THE BOARD OF THE EURASIAN ECONOMIC COMMISSION

RESOLUTION
Dated December 22, 2015, N 174

ON APPROVAL OF
REGULATIONS OF MEDICAL DEVICE SAFETY, QUALITY AND EFFECTIVENESS MONITORING

In accordance with paragraph 2 of Clause 31 of the Treaty on the Eurasian economic Union dated May 29, 2014, paragraph 2 of Clause 8 of the Agreement on Common Principles and Regulations of Medical Devices (Medical Products and Medical Equipment) Circulation within the Eurasian Economic Union dated December 23, 2014, paragraph 25 of Appendix N 2 to the Regulations of the Eurasian Economic Commission, approved by the Resolution of the Supreme Eurasian Economic Council dated December 23, 2014, N 98, in order to implement the Resolution of the Supreme Eurasian Economic Council dated December 23, 2014 N 109 " Agreement on Common Principles and Regulations of Medical Devices (Medical Products and Medical Equipment) Circulation within the Eurasian Economic Union" the Board of the Eurasian Economic Commission decided:

1. To approve the enclosed Regulations of carrying out monitoring of safety, quality and effectiveness of medical devices.

2. This Resolution shall enter into force in 30 calendar days from the date of entry into force of the Agreement on Common Principles and Regulations of Medical Devices (Medical Products and Medical Equipment) Circulation within the Eurasian Economic Union dated December 23, 2014 or from the date of entry into force of the Protocol signed on December 2, 2015, on the accession of the Republic of Armenia to the Agreement on Common Principles and Regulations of Medical Devices (Medical Products and Medical Equipment) Circulation within the Eurasian Economic Union dated December 23, 2014, whichever date is later, but not earlier than upon expiry of 30 calendar days from the date of official publication of this Resolution.

Chairman of the Board
The Eurasian Economic Commission
V. KHRISTENKO

Approved
By the Resolution of the Board
of the Eurasian Economic Commission
dated December 22, 2015 N 174

REGULATIONS OF MEDICAL DEVICE SAFETY, QUALITY AND EFFECTIVENESS MONITORING

1. These Regulations are developed in accordance with paragraph 2 of Clause 31 of the Treaty on the Eurasian Economic Union dated May 29, 2014, and paragraph 2 of Clause 8 of the Agreement on Common Principles and Regulations of Medical Devices (Medical Products and Medical Equipment) Circulation within the Eurasian Economic Union dated December 23, 2014, and determine the procedure of medical products safety, quality and effectiveness monitoring (hereinafter – monitoring).

2. The objectives of monitoring are to ensure the safety of users, maintenance and promotion of health of population, improvement of the medical care quality, prevention and detection of side effects and adverse reactions that are not mentioned in the instructions for use or user manual of a medical product (hereinafter instructions for use), adverse events (incidents), circulation of medical devices that do not comply with general requirements to safety and effectiveness of medical devices, the requirements for the labeling and operational documentation for them approved by the Eurasian Economic Commission.

3. Monitoring involves collecting, recording, analysis of information on adverse events (incidents) and taking of appropriate decisions.

4. Monitoring is based on:

a) analysis of adverse events (incidents) reports at all stages of medical devices circulation in the Eurasian Economic Union (hereinafter – the Union) received from:

users of medical devices;

from manufacturers of medical devices;

in the implementation by the competent authorities of the member states of the Union of the state control (supervision) over circulation of medical devices;

b) the analysis of periodic reports of safety and clinical effectiveness of medical devices of the potential risk 3 class, as well as of medical devices implanted in the human body of potential risk class 2B and 3 in the post-marketing phase received from medical device manufacturers or from their authorized representatives;

c) in the system of data collection and analysis of the medical device manufacturer on the safety and effectiveness of medical devices at the post-production phase and the corrective actions in accordance with the requirements for implementation, maintenance and evaluation of the quality management system of medical devices according to potential risk of application approved by the Eurasian Economic Commission.

5. For the purposes of these Regulations the terms meaning the following are used:

"corrective action" - an action taken by the manufacturer of medical devices with the aim to eliminate the causes of a detected nonconformity or an undesirable event;

“corrective action on medical device safety" - an action taken by the manufacturer of medical devices with the aim to reduce the risk of death or serious deterioration in the health of users or third parties associated with the use of a medical device. Such actions may include:

return of a medical device to the manufacturer of medical devices or his authorized representative;

modification of a medical device (modernized in accordance with the changes made by the manufacturer of the medical devices in the medical device design, change of use instructions, upgrade of the medical device software);

replacement of the medical device;

withdrawal of the medical device from circulation;

destruction of the medical device;

reporting about actions of the users of medical devices if a medical device is withdrawn from circulation but its use is possible;

"adverse event (incident)" - any malfunction or deterioration in the characteristics or malfunctioning of a medical device, or insufficiency or incorrectness of accompanying information (documentation) for a medical device, or a side effect not mentioned in the instruction manual that directly or indirectly led or could lead to death or serious deterioration in the health of users or third parties (the serious deterioration of state of health means a life-threatening disease, a grave disturbance of the body function or permanent damage to body structure, status, requiring medical or surgical intervention to prevent life-threatening diseases or persistent lesions of body function or permanent damage of the body structure condition that requires hospitalization or a significant increase in duration of stay in hospital of the already admitted patient, functional disorders in the fetus, its death, congenital anomaly, or birth trauma);

"undesirable event" is any undesirable medical event, disease or unpredictable damage or undesirable clinical signs (including laboratory parameters different from the norm) or third parties involving the use of a medical device;

"user" - a patient, a medical specialist or any other natural person using a medical device for the purpose specified by the manufacturer of medical products;

"reference state" - the member state of the Union chosen by the applicant the competent authority of which carries out registration of the medical device;

"serious threat to health" - any malfunction or deterioration in the characteristics or malfunctioning of a medical device, or failure or the incorrectness of accompanying information (documentation) for a medical device, or a side effect not mentioned in the instructions for use that have led or may lead to imminent risk of death, life-threatening disease, irreversible damage of the body function, permanent damage to the body structure or condition, requiring medical or surgical intervention to prevent irreversible damage to body function or permanent damage to body structure, which require urgent medical action;

"supporting information (documentation)” - labeling, instructions for use and other information pertaining to identification, description, purpose, operational instruction of the medical device, excluding shipping documents;

"entities of medical devices circulation" - an organization set up in the established order in the member States of the Union, or representative offices of foreign organizations accredited in the established procedure in the member-states of the Union, or individual entrepreneurs registered in the member-states of the Union or individuals engaged in technical testing, examination (tests) to assess the biological action, clinical trials, assessment of

safety, quality and effectiveness of medical devices, registration, manufacture (production), storage, transportation, implementation, installation, commissioning, use (operation), maintenance, repair and disposal;

"medical device safety notice" - a message sent by the manufacturer of medical devices or his authorized representative to entities of medical device circulation in connection with corrective action on safety of medical devices;

"authorized representative of the manufacturer" - a legal entity or a natural person registered as individual entrepreneur who are residents in a member state of the Union, authorized under a power of attorney of the manufacturer of medical devices to represent him and to be responsible for the circulation of medical devices in the Union and execution of mandatory requirements for medical devices.

6. The manufacturer of medical devices or his authorized representative shall submit to the competent authority of a member-state of the Union in whose territory an adverse event (incident) occurred a report of an adverse event (incident) (hereinafter referred to as the adverse event report) and a report on corrective actions on safety of medical devices (hereinafter - a corrective action report) in accordance with blanks under appendices N 1 and 2 by filling in them in the information resource of the competent authority of a member state of the Union in the information and telecommunications network Internet (hereinafter - the Internet).

The initial incident report is sent within the following timeframe:

in the event of a serious threat to health immediately (without undue delay) but not later than within 2 calendar days after the manufacturer of medical devices became aware of the threat existence;

in the event of the death or unanticipated serious deterioration in state of health of the user immediately (without undue delay) after the manufacturer of medical products established a link between the use of a medical device and the incident but no later than within 10 calendar days after the manufacturer of medical devices became aware of the event;

in other cases - immediately (without undue delay) after the manufacturer of medical products has established a link between the use of a medical device and the incident, but no later than 30 calendar days after the manufacturer of medical devices became aware of the event.

Medical organizations operating in the sphere of circulation of medical devices must inform the manufacturer of medical devices or his authorized representative on undesirable events that are signs of adverse events (incidents) and to provide access to medical products, which can be related to these events.

Reports of adverse event (incident) is directed to the designated authority of a member state of the Union in whose territory occurred the event that any of the subjects of circulation of medical products, including exercising their application (users, health care organizations), in the form of a notice of adverse event (incident) according to the Appendix N 3. The notice is filled in by typewritten or handwritten means in Russian and (or) the official language of the member-state of the Union.

The notice shall specify reliable information supported by relevant documents, copies of which are enclosed with the notice.

7. A competent authority of a member state of the Union in whose territory occurred adverse event (incident), registers the received initial report about the incident, inform the manufacturer of medical devices or his authorized representative on receipt of the report and agrees with the submission of subsequent or final report about the incident, and the timing of the submission of the initial subsequent (if necessary) and final reports on corrective actions.

A manufacturer of medical devices or his authorized representative shall have the right to take corrective actions before the competent authority of a member state of the Union in whose territory an adverse event (incident) occurred sends an initial report about corrective actions in urgent cases protection of users or third parties from a threat of death or serious deterioration in state of health. In this case the initial report about the corrective actions should be sent to the competent authority of a member state of the Union within not later than 2 calendar days after the manufacturer of medical devices or his authorized representative corrective action.

8. If a manufacturer of medical devices or his authorized representative has no ability to investigate the adverse event (incident), he shall without delay notify the competent authority of a member state of the Union in the territory of which an event (incident) occurred.

9. A manufacturer of medical devices or his authorized representative may apply to the competent authority of a member-state of the Union in the territory of which an adverse event (incident) occurred for assistance in the implementation of the access to the medical device to determine the causal relation of the medical device with the adverse event and compliance of the adverse event with the adverse event (incident) criteria within the shortest possible time.

10. If in the process of investigating of the adverse event (incident) several manufacturers of medical devices are involved, the competent authority of a member state of the Union should coordinate their actions.

11. The competent authority of a member state of the Union in whose territory the adverse event (incident)

occurred not later than 30 working days from the date of receipt from manufacturer of medical devices or his authorized representative of the final incident report, the final corrective action report must inform the manufacturer of medical devices or his authorized representative and the competent authorities of other member states of the Union on the outcome of these reports.

Informing the competent authorities of the member States of the Union is carried out through the use of information system of the Union in the sphere of circulation of medical products.

12. The manufacturer of medical devices or his authorized representative shall issue a medical device safety notice in the form according to Appendix N 4 and bring it to users.

13. Reports about the incident, reports about the corrective actions and security notifications are medical devices competent authority of the member state of the Union in whose territory occurred adverse event (incident), into a single information database for monitoring safety, quality and effectiveness of medical devices.

14. In respect of adverse events (incidents) associated with was the Union of the medical products occurring in States that are not members of the Union, a manufacturer of medical devices or his authorized representative shall send notification of safety medical devices to the competent authority of the reference state.

A competent authority of the reference state posts the medical device safety notice in a single information database for monitoring safety, quality and effectiveness of medical devices.

15. Incident reports may not be submitted to the competent authority of a member state of the Union:

a) for each individual adverse event (incident) from those described in the medical device safety notices and occurred after investigation of adverse events (incidents) and distribution by the manufacturer of medical devices or his authorized representative of such notices and corrective actions. Instead, the manufacturer of medical devices or his authorized representative may agree with the competent authority of a member state of the Union on the periodic submission of summary reports on specified adverse events (incidents), as well as on their content and submission deadlines;

b) for each individual adverse event (incident) from those frequently occurring and documented adverse events (incidents) (specified as such in the analysis of risks related to the medical device about which reports analyzed by the manufacturer of the medical devices or his authorized representative and the competent authority were submitted). Instead it is allowed submitting periodic summarized reports. The contents and deadlines of submission of periodic summarized reports must be approved with the authorized member-state of the Union.

c) for adverse events (incidents) that didn't lead to serious deterioration of health or death because of design features that protect against threats due to a malfunction of the medical device;

d) for expected and foreseeable adverse events (incidents) that meet all the following criteria:

adverse events (incidents) are clearly identified in accompanying information (documentation) for a medical device;

adverse events (incidents) are well known in clinical practice, they can qualitatively and quantitatively predict if the medical device is used and operates in accordance with its intended purpose;

adverse events (incidents) are documented in the technical documentation for a medical device with an appropriate risk assessment before the occurrence of the adverse event (incident);

adverse events (incidents) are clinically acceptable from the point of view of use of the medical device for each individual patient;

e) if the risk of death or serious deterioration in state of health was analyzed and found negligible, if no death or serious deterioration of health did not happen, and the risk was identified and documented as valid in the report about the risk analysis presented in the registration dossier when registering a medical device.

16. The manufacturer of medical devices or his authorized representative must inform the competent authority of a member state of the Union about the mistakes made when using medical devices that led to death or serious deterioration in the health of the user.

17. Upon receipt from the competent authority of a member state of the Union reports of adverse events the manufacturer of medical devices or his authorized representative must verify the information on compliance of the adverse event (incident) with the adverse event (incident) criteria and send to the competent authority of a member state of the Union in the territory of which an adverse event occurred reports on adverse event and corrective actions.

If in accordance with the estimation of the manufacturer of medical devices or his authorized representative an adverse event does not meet criteria adverse event (incident), the manufacturer of medical device or his authorized representative should submit to the competent authority of a member state of the Union in whose territory an adverse event occurred the justification that the specified event is an adverse event (incident).

18. The medical device safety notice is sent by the manufacturer of medical devices or his authorized representative with use of information and telecommunication means ensuring their receipt by the interested companies with acknowledgment of receipt.

19. For medical devices of the potential risk class 3 as well as for medical devices implanted in the human body of the potential risk class 2B, the manufacturer of medical devices or his authorized representative shall conduct a post-marketing clinical monitoring of safety and effectiveness of medical devices (hereafter – the post-marketing clinical monitoring) and annually for 3 years, submit to the competent authority of the reference state reports on post-marketing clinical monitoring.

Initial, subsequent and final reports of post-marketing clinical monitoring shall be submitted by the manufacturer of medical devices or his authorized representative to the competent authority of the reference state not later than on February 1, beginning with the year following the year of receipt of the registration certificate.

20. Clinical post-marketing monitoring is conducted in accordance with the plan included in the report on clinical proof of efficacy and safety of a medical device provided by the manufacturer of a medical device or his authorized representative in the registration dossier when registering a medical device.

21. The post-marketing clinical monitoring plan should include:

a) the goals and objectives of post-marketing clinical monitoring based on existing clinical data, specific features and risk factors associated with the medical device;

b) scheme of post-marketing clinical monitoring, including justification of the methods of obtaining and statistical analysis of clinical data, choice of study population, inclusion criteria (exclusion) and the minimum number of subjects in the study group and, where applicable, the need for inclusion in the study of comparison groups.

22. Reports of post-marketing clinical monitoring of safety and effectiveness of medical devices in the form according to Appendix No. 5 shall be submitted by the manufacturer of medical devices or his authorized representative to the competent authority of the reference state with use of the information resource of the competent authority of the reference state in Internet.

23. The competent authority of the reference state has the right to engage expert organization to analyze the reporting of post-marketing clinical monitoring. On the basis of the expert conclusion of the competent authority of the reference state is entitled to take Resolution on the need for a manufacturer of medical devices corrective action.

24. Reports of post-marketing clinical monitoring are sent to the competent authority by the competent authority of the reference state to the expertise of the organization.

25. Review organization not later than 20 working days from the date of receipt of the report on post-marketing clinical monitoring sends to the competent authority of the reference state the conclusion about possibility (impossibility) of completing a post-registration clinical monitoring.

26. On the basis of the expert conclusion of the competent authority of the reference state takes one of the following decisions:

a) to complete post-marketing clinical monitoring;

b) to extend post-marketing clinical monitoring with an indication of the additional period, if the received data are didn't take necessary corrective actions based on the received data;

c) to suspend the registration certificate of medical devices and to extent the post-marketing clinical monitoring with an indication of the additional period;

d) to cancel (revoke, withdraw) the registration certificate and, if necessary, to withdraw medical devices from circulation.

27. The competent authority of the reference state within not later than 10 working days from the date of acceptance in accordance with paragraph 26 of these Regulations of the decision shall inform the manufacturer of medical devices hereof.

28. If the manufacturer of medical devices or his authorized representative became aware of an adverse event (incident), but he did not report it to the competent authority of the state member of the Union in the territory of which an adverse event (incident) occurred or violated the deadline set for the message, the specified authority may suspend the issued registration certificate of medical devices and to conduct his own investigation of the adverse event (incident) or suspend or prohibit the use of medical products on the territory of the state.

29. If the manufacturer of medical devices or his authorized representative did not submit to the authority of the state member of the Union in whose territory occurred adverse event (incident), follow-up or final report on the incident, the competent authority after notifying the manufacturer of medical devices or his authorized representative that the violation has the right to suspend issued the registration certificate for medical products or make the Resolution to initiate the procedure for cancellation (cancelled, ratings) not earlier than 30 business days from the date of manufacturer of medical devices or his authorized representative, the appropriate notification or to suspend or ban the use of medical products on the territory of the state.

30. If the manufacturer of a medical device or its authorized representative did not submit to the competent authority of the reference state the initial, subsequent or final report of post-marketing clinical monitoring, the

competent authority after notifying the manufacturer of a medical device or its authorized representative about this violation has the right to suspend the registration certificate for medical products or take the resolution to initiate the procedure for its cancellation (withdrawal, revocation ratings) not earlier than 30 business days from the date of sending to the manufacturer of medical devices or his authorized representative of a corresponding notice.

Appendix N 1
To Regulations of Medical Device Safety,
Quality and Effectiveness
Monitoring

BLANK OF
ADVERSE EVENT (INCIDENT) REPORT

<table>
<tr><td colspan="2">1. Administrative information</td></tr>
<tr><td>Competent authority <1>, <2>, <3></td><td rowspan="2">Place for the mark of the competent authority (incoming date, registration number)</td></tr>
<tr><td>Address of the competent authority <1>, <2>, <3></td></tr>
<tr><td colspan="2">Report type <1>, <2>, <3>:
☐ Initial report
☐ Subsequent report
☐ Final report</td></tr>
<tr><td colspan="2">Report date <1>, <2>, <3></td></tr>
<tr><td colspan="2">Registration number of the adverse event (incident) (to be assigned by the manufacturer) <1>, <2>, <3></td></tr>
<tr><td colspan="2">Registration number of the adverse event (incident) (to be assigned by the competent authority) <2>, <3></td></tr>
<tr><td colspan="2">Does the adverse event (incident) constitute a serious threat to the public health? <1>, <2>, <3>
☐ Yes
☐ No</td></tr>
<tr><td colspan="2">Incident classification <1>, <2>, <3>:</td></tr>
</table>

☐ Death ☐ Unexpected serious серьезное ухудшение состояния здоровья ☐ Other criteria	
Other competent authorities in which a report was sent	
2. Data about the person who submitted a report	
Status of the person submitting the report <1>, <2>, <3>: ☐ Manufacturer ☐ Authorized representative	
3. Information about the manufacturer	
Name of the manufacturer <1>, <2>, <3>	
Surname, name, patronymic (if any) of the contact person <1>, <2>, <3>	
Address <1>, <2>, <3>	
ZIP code <1>, <2>, <3>	City (town) <1>, <2>, <3>
Phone <1>, <2>, <3>	Fax (if any) <1>, <2>, <3>
E-mail <1>, <2>, <3>	Country <1>, <2>, <3>
4. Information about the authorized representative (if any)	
Name of the authorized representative <1>, <2>, <3>	
Surname, name, patronymic (if any) of the contact person <1>, <2>, <3>	
Address <1>, <2>, <3>	
ZIP code <1>, <2>, <3>	City (town) <1>, <2>, <3>
Phone <1>, <2>, <3>	Fax (if any) <1>, <2>, <3>
E-mail <1>, <2>, <3>	Country <1>, <2>, <3>

5. Data on medical device	
Potential hazard class of the medical device use <1>, <2>, <3>: ☐ 3 ☐ 2б ☐ 2а ☐ 1	
Code of the medical device type in accordance with the nomenclature of the medical devices applied in the Eurasian Economic Union <2>, <3>	
Unique medical device identifier (Unique device identifier (UDI) (if any) <2>, <3>	
Identification of the medical device <1>, <2>, <3>	
Model (if applicable) <2>, <3>	Catalogue number (if applicable) <2>, <3>
Serial number(if applicable) <2>, <3>	Batch (series) number (if applicable) <2>, <3>
Software version (if applicable) <2>, <3>	
Date of mantufacture <2>, <3>	Expiry date (if applicable) <2>, <3>
Implantation date (only for implants) <2>, <3>	Explantation date (only for implants) <2>, <3>
Implantation duration (to be filled in if the exact implantation date or operation date is known) <2>, <3>	
Accessories and (or) jointly used medical devices (if applicable) <2>, <3>	
Number of registration certificate in the single register of medical devices registered in the Eurasian Economic Union <1>, <2>, <3>	
Number of registration certificate in the national register of registered medical devices (if any) <2>, <3>	
6. Information about an adverse event (incident)	
Date when an adverse event (incident) occured <2>, <3>	
Description of the adverse event (incident) <1>, <2>, <3>	
Number of the report of the medical device producer (if applicable) <2>, <3>	
Data when the manufacturer received information about an adverse event (incident) <1>, <2>, <3>	

Number of involved patients (if known) <2>, <3>	Number of involved medical devices (if known) <2>, <3>
Location of the medical device at this moment (if known) <1>, <2>, <3>	
Who use the medical device at the moment of the adverse event (incident) (select one option) <2>, <3>: ☐ Medical staff ☐ Patient ☐ Other	
Use of the medical device (select one) <2>, <3>: ☐ primary use ☐ repeated use of single-use medical device ☐ repeated use of muptilple-use medical device ☐ medical device after maintenance or repair ☐ other ☐ The problem was detected before use	
7. Information about the patient	
Description of the patient's problem <2>, <3>	
Code and term of the patient's problem due to the adverse event (incident) in accordance with the International Statistical Classification of Diseases and Related Health Problems, 10th revision (МКБ-10) <3>	
Country, where an adverse event (incident) took place <1>, <2>, <3>	

Actions and help rendered by the medical organization to the patient <2>, <3>	
Sex (if applicable) <2>, <3>: ☐ Male ☐ Female	
Patient's age (if applicable) <2>, <3>: years ☐ months ☐ days ☐	
Patient's weight (kg) (if applicable) <2>, <3>	
8. Information about the medical organization (if applicable)	
Name of the medical organization <1>, <2>, <3>	
Surname, name, patronymic (if any) of the contact person of the medical organization <2>, <3>	
Address <1>, <2>, <3>	
ZIP code <2>, <3>	City (town) <1>, <2>, <3>
Phone <2>, <3>	Fax (if any) <2>, <3>
E-mail <2>, <3>	Country <1>, <2>, <3>
9. Preliminary conclusion of the manufacturer (for initial/subsequent report)	
Initial analysis conducted by the manufacturer <1>, <2>	
Type of the adverse event (incident) (code and term of level 1 - ISO/TS 19218-1) <2>, <3>	
Type of the adverse event (incident) (code and term of level 2 - ISO/TS 19218-1) <2>, <3>	
Initial corrective actions performed by the manufacturer <1>, <2>	
Supposed date of the subsequent report <1>, <2>	
10. Results of final investigation of the manufacturer (for the final report)	
Results of analysis conducted by the manufacturer <3>	
Evaluation of the adverse event (incident) (code and term of level 1 - ISO/TS 19218-2)	
Evaluation of the adverse event (incident) (code and term of level 2 - ISO/TS 19218-2)	
Corrective safety actions at the local level <3>	
Timeframe of the specified measures implementation <3>	
Final comments of the manufacturer	
Is the manufacturer aware of similar adverse events (incidents) with the same type of the medical device with the similar major cause? <3>	

☐ Yes ☐ No If yes, specify in which countries and specify numbers of adverse events (incidents)
Number of similar adverse events (incidents) <3>
A medical device was sold in the following states (if any) <3>: ☐ Republic of Armenia ☐ Republic of Belarus ☐ Republic of Kazakhstan ☐ Kyrgyz Republic ☐ Russian Federation ☐ Other states (please specify)

<1> A mandatory field to be filled out for the initial report.
<2> A mandatory field to be filled out for the subsequent report.
<3> A mandatory field to be filled out for the final report.

Note. This report is not an acknowledgment of responsibility of the manufacturer or his authorized representative for the adverse event (incident) and its consequences, information contained in it might be incomplete and inaccurate. This report is not an acknowledgement that the medical device led to the supposed aggravation of the state of health or a death of the person or contributed to that.

I confirm that to the best of my knowledge the submitted information is reliable.

_____ _____ _____

(position) (signature) (initials, surname)

_____ "___" 20__

Appendix N 2
To Regulations of Medical Device Safety,
Quality and Effectiveness
Monitoring

ФОРМА
of the corrective action report по безопасности
medical device

1. Administrative information	
Competent authorities in which a report is sent <1>, <2>, <3>	Place for the mark of the competent authority (date, registration number)
Report type <1>, <2>, <3>: ☐ Initial report ☐ Subsequent report ☐ Final report	
Report date <1>, <2>, <3>	
Registration number of the corrective action report (to be assigned by the manufacturer) <1>, <2>, <3>	
Registration number of the corrective action report (to be assigned by the competent authority) <2>, <3>	
Registration number of the adverse event (incident) (to be assigned by the competent authority) <2>, <3>	
Name of the coordinating competent authority (if applicable)	
2. Information about the person submitting the report	
Status of the person submitting the report <1>, <2>, <3>: ☐ Manufacturer ☐ Authorized representative	
3. Data about the manufacturer	

Name of the manufacturer <1>, <2>, <3>	
Surname, name, patronymic (if any) of the contact person <1>, <2>, <3>	
Address <1>, <2>, <3>	
ZIP code <1>, <2>, <3>	City (town) <1>, <2>, <3>
Phone <1>, <2>, <3>	Fax (if any) <1>, <2>, <3>
E-mail <1>, <2>, <3>	Country <1>, <2>, <3>
4. Data of the authorized representative (if any)	
Name of the authorized representative <1>, <2>, <3>	
Surname, name, patronymic (if any) of the contact person <1>, <2>, <3>	
Address <1>, <2>, <3>	
ZIP code <1>, <2>, <3>	City (town) <1>, <2>, <3>
Phone <1>, <2>, <3>	Fax (if any) <1>, <2>, <3>
E-mail <1>, <2>, <3>	Country <1>, <2>, <3>
5. Data on medical device	
Potential hazard class of the medical device use <1>, <2>, <3>: ☐ 3 ☐ 2б ☐ 2а ☐ 1	
Code of the medical device type in accordance with the nomenclature of the medical devices applied in the Eurasian Economic Union <2>, <3>	
Unique medical device identifier (Unique device identifier (UDI) (if any) <2>, <3>	
Identification of the medical device <1>, <2>, <3>	
Model <2>, <3> (if applicable)	Catalogue number (if applicable) <2>, <3>
Serial number(if applicable) <2>, <3>	Batch (series) number (if applicable) <2>, <3>

Software version (if applicable) <2>, <3>	
Date of mantufacture <2>, <3>	Expiry date (if applicable) <2>, <3>
Accessories and (or) jointly used medical devices (if applicable) <2>, <3>	
Number of registration certificate in the single register of medical devices registered in the Eurasian Economic Union <1>, <2>, <3>	
Number of registration certificate in the national register of registered medical devices (if any) <2>, <3>	
6. Information about corrective actions on the medical device safety	
General information and reason of corrective actions <1>, <2>, <3>	
Description and justification of corrective actions <1>, <2>, <3>	
Recommendations for users <1>, <2>, <3>	
Measures and deadline of corrective actions implementation <2>, <3>	
Appendix to report <1>, <2>, <3>: ☐ Medical device safety notice in Russian ☐ Medical device safety notice in the national language Member states of the Eurasian Economic Union in the territory of which an adverse event (incident) occured ☐ Other	
The medical device was sold in the following states <1>, <2>, <3>: ☐ Republic of Armenia ☐ Republic of Belarus ☐ Republic of Kazakhstan ☐ Kyrgyz Republic	

☐ Russian Federation ☐ Other states (please specify)
7. Comments

<1> A mandatory field to be filled out for the initial report.
<2> A mandatory field to be filled out for the subsequent report.
<3> A mandatory field to be filled out for the final report.

Note. This report is not an acknowledgment of responsibility of the manufacturer or his authorized representative for the adverse event (incident) and its consequences, information contained in it might be incomplete and inaccurate. This report is not an acknowledgement that the medical device led to the supposed aggravation of the state of health or a death of the person or contributed to that.

I confirm that to the best of my knowledge the submitted information is reliable.

_____ _____ _____
(position) (signature) (initials, surname)

_____ "___" 20__

Appendix N 3
To Regulations of Medical Device Safety,
Quality and Effectiveness
Monitoring

BLANK OF
The adverse event (incident) notice related to the medical device use

1.	a) name of the person (an entity of the medical device circulation) submitting a notice	
	b) address	
	c) contact phone, fax	
2.	a) name medical device	
	b) model	
	c) serial number	
	d) batch or series number	
	e) registration certificate number	

3.	a) name of the manufacturer	
	b) address (if information is available)	
4.	a) name of the supplier (if information is available)	
	b) contact info (address, phone)	
5.	Medical device production date (day/month/year)	
6.	Expiry date (day/month/year) (if information is available)	
7.	Warranty period termination and expiry date set by the manufacturer (day/month/year) (if information is available)	
8.	Date of identification of serious and (or) unexpected side effects, adverse reactions, disadvantages, failures or discrepancies (day/month/year)	
9.	Category of the adverse event (incident) related to use of the medical device (to select the required option): ☐ Serious and (or) unexpected side reaction not specified in the instruction manual or in the directions for use of the medical device ☐ Side effects during operation of the medical device ☐ Peculiarities of medical devices interaction ☐ Unduly quality of the medical device ☐ Circumstances creating hazard to life and health of the population and medical personnel when medical devices are used and operated ☐ Other cases of the adverse event (incident)	
10.	Measures to eliminate the adverse event (incident) taken by the user or the medical organization	
11.	Harm caused	
12.	Remark	

I guarantee consistency of data contained in this notice.

Appendix: copies of documents attesting the adverse event (incident), on ___ sheets in 1 copy.

A person sending the notice:

_____ _____ _____

(position) (signature) (initials, surname)

Stamp here (if any)

_____ "___", 20___

Appendix N 4
To Regulations of Medical Device Safety, Quality and Effectiveness Monitoring

BLANK OF MEDICAL DEVICE SAFETY NOTICE

MEDICAL DEVICE SAFETY NOTICE	
N _____	Date: _____

Type of corrective action:

☐ Suspension of the medical device use

☐ Replacement of the medical device by the manufacturer or by its authorized representative

☐ Return of the medical device to the manufacturer or its authorized representative

☐ On-site medical device modernization

☐ Destruction of the medical device

☐ Change of the instructions for use or instruction manual for the medical device

☐ Software renewal

☐ Other	
Medical device Design variant/model/serial number/catalogue number (as applied):	
Registration certificate number:	
Description of the problem:	
Description of actions that the user of the medical device must perform:	
Indication about the necessity of the submission of the notice to persons who must be informed about the problem and (or) must perform corrective actions:	
Indication about necessity to submit to the manufacturer (an authorized representative of the manufacturer) of the information about medical devices sent to other organizations and submission of the notice to these organizations (if any):	
Contact information	
Surname, name, patronymic (if any) of the person who sent the notice <1>, <2>, <3>	
Address <1>, <2>, <3>	
ZIP code <1>, <2>, <3>	City (town) <1>, <2>, <3>
Phone <1>, <2>, <3>	Fax (if any) <1>, <2>, <3>
E-mail <1>, <2>, <3>	Country <1>, <2>, <3>

I confirm that the respective competent authority was informed about this problem and about this medical device safety notice.

_____ _____ _____

(position) (signature) (initials, surname)

Stamp here

_____ "_____" 20__

Appendix N 5
To Regulations of Medical Device Safety,
Quality and Effectiveness
Monitoring

BLANK OF
Post-Marketing Medical Device Safety and Effectiveness Clinical Monitoring

1. Administrative information	
Competent authority	Place for the mark of the competent authority (date, registration number)
Address of the competent authority	
Report type: ☐ Initial report ☐ Subsequent report ☐ Final report	
Report date	
Registration number report (to be assigned by the manufacturer)	
Registration number report (to be assigned by the competent authority)	
2. Information about the person submitting the report	
Status of the person submitting the report: ☐ Manufacturer ☐ Authorized representative	
3. Information about the manufacturer	
Name of the manufacturer	

Surname, name, patronymic (if any) of the contact person	
Address	
ZIP code	City (town)
Phone	Fax (if any)
E-mail	Country
4. Information about the authorized representative (if any)	
Name of the authorized representative	
Surname, name, patronymic (if any) of the contact person	
Address	
ZIP code	City (town)
Phone	Fax (if any)
E-mail	Country
5. Information about the medical device	
Potential hazard class of the medical device use: ☐ 3, not implanted ☐ 3, implanted ☐ 2б, implanted	
Code of the medical device type in accordance with the nomenclature of medical devices used in the Eurasian Economic Union	
Name of the medical device	
Options of design (modification) of the medical device	
Registration certificate number in the single register of medical devices registered in the Eurasian Economic Union	
6. List of identified residual risks related to the medical device	
7. Objectives and tasks of the post-marketing clinical medical device safety and effectiveness monitoring	
8. Scheme of the post-marketing clinical medical device safety and effectiveness monitoring	

9. Clinical data received in the reporting period
10. Evaluation of clinical data received in the reporting period
11. Evaluation of all clinical data received during the post-marketing clinical medical device safety and effectiveness monitoring
12. Conclusion about necessity (no necessity) to correct a plan of the post-marketing clinical medical device safety and effectiveness monitoring
13. Conclusion about necessity (no necessity) of the medical device safety corrective actions performance
14. Description of the medical device safety corrective actions (if any)
15. Conclusion (substantiation) of the medical device clinical safety and effectiveness
16. Conclusion about necessity (no necessity) to extend the cycle of the post-marketing clinical medical device safety and effectiveness monitoring (for the final report)
17. Comments

I confirm that to the best of my knowledge the submitted information is reliable.

_____ _____ _____

(position) (signature) (initials, surname)

Stamp here

_____ “___” 20 ___