspection shall not exceed 120 calendar days from the date of receipt of the notification of the need for it.

      The timing of the organization and conduct of the inspection shall not be included in the period for the examination of medical devices carried out in the manner prescribed by paragraph 4 of Article 23 of the Code.

      14. The applicant, within 30 (thirty) calendar days from the date of receipt of the notification of the need for an inspection, shall send to the expert organization:

      1) a letter of consent to inspect with an indication of the planned time frame;

      2) quality manual;

      3) the dossier of the production site (if any);

      4) a list of medical devices manufactured (planned for production) at the production site;

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

      6) a copy of the report on the results of the certification body (for certified quality management systems) of the last audit of the quality management system of medical devices (if any).

      The applicant shall provide documents in electronic form with translation into Kazakh and (or) Russian.

      15. The expert organization shall consider the submitted documents within 15 calendar days.

      16. Refuses to appoint an inspection if the comments on the submitted documents are not eliminated within a period not exceeding 30 calendar days.

      17. The expert organization shall draw up a schedule of inspections and send electronic copies of the documents listed in paragraph 13 of the Rules to the inspection team.

      18. The applicant shall ensure that the inspection team is accompanied by the personnel of the subject of inspection and the translation of information into Kazakh and (or) Russian (if necessary) during the inspection.

      19. The head of the inspection shall ensure the development of the inspection program (hereinafter referred to as the Inspection program) in the form in accordance with Annex 1 to these Rules. The inspection program shall be signed by the inspection team and sent to the subject of inspection 7 calendar days before the start of the inspection at the facility.

      20. The head of the inspection shall assign functions to the inspection team and coordinates the preparatory activities.

      21. The inspection team shall preliminarily examine the documents submitted by the inspectorate related to the inspected activity.

      22. If the manufacturer transfers part of the production process and analyzes the contract to another person (outsourcing), the outsourcing company shall be additionally inspected. The data of the outsourcing company shall be provided by the subject of the inspection.

      23. The inspection shall begin with an introductory meeting with the responsible persons of the inspected facility, during which the head of the inspection team informs about the purpose, timing, program of the inspection and the content of the inspection, introduces the members of the inspection team, hears a brief overview of the quality system and activities at the site, and discusses and organizational issues are being resolved.

      The head of the inspection shall inform the subject of inspection about the objectives, terms, content of the inspection, introduce the members of the inspection team, discuss organizational issues, allow the subject of inspection to make a brief overview of the quality system, and activities at the facility.

      24. During the inspection, changes and (or) additions shall be made to the program in case of inconsistencies that pose a high risk concerning product quality, process, or quality system.

      25. The subject of the inspection shall cooperate with the inspection team and creates conditions for the inspection. During the inspection, the subject of inspection shall provide the inspection team with the necessary information, documents, records, provide access to transport, production, storage, auxiliary premises, quality control rooms, as well as other premises of the subject.

      26. During the inspection, the members of the inspection team shall be guided by the requirements for the implementation, maintenance, and assessment of the quality management system for medical devices provided for in Annex 2 to these Rules, as well as the provisions of ISO 13485 or an equivalent regional, national standard.

      27. During the inspection, the members of the inspection team shall interview responsible persons and observe activities in the workplace and study:

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

      2) processes of incoming control of raw materials and substance;

      3) processes of production and final control, including the management of control, measuring and testing equipment, methods of control and testing at all stages of production, organization of storage conditions, types of packaging, labeling of medical devices;

      4) processes for managing documents and records;

      5) processes of corrective and preventive actions;

      6) processes associated with the consumer.

      The information received shall be reflected in the working records of the members of the inspection team.

      28. The inspection team during an inspection shall:

      1) in case of violation of the conditions of storage, transportation, production, affecting the quality and safety of medical devices, select and conduct laboratory tests of samples of medical devices;

      2) carry out audio (video) recording and photography, as well as make copies of documents that may be used as evidence when inconsistencies are detected;

      3) receive clarifications from the subject of inspection on issues arising during the inspection;

      4) terminate the inspection if the implementation is hindered;

      5) take action or requires action concerning items (material evidence), presumably indicating non-compliance with the provisions of ISO 13485 or equivalent regional, national standards.

      29. The Inspection Head, following the results of each inspection day, shall hold meetings with the members of the inspection team to develop preliminary inconsistencies, which are discussed with the personnel of the inspected subject.

      30. The inspection shall end with a final meeting with the responsible persons of the subject of inspection, at which the head of the inspection informs about the results of the inspection, listing all non-conformities identified during the inspection.

      31. In the event of critical inconsistencies, the head of the inspection shall draw up a protocol of inconsistencies and notify the state body of the need to take measures in accordance with subparagraph 3) of paragraph 2 of Article 54 of the Code.

      32. The protocol of discrepancies, which contains a brief description of the identified deviations, shall be drawn up in the form in accordance with Annex 3 to these Rules and is an integral part of the report on the results of the inspection of the production of a medical device.

      33. The protocol of non-conformities shall be drawn up in two copies, signed by the members of the inspection team. One copy shall be transferred to the subject of inspection, the other - to the expert organization.

      34. Based on the results of the production inspection, within 30 calendar days, a report on the results of the inspection of the production of a medical device (hereinafter referred to as the Report) shall be generated in the form in accordance with Annex 4 to these Rules. The report shall be drawn up in 2 (two) copies, of which the first shall be sent to the inspection object, the second remain in the expert organization and included in the registration dossier of the medical device.

      The report shall be valid for 3 (three) years from the date of the last day of the inspection.

      35. To inspect without visiting the inspected facilities, the inspected subject shall attach documents in accordance with Annex 5 to these Rules.

      The report on the results of the inspection without visiting the inspected facilities shall contain an indication that the inspection was carried out based on a remote inspection without visiting the production site.

      36. If, during the inspection, inconsistencies were identified, the subject of inspection, no later than 30 calendar days from the date of receipt of the report, shall send a response to the expert organization with the attachment of a plan of corrective and preventive actions and a report on its implementation, which are familiarized with the lead inspector and all members the inspection team that carried out the inspection.

      37. Within 15 calendar days from the date of receipt of the said response, the inspection team shall assess the completeness and effectiveness of the corrective and preventive action plan and the report on its implementation.

      38. The results of the assessment shall be supplemented by the inspection team in Sections 5 and 6 of the inspection report specified in Annex 4 to this Regulation.

      39. One copy of the assessment report shall be sent to the inspected entity (with a cover letter) no later than 5 calendar days from the date of its signing, the second copy stored in the archive of the expert organization.

      40. In the case of the collection of samples (patterns), the inspection report shall be drawn up after receiving the test results from the testing laboratory. In this case, the period specified in paragraph 34 of these Rules shall begin to be calculated from the day the expert organization receives the test results.

      41. The results of the inspection shall be an integral part of the registration dossier of a medical device and are taken into account when forming the results of the examination of medical devices, carried out in the manner prescribed by paragraph 4 of Article 23 of the Code, and shall be also the basis for the adoption by the state body of decisions provided for in paragraph 2 of Article 259 of the Code.

      42. Information on the inspections of medical devices carried out is quarterly sent by the expert organization to the state body in the field of circulation of medicines and medical devices in the form in accordance with Annex 6 to these Rules.

      43. The expert organization shall be maintained and store for at least 10 (ten) years documents and records related to the production inspection (reports on the results of the production inspection; records of monitoring the implementation of corrective actions based on the results of inspections, as well as complaints and appeals based on the results of production inspection).

      44. The entity of inspection shall inform the expert organization about any planned changes in the organization that affect the information specified in the application (change of name, address, change in volume, significant change in premises, equipment, operations).

      45. In cases of disagreement with the results of the inspection, the manufacturer of the medical device or his authorized representative shall appeal in accordance with the procedure established by the legislation of the Republic of Kazakhstan.

|  |  |
| --- | --- |
|  | Annex 1 to the Rules for the Inspection of Medical Devices |

**The inspection program of medical device manufacturing**

      Period from "\_\_" \_\_\_\_\_\_\_\_ to "\_\_" \_\_\_\_\_\_\_\_ 20\_\_\_

      Name of the entity of inspection \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      Inspection purpose \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      List of production sites subject to inspection (to be completed when inspecting several production sites)

|  |  |  |
| --- | --- | --- |
| No. | Name and location (country, city, town) | Date of visit |
|  |  |  |
|  |  |  |

      Basis for the inspection of production \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Composition of the inspection team

|  |  |  |  |
| --- | --- | --- | --- |
| No. | last name, first name, patronymic (if any) inspectors | Position | Status (head, member) |
|  |  |  |  |
|  |  |  |  |

       Production inspection schedule

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| No. | Date Time | Production areas, departments, systems, processes subject to inspection | Inspector | Representatives of the manufacturing organization |
|  |  |  |  |  |
|  |  |  |  |  |

      Head of the inspection team

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

*Signature Last name, first name, patronymic (if any)*

      Inspection team members

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

*Signature Last name, first name, patronymic (if any)*

       "\_\_\_\_\_\_" \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_20\_\_\_\_\_\_\_

|  |  |
| --- | --- |
|  | Annex 2 to the Rules for the Inspection of Medical Devices |

**Requirements for the implementation, maintenance, and evaluation of a quality management system for medical devices**

      1. Manufacturers of medical devices (except for manufacturers of medical devices of potential risk class 1 and non-sterile medical devices of potential risk class 2a), before submission of documents for examination and registration of medical devices, shall implement a quality management system for medical devices in accordance with ISO 13485 or equivalent regional, national standard.

      2. Manufacturers of medical devices of potential risk class 1 and non-sterile medical devices of potential risk class 2a shall voluntarily implement and maintain a quality management system for medical devices in accordance with ISO 13485.

      3. Manufacturers of sterile medical devices of potential risk classes 2a and 2b, before submitting documents for examination and registration of medical devices, shall introduce a quality management system for medical devices in accordance with the ISO 13485 standard, except for the implementation of design and development processes.

      4. Manufacturers of medical devices of potential risk class 3, before submission of documents for examination and registration of medical devices, shall implement a quality management system for medical devices in accordance with ISO 13485, including design and development processes.

      5. To implement a quality management system for medical devices, a manufacturer of medical devices shall :

      1) develop documented requirements for risk management at all stages of the life cycle of medical devices;

      2) determine the processes necessary for the effective functioning of the quality management system of medical devices (hereinafter referred to as processes), and the application of processes in the organization - manufacturer of medical devices;

      3) determine the sequence and relationship of processes;

      4) define the criteria and methods necessary to ensure effectiveness, both in the implementation of processes and in the management of processes;

      5) ensure the availability of production conditions, resources, and information necessary to maintain processes and monitor processes;

      6) monitor, measure and analyze processes;

      7) take actions necessary to achieve planned results and maintain the effectiveness of processes.

      6. All elements of the quality management system for medical devices (organizational structure, methods, and description of processes) shall be documented and kept up to date.

      7. The documentation of the quality management system of a medical device shall contain a description of:

      1) requirements for the technical characteristics of a medical device, standards, or individual sections (paragraphs, subparagraphs) of the applicable standards. If the relevant standards are not applied, a description of the methods applicable to the manufactured medical devices and guaranteeing the safety and effectiveness of the use of the medical device;

      2) methods and depth of third-party control if development, production, and (or) final control is performed by a third party;

      3) manufacturing processes, quality control and quality assurance of a medical device, processes and systematic measures that are used to control quality and ensure the quality of a medical device, including processes of corrective and preventive actions;

      4) documents for recording quality indicators of a medical device (reports on internal audits, inspections, test results, and other documents);

      5) means of control over the achievement of the required quality of the medical device and the effective functioning of the quality system of the medical device;

      6) plans, procedures, and documents for customer feedback (including monitoring the safety and effectiveness of a medical device at the post-sale stage).

      8. Manufacturers of medical devices that have implemented a quality management system for medical devices shall keep it up to date and ensure its effectiveness.

      9. Assessment of the quality management system of medical devices shall be carried out for the following processes:

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

      2) processes for managing documents and records;

      3) production and final inspection processes;

      4) processes of corrective and preventive actions;

      5) processes associated with the consumer.

      If a manufacturer of a medical device has implemented a quality management system for medical devices in accordance with the requirements of standards equivalent to the ISO 13485 standard, then evidence of the quality management system compliance with the requirements of these standards (certificate of conformity, audit reports of the quality management system of medical devices) shall ensure its compliance with these Requirements in terms of processes and procedures related to the functioning of the quality management system for medical devices.

      In this case, the inspection is limited to checking the fulfillment of the requirements related to the design, development, production, and final inspection of the medical device and to the processes associated with the consumer (in terms of post-sales monitoring).

      10. Assessment of the design and development processes of the quality management system for medical devices shall include:

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

      2) analysis of documents describing the design procedure and covering the range of medical devices;

      3) confirmation, based on selected medical device design records, that design and development procedures have been established and applied;

      4) confirmation that the input to the design process has been developed taking into account the purpose of the medical device and the relevant provisions of the General Requirements for Safety and Effectiveness;

      5) analysis of specifications for medical devices to confirm that the design outputs of the medical device, ensuring the safety and effectiveness of the medical device when used as intended, have been determined;

      6) confirmation that the risk management activities have been identified and implemented, the criteria for risk acceptability have been established and are appropriate, any residual risk has been assessed and, if necessary, communicated to the customer in accordance with the General Requirements for Safety and Efficiency.

      11. Assessment of the processes of document and record management of the medical device quality management system shall include:

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

      2) confirmation of the availability of documents necessary for the organization to ensure the planning, implementation, and management of production processes;

      3) confirmation that the documentation for the medical device shall include:

      certificates of compliance of medical devices with requirements (including the requirements of applicable standards);

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

      consolidated documentation on verification and validation of projects (including data from clinical trials (trials) in accordance with the procedure established by paragraph 6 of Article 238 of the Code, as well as in accordance with the Rules for conducting clinical and clinical laboratory trials (studies) of medical devices, approved by the Decision Council of the Eurasian Economic Commission dated February 12, 2016, No. 29);

      medical device labeling;

      risk management documents.

      12. Assessment of production processes and final inspection of medical devices shall include:

      1) analysis of production processes for the manufacture of serial products (including production conditions);

      2) assessment of sterilization processes (for medical devices manufactured in sterile form), including:

      the determination that sterilization processes have been documented, records of sterilization process parameters for each batch of medical devices to be sterilized are maintained;

      the determination that the sterilization process has been validated;

      3) confirmation that production processes are controlled and controlled and operate in accordance with regulatory documents, as well as confirmation of ensuring the required level of control of products and (or) services of critical suppliers;

      4) confirmation of the identification and traceability of medical devices and their production processes, as well as their compliance with technical specifications;

      5) confirmation that the final inspection activity of medical devices ensures the compliance of medical devices in accordance with regulatory documents and has been documented.

      13. Assessment of the processes of corrective and preventive actions of the quality management system of medical devices shall include:

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

      2) confirmation that the controls prevent the distribution of medical devices, the quality of which does not meet the requirements for the examination of medical devices in the manner prescribed by paragraph 3 of Article 239 of the Code, as well as the General requirements for the safety and effectiveness of medical devices approved by the Decision of the Board of the Eurasian Economic Commission dated February 12, 2016, No. 27;

      3) confirmation that corrective and preventive actions are effective;

      4) confirmation that the manufacturer of the medical device has developed an effective procedure for the issuance and application of notifications on the safety of medical devices in accordance with the procedure established by paragraph 3 of Article 261 of the Code, as well as in accordance with the Rules for monitoring the safety, quality and efficacy of medical devices approved by the Decision Of the Board of the Eurasian Economic Commission No. 174 dated December 22, 2015 (hereinafter referred to as the EEU Monitoring Rules).

      14. Assessment of consumer-related processes of the medical device quality management system shall include:

      1) confirmation that the manufacturer of the medical device has taken the measures necessary to establish communication with consumers to take the necessary corrective and preventive actions, has a system for collecting and analyzing data on the safety and effectiveness of medical devices at the post-sale stage, and keeps it up to date, and also sends to the authorized body reports on the results of post-sale monitoring of the safety and effectiveness of medical devices in accordance with the procedure established by paragraph 3 of Article 261 of the Code, as well as in accordance with the EEU Monitoring Rules;

      2) confirmation that customer feedback shall be analyzed by the medical device manufacturer during the product life cycle processes and is used to reassess risk and, if necessary, to update risk management activities.

|  |  |
| --- | --- |
|  | Annex 3 to the Rules for the Inspection of Medical Devices |

**Protocol of inconsistencies**

      dated "\_\_" \_\_\_\_\_\_ \_\_\_\_\_\_

      Name, address, details of the inspection object

      Date(s) of the production inspection

|  |  |  |
| --- | --- | --- |
| Inconsistencies | Brief description of inconsistencies | Note |
| Critical |  |  |
| Significant |  |  |
| Minor |  |  |
| Comments |  |  |

      Note:

      "Critical inconsistency" is an inconsistency that causes or leads to a significant risk of the possibility of manufacturing a medical device hazardous to human health and life.

      A combination of significant inconsistencies, none of which are critical in themselves, but which collectively represent critical inconsistencies, are explained and recorded thereof.

      A "major inconsistency" is not a critical inconsistency that:

      led to the production or may lead to the production of a medical device that does not comply with the documents of the registration dossier of this medical device;

      indicates a significant deviation from the ISO13485 standard and (or) the standard of good manufacturing practice (hereinafter referred to as GMP) of the Republic of Kazakhstan, or the requirements of other legislative acts in the field of circulation of medical devices;

      a combination of inconsistencies, none of which are significant in themselves, but which collectively represent a significant inconsistency and must be explained and recorded as such.

      "Minor inconsistency" is an inconsistency that is not classified as critical or significant, but indicates a deviation from ISO13485 standards and (or) the GMP standard of the Republic of Kazakhstan.

      Comments from the representative of the manufacturing organization (or quality control laboratory) (optional)

      Head of the inspection team:

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

*signature Last name, first name, patronymic (if any)*

      Members of the inspection team:

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

*signature Last name, first name, patronymic (if any)*

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

       signature Last name, first name, patronymic (if any)

       "\_\_\_\_" \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 20\_\_\_

      Representatives and authorized persons of the inspected object:

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

*signature Surname, name, patronymic (if any)*

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

      signature Surname, first name, patronymic (if any) "

      \_\_\_\_" \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 20\_\_\_

|  |  |
| --- | --- |
|  | Annex 4 to the Rules for the Inspection of Medical Devices |

**Medical Device Manufacturing Inspection Report**  
**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  
**(name of the manufacturer)**   
**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  
**(name of the medical device)**

      1. Manufacturer information:

|  |
| --- |
| Name, legal address of the manufacturer |
| Name, address details of the production site (s) |
| Dates of production inspection |
| Composition of the commission (last name, first name, patronymic (if any), position) |
| Grounds for a production inspection |
| Brief description of the manufacturer and production organization |
| List of manufactured medical devices |
| List of critical suppliers |
| Production areas subject to production inspection |
| Personnel of the manufacturing organization involved in the production inspection |
| Documents submitted by the manufacturing organization before the production inspection |
| Manufacturing license numbers |
| ISO 13485 Certificate of conformity numbers |
| Application numbers for examination at state registration |

      2. Observations and inspection results

|  |
| --- |
| General description of the audited activity and (or) technological processes |
| Quality control |
| Medical device documentation |
| Design and development (description of the studied projects) |
| Staff |
| Premises and equipment |
| Manufacturing process including sterilization, control during production |
| Documentation and records |
| Measurement, analysis, and improvement |
| Procurement management |
| Outsourcing |
| Monitoring of adverse events (incidents) |
| Consumer processes, including the results of clinical trials |

      3. List of inconsistencies

|  |  |
| --- | --- |
| Critical |  |
| Significant |  |
| Minor |  |

      4. Optional

|  |
| --- |
| Information on inconsistencies eliminated during the inspection, as well as on the timing of corrective actions for unresolved inconsistencies, and forms of confirmation of corrective actions (submission of supporting documentation or on-site verification) |
| Obstacles |
| Areas that have not been inspected |
| 5. Results of consideration of elimination of deviations and conclusions of the inspection |

      6. Conclusion

|  |  |
| --- | --- |
| Conclusion |  |

      Head of the inspection team

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

      Signature Last name, first name, patronymic (if any)

      Inspection team members

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

      Signature Last name, first name, patronymic (if any)

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

      Signature Last name, first name, patronymic (if any)

      "\_\_\_\_\_\_" \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_20\_\_\_\_\_\_\_

|  |  |
| --- | --- |
|  | Annex 5 to the Rules for the Inspection of Medical Devices |

**The list of documents submitted by the entity of inspection during inspection without visiting the object of inspection**

|  |  |  |
| --- | --- | --- |
| Requirements (justification) | During the initial inspection | With periodic (planned) inspection |
| Description of the quality management system of medical devices depending on the potential risk of their use in accordance with ISO 13485 or an equivalent regional, national standard | Full system description  quality management of medical devices depending on the potential risk of their use in accordance with ISO 13485 or an equivalent regional, national standard | Summary of changes made since the last inspection |
| Notarized copy of the production permit (license) issued by the national competent authority | Copies of all original licenses and changes made | Copies of licenses and changes made in the last 3-5 years |
| Production site dossier | Site dossier, complete or updated 6 months before the inspection date. Any planned changes to be made | Site dossier, complete or updated 6 months before the inspection date.  Information about planned changes |
| List of employees involved in the process of evaluating the quality management system of medical devices | Certificate of the actual number of employees involved in the assessment processes of the quality management system of medical devices |  |
| List of medical devices manufactured (planned for production) at the production site | Trade names | Trade names |
| Technical files for medical devices | Searchable electronic technical files | Searchable electronic technical files |
| A copy of the report on the results of the last audit of the quality management system of medical devices by the certification body and the report on the results of the last inspection of production, with a notarized translation, if necessary  ISO 13485 certificates | Report on the results of the last audit of the quality management system of medical devices by the certification body and the report on the results of the last production inspection | Report on the results of the last audit of the quality management system of medical devices by the certification body and the report on the results of the last production inspection |
| Processes for the design and development of a quality management system for medical devices | a) design and development procedures (including risk management);  b) documents describing the design procedure and covering the range of medical devices;  c) medical device design records that design and development procedures are established and applied;  d) the input data of the design process are developed taking into account the purpose of the medical device and the relevant provisions of the General Requirements for Safety and Effectiveness;  e) specifications for medical devices to confirm that the design outputs of the medical device, which ensure the safety and effectiveness of the medical device when used as intended, are defined;  f) documents confirming that risk management activities have been identified and implemented, criteria for risk acceptability are established and are appropriate, any residual risk is assessed and, if necessary, brought to the attention of the consumer in accordance with the General Requirements for Safety and Efficiency |  |
| Processes for managing documents and records of a quality management system for medical devices | a) procedures for identifying, storing, and deleting (destroying) documents and records (including change management) are developed;  b) documents necessary for the organization to ensure the planning, implementation, and management of production processes;  c) evidence of compliance of medical devices with requirements (including the requirements of applicable standards);  description of medical devices, including instructions for use (manuals), materials, and specification;  consolidated documentation on verification and validation of projects (including data from clinical trials (researches) in accordance with the procedure established by paragraph 6 of Article 238 of the Code, and (or) in accordance with the Rules for conducting clinical and clinical laboratory trials (studies) of medical devices, approved by the Decision of the Council of the Eurasian Economic Commission dated February 12, 2016, No. 29);  medical device labeling;  risk management documents |  |
| Production processes and final inspection of medical devices | a) documents of production processes for the manufacture of serial products (including production conditions);  b) documents on the sterilization process (for medical devices manufactured in sterile form), including:  confirmation that sterilization processes are documented, 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 production processes are controlled and controlled and functioning within established limits, as well as confirmation of ensuring the necessary level of control of products and (or) services of critical suppliers;  d) documents confirming the identification and traceability of medical devices and their production processes, as well as their compliance with the established requirements;  e) documents confirming that the final inspection of medical devices ensures the compliance of medical devices with the established requirements and is documented |  |
| Processes of corrective and preventive actions of the quality management system of medical devices | a) documents confirming that corrective and preventive action procedures are in place;  b) documents confirming that the controls prevent the distribution of medical devices, the quality of which does not meet the requirements for the examination of medical devices in the manner prescribed by paragraph 3 of Article 239 of the Code and (or) the General requirements for the safety and effectiveness of medical devices approved by the Decision of the Board of the Eurasian Economic Commission dated February 12, 2016, No. 27;  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 notifications on the safety of medical devices in accordance with the procedure established by paragraph 3 of Article 261 of the Code and (or) in accordance with the Rules for monitoring the safety, quality and effectiveness of medical devices approved by the Decision of the Board of the Eurasian Economic Commission dated December 22, 2015, No. 174. |  |
| Assessment of customer-related processes of the medical device quality management system | a) documents confirming that the manufacturer of the medical device has taken the measures necessary to establish communication with consumers to take the necessary corrective and preventive actions, has a system for collecting and analyzing data on the safety and effectiveness of medical devices at the post-sale stage and maintains it up-to-date condition, and also sends to the authorized body (expert organization) reports on the results of post-sale monitoring of the safety and effectiveness of medical devices in accordance with the procedure established by paragraph 3 of Article 261 of the Code and (or) in accordance with the EEU Monitoring Rules;  b) documents confirming that customer feedback is analyzed by the manufacturer of the medical device during the product life cycle processes and is used to reassess the risk and, if necessary, to update the risk management activities |  |

|  |  |
| --- | --- |
|  | Annex 6 to the Rules for the Inspection of Medical Devices |

**Information on the conducted inspections of the production of medical devices**

|  |  |  |  |
| --- | --- | --- | --- |
| No. | Production inspection form | Medical device manufacturer | |
| foreign | domestic |
| 1. | The total number of initial inspections, including: |  |  |
| in work |  |  |
| completed |  |  |
| 2. | The total number of scheduled inspections, including: |  |  |
| in work |  |  |
| completed |  |  |
| 3. | The total number of unscheduled inspections, including: |  |  |
| in work |  |  |
| completed |  |  |
| 4. | TOTAL |  |  |

      Head of the structural unit of the expert organization:

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

      signature Surname, name, patronymic (if any)

      Deputy head of the expert organization:

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

      signature Surname, name, patronymic (if any)

© 2012. «Institute of legislation and legal information of the Republic of Kazakhstan» of the Ministry of Justice of the Republic of Kazakhstan