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 "On public health and healthcare system" **I HEREBY ORDER**:

Footnote. The preamble as amended by the Order of the Minister of Healthcare of the Republic of Kazakhstan dated 07.04.2023 № 63 (shall come into force upon expiry of ten calendar days after its first official publication).

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
№ ҚР ДСМ-315/2020

Rules for conducting inspections of medical devices

Footnote. The Rules as amended by the Order of the Minister of Healthcare of the Republic of Kazakhstan dated 07.04.2023 № 63 (shall come into force upon expiry of ten calendar days after its first official publication).

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 "On public health and healthcare system" (hereinafter referred to as the Code) and determine the procedure for conducting inspections of medical devices in accordance with requirements for the implementation, maintenance, and assessment of the quality management system for medical devices, depending on the potential risk of their use.

Conducting an inspection of a medical device submitted for registration within the Eurasian Economic Union shall be carried out in accordance with the requirements for the implementation, maintenance and evaluation of the quality management system of medical devices depending on the potential risk of their use, approved by Decision of the Board of the Eurasian Economic Commission dated November 10, 2017 № 106 (hereinafter referred to as the EEC Decision № 106).

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

By decision of the expert organization, inspections, except for entities located in the territory of the Republic of Kazakhstan, by documents using means of remote interaction, by

means of audio or video communication without visiting the production facility shall be carried out in the following cases:

1) threat of emergencies and (or) threat of emergence, prevention and liquidation of consequences of emergencies and (or) threat of emergence, spread of especially dangerous infectious diseases and liquidation of their consequences, as well as threat of exposure to adverse chemical, biological, radiation factors and liquidation of their consequences;

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

4. A production site (site) of a manufacturer of medical devices designed to perform the entire production process of medical devices or certain stages thereof is subject to inspection.

5. Inspection shall be carried out during the period of expertise during state registration of medical devices, 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, carried out in in accordance with the Order of the Minister of Healthcare of the Republic of Kazakhstan dated January 27, 2021 № ҚР ДСМ-10 “On approval of the rules for expert examination of medicines and medical devices” (registered in the Register of State Registration of Regulatory Legal Acts under № 22144) (hereinafter referred to as the Order № ҚР ДСМ-10) and (or) conducting inspection of rpoduction in accordance with the Decision of the Board of the Eurasian Economic Commission dated February 12, 2016 № 46 (as amended by the Decision of the Board of the Eurasian Economic Commission dated December 24, 2021 № 144).

The inspection results shall be applied to a group (subgroup) of medical devices depending on the potential risk class of application of the medical devices manufactured according to the List of groups and subgroups of medical devices provided for in Annex 2 to EEC Decision № 106. For medical devices of potential application risk class 2a, the results of the inspection shall apply to groups of medical devices. For medical devices of classes of potential risk of use 2b and 3, the results of the inspection shall apply to subgroups of medical devices;

2) periodic (scheduled) inspection of facilities subjected to initial inspection is conducted once every three (3) years to confirm the effectiveness of the quality management system in ensuring compliance of medical devices put into circulation;

3) unscheduled inspection:

if it is necessary to confirm the fact that violations have been eliminated based on the results of the inspection of production;

when conducting investigations related to the safety and effectiveness of a medical device, carried out in accordance with the Order of the Minister of Healthcare of the Republic of

Kazakhstan dated December 23, 2020 № ҚР ДСМ-320/2020 "On approval of the rules for conducting pharmacovigilance and monitoring the safety, quality and effectiveness of medical devices" (registered in the Register of State Registration of Regulatory Legal Acts under № 21896) (hereinafter referred to as the Order № ҚР ДСМ-320/2020).

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. To conduct an inspection, an inspection team shall be established, consisting of a leading inspector (team leader), team members, including inspectors, involved experts.

Requirements for the number of the inspection team, qualification level of inspectors and experts involved in the work of the inspection team shall be established by the procedures of the quality management system of the expert organization.

The composition of the inspection team shall be approved by the Order of the expert organization.

8. 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.

The inspection team, lead inspector (team leader) and members participating in the production inspection are not involved in activities that would affect the independence of their judgment or their impartiality with respect to the results of the production inspection, are not developers, manufacturers, suppliers of medical devices, do not perform maintenance (repair) of medical devices they evaluate, or are not representatives of the developer, manufacturer, supplier of medical devices, persons performing maintenance (repair) of medical devices.

9. The duration of inspection of one site (area) depends on the amount of work performed, type and complexity of production processes.

Chapter 2. Procedure for inspection of medical devices

10. 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 organizing and conducting, the inspection shall not exceed 120 (one hundred and twenty) calendar days from the date of submission by the applicant of an application for inspection of a medical device through the “personal account” via the information system of the expert organization.

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 the Order № ҚР ДСМ-10.

11. Upon receipt of a notification of the need for inspection, the applicant shall conclude a contract for inspection and through the “personal account” through the information system of the expert organization submit the following documents:

1) application for inspection of medical device production in the form according to Annex 1 to these Rules;

2) manual on quality;

3) technical file for the medical device and file of the production site;

4) list of medical devices produced (planned to be produced) at the production site;

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

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

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

The time limit for the conclusion of a contract by the applicant is not included in the total time limit for organizing and conducting an inspection provided for in the paragraph 10 of these Rules.

12. The expert organization shall consider the submitted documents within 15 (fifteen) calendar days.

If the applicant submits an incomplete set of documents, the expert organization within 5 (five) calendar days through the information system of the expert organization shall send a letter (in free form) to the applicant indicating the identified comments and the need to eliminate them in full within a period not exceeding 60 (sixty) calendar days.

The period of elimination of remarks shall not be included in the inspection period.

13. If additional questions arise concerning the information provided by the applicant in the response to the previous request, the applicant shall send the response and the necessary documents to the expert organization within thirty (30) calendar days of receipt of the request.

If the applicant fails to eliminate the remarks or violates the established deadline, the applicant shall be sent a notice of refusal to conduct the inspection.

14. The expert organization shall draw up a schedule of inspections on the basis of applications for conducting an inspection.

15. 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.

16. The inspection team shall ensure the development of a program of inspection of production of medical devices (hereinafter referred to as the Inspection program) in the form according to Annex 2 to these Rules. The inspection program shall be sent to the subject of inspection 7 (seven) calendar days before the start of the inspection at the facility.

The inspection program shall include information on the purpose, timing of the inspection , members of the inspection team, the subject matter and procedure of the inspection, production sites, processes to be inspected, on the review of the quality system and activities at the production facility.

17. The head of the inspection team shall assign functions to the inspection team.

18. During the initial inspection of production, the inspection team shall inspect the production of all production, outsourced (contracted) production sites (sites) declared by the manufacturer of medical devices.

19. During the inspection, the inspection program shall be amended and (or) supplemented in case of non-compliance with the requirements for the implementation and maintenance of the quality management system for medical devices stipulated in Annex 3 to these Rules and (or) EEC Decision № 106 (hereinafter referred to as the non-compliance) that represent a high risk to the quality of the medical device, process or quality system.

20. 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 premises, participating in production processes and in quality control processes.

21. 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 3 to these Rules and (or) EEC Decision № 106.

22 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 input control of raw materials and supplies;

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

4) documentation and records management processes;

5) processes of corrective and preventive actions

6) processes, associated with the consumer of medical devices.

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

23. 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) perform audio (video) recording and photography, as well as makes copies of documents as evidence in case of identification of incosistencies;

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

4) notifie the manufacturer of the need to take action on identified incosistencies.

24. If there are incosistencies, the head of the inspection team shall draw up a protocol of incosistencies in the form according to Annex 4 to these Rules. The protocol of incosistencies shall be drawn up in 2 (two) copies, signed by the members of the inspection team. One copy shall be handed over to the subject of inspection, the other copy shall be handed over to the expert organization.

25. Based on the results of the manufacturing inspection within 30 (thirty) calendar days, a report on the results of the medical device manufacturing inspection (hereinafter referred to as the report) shall be prepared in the form according to Annex 5 to these Rules. The report shall be prepared in 2 (two) copies, of which the first shall be sent to the subject of inspection, the second shall be kept by 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.

26. To inspect without visiting the inspected facilities, the inspected subject shall attach documents in accordance with Annex 6 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 (site).

27. In case of identification of incosistencies during the inspection, the inspection subject shall, not later than 30 (thirty) calendar days from the date of receipt of the report, send to the expert organization a response with an attachment of the corrective and preventive action plan and a report on its implementation.

28. 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.

29. The results of the assessment shall be supplemented by the inspection team in sections 5 and 6 of the inspection report.

30. One copy of the assessment report shall be sent with a cover letter to the subject of inspection not later than 5 (five) calendar days from the date of its signing, the second copy shall be kept in the archive of the expert organization.

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

31. In case of sampling (specimens) of medical devices, the inspection report shall be prepared after receipt of test results from the testing laboratory.

32. The results of the conducted inspection shall be an integral part of the registration dossier of a medical device and shall be taken into account in the formation of the results of expert examination of medical devices, carried out in the manner prescribed by Order № ҚР

ДСМ-10, and are the basis for the adoption by the state body of decisions provided for in the Order of the Minister of Healthcare of the Republic of Kazakhstan dated 24.12.2020 № ҚР ДСМ-322/2020 “On Approval of the Rules for Suspension, Prohibition or Withdrawal from Circulation or Restriction of the Use of Medicinal Products and Medical Devices” (registered in the Register of State Registration of Regulatory Legal Acts under № 21906).

33. Information on conducted inspections of medical devices production shall be sent quarterly by the expert organization to the state body in the form according to Annex 7 to these Rules.

34. The inspection subject shall inform the expert organization about changes in the organization affecting the information specified in the application on the results of the production inspection (change of name, address of the manufacturer and production sites, production processes) after the inspection.

35. In case of disagreement with the results of the conducted inspection, the subject of inspection shall appeal against them in accordance with the procedure established by the legislation of the Republic of Kazakhstan on civil proceedings.

Annex 1 to the Rules
for conducting inspections of medical devices

Application for the inspection of production of a medical device

1.	Inspection type:	initial □ scheduled □ extraordinary □
2.	Trade name of medical device(s)	in Kazakh: in Russian:
3.	Class according to the degree of potential risk of the use of the medical device	Class 1 - with low risk □ Class 2a - medium risk □ Class 2b - with increased risk □ Class 3 - high risk □
4.	Data of the subject of inspection (name of legal entity (individual entrepreneur)):	4.1. manufacturer (name): 4.1.1. legal address, actual address, phone (fax), e-mail 4.2. production site (name): 4.2.2. legal address, actual address, phone (fax), e-mail 4.3. contract and (or) outsourcing production site (name, address):
5	Preliminary terms of inspection	
6.	Format of inspection	
7.	Contract for inspection	Number_____ Date_____

Applicant: _____

legal address, actual address, phone/fax, e-mail

_____

Фамилия, имя, отчество (if any) of the authorized person
legal address, actual address, phone/fax, e-mail

_____

signature

Annex 2 to the Rules
for conducting inspections of medical devices

Inspection program of the production of a medical device

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)

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

Basis for the inspection of production _____

Composition of the inspection team

№	Surname, Name, Patronymic (if any) of inspectors	Position	Status (head, member)

Production inspection schedule

№	Date Time	Production sites, departments, systems, processes subject to inspection	Inspector	Representatives of the manufacturing organization

Head of the inspection team

_____ _____

Signature Surname, Name, Patronymic (if any)

Inspection team members

_____ _____

Signature Surname, Name, Patronymic (if any)

"_____" _____ 20_____.

Annex 3 to the Rules
for conducting inspections 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 class 1 potential risk of use and non-sterile medical devices of class 2a) potential risk of use, before submission of documents for examination and registration of medical devices, shall implement a quality management system for medical devices depending on the potential risk class of their use.

2. Manufacturers of sterile medical devices of class 2a and 2b potential risk of use before submitting documents for examination and registration of medical devices shall implement a quality management system for medical devices in accordance with International Standard ISO 13485:2016 "Medical devices. Quality Management System. Requirements for Regulation" (hereinafter referred to as the ISO standard) except for implementation of design and development processes.

3. Manufacturers of medical devices of class 3 potential risk of use submitting documents for examination and registration of medical devices shall implement a quality management system for medical devices in accordance with ISO standard, including the processes of design and development.

4. 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) 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.

5. 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.

6. 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).

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

8. 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 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 for the implementation, maintenance, and evaluation of a quality management system for medical devices 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).

9. 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 model 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.

10. 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 the documents necessary to enable the organization to plan, implement and manage production processes;

3) confirmation that the medical device documentation shall include:

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

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

summary documentation of verification and validation projects;

labeling of medical devices;

risk management documents.

11. 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.

12. 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 Order № KP ДСМ-10, 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 № 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 Order № KP ДСМ-320, as well as in accordance with the Decision of the Board of the Eurasian Economic Commission dated December 22, 2015 № 174 "On approval of the rules for monitoring of safety, quality and efficacy of medical devices" (hereinafter referred to as the EAEU Monitoring Rules).

13. 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 Order № KP ДСМ-320, as well as in accordance with the EAEU 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 4 to the Rules
for conducting inspections 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

Note:

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

Head of the inspection team

_____ _____

signature Surname, Name, Patronymic (if any)

Members of the inspection team

_____ _____

signature Surname, Name, Patronymic (if any)

_____ _____

signature Surname, Name, Patronymic (if any)

"_____" _____20_____

Representatives and authorized persons of the inspected object:

_____ _____

signature Surname, Name, Patronymic (if any)

_____ _____

signature Surname, Name, Patronymic (if any)

"____" _____ 20___.

Annex 5 to the Rules
for conducting inspections of medical devices

Medical Device Manufacturing Inspection Report

_____

(name of organization-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 Standard 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. Additional

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

		Information on elimination of inconsistencies (	

List of inconsistencies	Qualification of inconsistencies	summary of corrective and preventive actions, supporting document)	Assessment of elimination of inconsistencies

6. Conclusion

Conclusion	

Note:

“Critical inconsistency” - is an inconsistency that has a direct impact on the safety, efficacy and quality of a medical device when it relates to requirements related to the design, development, manufacturing and final inspection processes of the medical device.

A combination of significant inconsistencies, none of which by itself is critical, but which together constitute a critical inconsistency, shall be explained and recorded as such.

“Significant inconsistency” - is a non-critical inconsistency that:

has an indirect effect on the safety, efficacy and quality of a medical device and affects requirements related to the operation of the quality management system for medical devices.

a combination of inconsistencies, none of which by itself is significant, but which together constitute 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 an abnormality related to the functioning of the quality management system for medical devices.

Head of the inspection team

_____ _____

signature Surname, Name, Patronymic (if any)

Members of the inspection team

_____ _____

signature Surname, Name, Patronymic (if any)

_____ _____

signature Surname, Name, Patronymic (if any)

"_____" _____ 20_____

Annex 6 to the Rules
for conducting inspections 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	During periodic (planned) inspection
Description of the quality management system of medical devices depending on the potential risk of their use in accordance with the ISO Standard or an equivalent regional, national standard	Full description of the quality management system for medical devices subject to production inspection	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 all licenses and changes made, received over the last 3-5 years
Production site dossier	Production site file, complete or updated 6 months prior to the inspection date. Any planned changes to be made	Production site file, complete or updated 6 months prior to the inspection date. Information about planned changes
List of employees involved in the process of evaluating the quality management system of medical devices	Information on the actual number of employees involved in the processes of assessment 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	Technical files in electronic format with searching option	Technical files in electronic format with searching option
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 the ISO Standard certificates	Report on the results of the last quality management system audit of medical devices and report on the results of the last production inspection by the certification body	Report on the results of the last quality management system audit of medical devices and report on the results of the last production inspection by the certification body
Processes for the design and development of a quality management system for medical devices	1) design and development procedures (including risk management); 2) documents describing the design procedure and covering the model range of the medical device; 3) records of the design of the medical device, that the design and development procedures have been established and applied; 4) inputs to the design process are designed to meet the intended use of the medical device and the relevant provisions of the General Safety and Performance Requirements; 5) medical device specifications to confirm that the outputs of the medical device design that ensure the safety and effectiveness of the medical device when used for its intended purpose have been defined; 6) documents confirming that risk management activities have been defined and implemented, risk tolerance criteria have been established and are appropriate, any residual risk has been assessed and,	

	if necessary, communicated to the consumer in accordance with the General Safety and Effectiveness Requirements.	
Processes for managing documents and records of a quality management system for medical devices	1) procedures for identification, retention and disposal (destruction) of documents and records (including change management) are in place; 2) documents necessary for the organization to ensure the planning, implementation and management of production processes; 3) evidence of compliance of medical devices with requirements (including requirements of applicable standards); description of medical devices, including instructions for use (consolidated documentation on verification and validation of projects (including data of clinical trials (tests) in accordance with the procedure established by the Order of the Minister of Healthcare of the Republic of Kazakhstan dated December 11, 2020 № KP DSM-248 /2020 “On approval of the rules for conducting clinical trials of medicines and medical devices, clinical and laboratory tests of medical devices for diagnosis outside the living organism (in vitro) and requirements for clinical bases and provision of a state service " Issuance of authorization to conduct a clinical trial and (or) testing of pharmacological and medicinal products, medical devices”. (registered in the Register of State Registration of Regulatory Legal Acts under № 21772) and (or) in accordance with the Rules for conducting clinical and clinical-laboratory tests (studies) of medical devices, approved by the Decision of the Board of the Eurasian Economic Commission of February 12, 2016. № 29); labeling of medical devices; risk management documents	
	1) documents of production processes for manufacturing of serial	

Processes for managing documents and records of a quality management system for medical devices	products (including production conditions); 2) documents on sterilization process (for medical devices produced in sterile form), including: confirmation that sterilization processes are documented, records of sterilization process parameters for each batch of medical devices being sterilized are maintained; confirmation that the sterilization process is validated; confirmation that the sterilization process is performed in accordance with established parameters; 3) documents confirming that the production processes are managed and controlled and operate within the established limits, as well as confirmation that the necessary level of control of products and (or) services of critical suppliers is ensured; 4) documents confirming the identification and traceability of medical devices and their production processes, as well as their compliance with the established requirements; 5) documents confirming that the activities on output control of medical devices ensure compliance of medical devices with the established requirements and documented	
Production processes and final inspection of medical devices	1) documents confirming that corrective and preventive action procedures have been developed; 2) 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 accordance with the procedure established by the Order № КР ДСМ -10 and (or) the General Requirements for Safety and Effectiveness of Medical Devices, approved by the Decision of the Board of the Eurasian Economic Commission on February 12, 2016 № 27.;	

	3) documents confirming that corrective and preventive actions are effective; 4) documents confirming that the manufacturer of the medical device has developed an effective procedure for issuance and application of safety notifications for medical devices in accordance with the procedure established by the following procedure Order № КР ДСМ-320 and (or) in accordance with EAEU Monitoring Rules.	
Assessment of customer-related processes of the medical device quality management system	1) documents confirming that the manufacturer of the medical product has taken the measures necessary to communicate with consumers in order to take the necessary corrective and preventive actions, has a system for collecting and analyzing data on the safety and effectiveness of medical products at the post-marketing stage and keeps it up to date, as well as sends to the authorized body (expert organization) reports on the results of post-sale monitoring of safety and efficacy of medical devices in accordance with the procedure established by the Order № КР ДСМ-320 and (or) in accordance with EAEU Monitoring Rules; 2) documents confirming that consumer feedback is analyzed by the medical device manufacturer during product life cycle processes and is used to reassess risk and, if necessary, to update risk management activities	

Annex 7 to the Rules
for conducting inspections of medical devices

Information about the conducted inspections of the production of medical devices

№	Form of production inspection	Medical device manufacturer	
		Foreign	Domestic
1.	The total number of initial inspections, including:		
	work in progress		
	completed		

2.	The total number of planned inspections, including:		
	work in progress		
	completed		
3.	The total number of unscheduled inspections, including:		
	work in progress		
	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)

"_____" _____ 20_____ .