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EURASIAN ECONOMIC COMMISSION
BOARD

DECISION

December 22, 2015 **No. 174** city of Moscow

On Approval of Rules for the Monitoring of Safety, Quality and Efficacy of Medical Products

In accordance with paragraph 2 of Article 31 of the Treaty on the Eurasian Economic Union dated May 29, 2014, paragraph 2 of Article 8 of the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Medical Equipment) within the Eurasian Economic Union dated December 23, 2014, paragraph 25 of Annex No. 2 to the Rules of Procedure of the Eurasian Economic Commission approved by Decision No. 98 of the Supreme Eurasian Economic Council dated December 23, 2014, and in order to implement Decision No. 109 of the Supreme Eurasian Economic Council dated December 23, 2014 "On Implementation of the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Medical Equipment) within the Eurasian Economic Union", the Board of the Eurasian Economic Commission **decided:**

1. To approve the attached Rules for the Monitoring of Safety, Quality and Efficacy of Medical Products.

2. This Decision shall enter into force after 30 calendar days have elapsed from the effective date of the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Medical Equipment) within the Eurasian Economic Union dated December 23, 2014 or of the Protocol signed on December 2, 2015 on the accession of the Republic of Armenia to the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Medical Equipment) within the Eurasian Economic Union dated December 23, 2014, whichever comes later, but not earlier than after 30 calendar days have elapsed from the date of the official publication of this Decision.

Chairman of the Board
of the Eurasian Economic Commission V. Khristenko

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Eurasian Economic Commission. For documents

APPROVED
by Decision No. 174 of the Board of
the Eurasian Economic Commission
dated December 22, 2015

RULES
for monitoring of safety, quality and efficacy of medical products

1. These Rules are developed in accordance with paragraph 2 of Article 31 of the Treaty on the Eurasian Economic Union dated May 29, 2014 and paragraph 2 of Article 8 of the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Medical Equipment) within the Eurasian Economic Union dated December 23, 2014 and establish a procedure for the monitoring of safety, quality and efficacy of medical products (hereinafter referred to as the monitoring).

2. The purposes of the monitoring are to ensure safety of users, preserve and improve public health, improve quality of medical care, identify and prevent side effects and adverse reactions not listed in the instruction for use or operation manual of the medical product (hereinafter referred to as the instruction for use), adverse events (incidents), circulation of medical products that do not comply with the General Requirements for Safety and Efficacy of Medical Products, Requirements for Their Marking and Operational Documentation for Them approved by the Eurasian Economic Commission.

3. The monitoring includes collection, recording, analysis of the information on undesirable events (incidents) and adoption of appropriate decisions.

4. The monitoring is based on:

a) analysis of reports of adverse events (incidents) at all stages of circulation of medical products within the Eurasian Economic Union (hereinafter referred to as the Union), received:

from users of medical products;

from manufacturers of medical products;

when performing control (supervision) over medical product circulation by the authorized authorities of the Member States of the Union;

b) analysis of periodic reports of safety an clinical efficacy of medical products of class 3 of potential risk of use, as well as medical products of classes 2b and 3 of potential risk of use implantable into the human body at the post-authorization stage, medical products obtained from manufacturers or from their authorized representatives;

c) system of collection and analysis of data of manufacturers of medical products on safety and efficacy of medical products at post-authorization stage and corrective actions in accordance with the requirements to implementation, maintenance and evaluation of medical product quality management system depending on the potential risk of use, approved by the Eurasian Economic Commission.

5. For the purposes of these Rules the concepts are used having the following meanings:

“corrective action” - action taken by the manufacturer of the medical product in order to eliminate reasons of the detected incompliance or undesirable event;

“corrective action for medical product safety” – action taken by the manufacturer of the medical product in order to reduce the risk of death or serious deterioration of health of users and third persons, associated with the medical product. Such actions can include:

return of the medical product to the manufacturer of medical products or his authorized representative;

modification of medical products (modernization in accordance with changes made by the manufacturer of medical products, in the medical product construction, change of the instruction for use, update of the medical product software);

medical product replacement;

withdrawal of the medical product from circulation;

medical product destruction;

informing on actions of users of medical products In case the medical product is withdrawn from circulation, but there is a possibility to use it;

“adverse event (incident)” - any malfunction and (or) deterioration in performance, or malfunction of the medical product, or inadequacy or incorrectness of the supporting information (documentation) for the medical product or side effect not specified in the instruction for use which, directly or indirectly resulted in or could lead to death or serious deterioration in health of users or third persons (while a serious deterioration in health is understood as life-threatening disease, permanent damage of body function or irreparable damage of the body structure, condition requiring medical or surgical intervention to prevent a life-threatening disease, or permanent damage of the body function, or irreparable damage of the body structure, condition requiring hospitalization or significant increase of the period of stay in the hospital of the already hospitalized patient, functional impairment in the fetus, its death, congenital anomaly or birth trauma);

“undesirable event” - any undesirable medical event, unpredictable disease or damage or undesirable clinical signs (including laboratory indicators other than the norm) from users or third persons associated with the use of the medical product;

“user” - a patient, medical specialist or any other natural person who uses a medical product for the purpose as determined by the manufacturer of medical products;

“reference state” – a Member State of the Union chosen by the applicant, the authorized authority of which registers the medical product;

“serious health threat” - any malfunction and (or) deterioration in performance, or malfunction in the operation of the medical product, or inadequacy or incorrectness of the supporting information (documentation) for the medical product or side effect not specified in the instruction for use that led or can lead to the imminent risk of death, life-threatening disease, irreparable damage to the body function, irreparable damage to the body structure or condition requiring medical or surgical intervention in order to prevent irreparable damage to the body function or irreparable damage to the body structure, and which require urgent medical actions;

“supporting information (documentation)” - marking, instruction for use and other information related to identification, description, designation, rules for the operation of the medical product, except for shipping documents;

“subjects of medical product circulation” - organizations incorporated in accordance with the established procedure in the Member States of the Union, or representations of foreign organizations accredited in accordance with the established procedure in the Member States of the Union, or individual entrepreneurs registered in the Member States of the Union, or natural persons performing technical testing, trials (studies) to evaluate biological action, clinical trials, examination of safety, quality and efficacy of medical products, their registration, production (manufacture), storage, transportation, sale, installation, commissioning, use (operation), maintenance, repair, and disposal;

“notice of medical product safety” – a report sent by the manufacturer of medical products or his authorized representative to the subjects of medical product circulation in connection with the corrective action for medical product safety;

“authorized representative of the manufacturer” – a juridical or natural person registered as an individual entrepreneur who are residents of the Member State of the Union, authorized by a power of attorney of the manufacturer of the medical product to represent his interests and be responsible for circulation of medical products within the Union and compliance with mandatory requirements, presented to medical products.

6. The manufacturer of medical products or his authorized representative is obliged to submit to the authorized authority of the Member State of the Union in the territory of which the adverse event (incident) occurred, a report on the adverse event (incident) (hereinafter referred to as the incident report) and a report of corrective actions for the medical product safety (hereinafter –

referred to as the report of corrective actions) on the forms according to Annex No. 1 and Annex No. 2 by filling them on the information resource of the authorized authority of the Member State of the Union in the information and telecommunications network Internet (hereinafter referred to as the Internet).

The initial incident report is sent within the following periods:

in case of a serious threat to health -immediately (without undue delay), but not later than 2 calendar days after the manufacturer of the medical products became aware of the threat;

in case of death or unforeseen serious deterioration of the user's health - immediately (without undue delay) after the manufacturer of medical products has established a connection between the use of the medical product and the event that has occurred, but not later than 10 calendar days after the manufacturer of medical products has become aware of the event;

in other cases - immediately (without undue delay) after manufacturer of medical products has established a connection between the use of the medical product and the event that occurred, but not later than 30 calendar days after the manufacturer of medical products became aware of the event.

Medical organizations which conduct activities in the field of medical products circulation should inform the manufacturer of medical products or his authorized representative about undesirable events that have signs of an adverse event (incident), and also provide access to medical products to which these events can relate.

Reports of an adverse event (incident) are sent to the authorized authority of the Member State in territory of which the event occurred, by any subjects of medical product circulation, including those using them (by users, health organizations), in the form of notice of an adverse event (incident) in accordance with Annex No. 3. The notice is completed in a typewritten or manuscript manner in the Russian language and (or) national language of the Member State of the Union.

The notice contains reliable information, confirmed by the relevant documents, copies of which are attached to the notice.

7. The authorized authority of the Member State of the Union in the territory of which the adverse event (incident) occurred registers the submitted initial report of the incident, informs the manufacturer of medical products or his authorized representative about the receipt of this report and coordinates the terms of submission of the subsequent or final report of the incident, as well as time of submission of the initial, subsequent (if necessary) and final reports of corrective actions with him.

The manufacturer of medical products or his authorized representative is entitled to carry out corrective actions before sending the initial report of corrective actions in emergency cases of protection of users or third parties from the threat of death or serious deterioration of health to the authorized authority of the Member State of the Union in the territory of which the adverse event (incident) occurred. In this case, the initial report of corrective actions should be sent to the authorized authority of the Member State of the Union not later than 2 calendar days after the manufacturer of medical products or his authorized representative carried out corrective actions.

8. In case the manufacturer of medical products or his authorized representative does not have opportunity to conduct an investigation of an adverse event (incident), he must immediately notify the authorized authority of the Member State of the Union in the territory of which the specified event (incident) occurred.

9. The manufacturer of medical products or his authorized representative has a right to apply to the authorized authority of the Member State of the Union in the territory of which an adverse event (incident) occurred, for assistance in accessing the medical product to determine connection of the medical product with an undesirable event and compliance of the undesirable event with the criteria of the adverse event (incident) as soon as possible.

10. In case several manufacturers of medical products are involved in the investigation of the adverse event (incident), the authorized authority of the Member State of the Union should coordinate their actions.

11. The authorized authority of the Member State in the territory of which an adverse event (incident) occurred, should inform the manufacturer of the medical products or his authorized representative and authorized authorities of other Member States of the Union of the outcome of the examination of the specified reports within at most 30 working days from the date of receipt of the final incident report from the manufacturer of the medical product or his authorized representative, final report on corrective actions.

Authorized authorities of the Member States of the Union are informed using the information system of the Union in the field of medical product circulation.

12. Based on the results of corrective actions for safety of the medical product, the manufacturer of medical products or his authorized representative is obliged to issue a notice of the medical product safety in the form according to Annex No. 4 and deliver it to the users.

13. Incident reports, corrective action reports and notice of the medical product safety are placed in a common information database of monitoring of safety, quality and efficacy of medical products by the authorized authority of the Member State of the Union in the territory of which the adverse event (incident) occurred.

14. With respect to adverse events (incidents) associated with medical products registered in the territory of the Union and occurred in the states which are not members of the Union, the manufacturer of medical products or his authorized representative should send notices of the safety of medical products to the authorized authorities of the reference state.

The authorized authority of the reference state places the received notice of the safety of the medical product in a common information database of monitoring of safety, quality and efficacy of medical products.

15. Incident reports cannot be submitted to the authorized authority of a Member State of the Union:

a) on each individual adverse event (incident) from those described in notices of the medical product safety and occurred after the investigation of adverse events (incidents) and distribution of such notices and taking corrective actions by the manufacturer of medical products or his authorized representative. Instead of this, the manufacturer of medical products or his authorized representative can coordinate the possibility of periodical submission of summary reports on the indicated adverse events (incidents), as well as their content and terms of submission with the authorized authority of the Member State of the Union;

b) on each individual adverse event (incident) from the number of frequently occurring and documented adverse events (incidents) (identified as such in the analysis of risks associated with the medical device, which have already been reported, analyzed by the manufacturer of medical devices or his authorized representative and the authorized body). Instead, periodic summary reports are allowed. The content and deadlines for the submission of periodic summary reports must be agreed with the authorized body of the Member State of the Union;

c) on adverse events (incidents) related to obvious defects of medical products that the user can always identify immediately before using the medical product;

d) on adverse events (incidents) that did not lead to serious deterioration of health or death due to the design features protecting against the occurrence of threat due to a malfunction of the medical product;

e) on expected and foreseeable adverse events (incidents) that simultaneously satisfy all of the following criteria:

adverse events (incidents) are clearly indicated in the supporting information (documentation) for the medical product;

adverse events (incidents) are well known in clinical practice, they can be quantitatively and quantitatively predicted In case the medical product is used and operates in accordance with its purpose;

adverse events (incidents) are documented in the technical documentation for the medical product with an appropriate risk assessment conducted before the adverse event (incident) occurred;

adverse events (incidents) are clinically acceptable in terms of usefulness of the medical product for each individual patient;

f) if the risk of death or serious deterioration of health has been analyzed and recognized to be negligible, if neither death nor serious deterioration of health has occurred and the risk has been characterized and documented as permissible in the risk analysis report presented in the registration dossier at the time of the medical product registration.

16. The manufacturer of medical products or his authorized representative notifies the competent authority of the Member State of the errors made during the use of medical products which resulted in death or serious deterioration of the user's health.

17. When receiving information on undesirable events from the authorized authority of the Member State of the Union, the manufacturer of medical products or his authorized representative should check the received information for compliance with the criteria of the adverse event (incident) and forward incident and corrective actions reports to the authorized authority of the Member State of the Union in the territory of which the undesirable event occurred.

If, in the opinion of the manufacturer of medical devices or his authorized representative, an undesirable event does not meet the criteria for an adverse event (incident), the manufacturer of medical devices or his authorized representative must present to the authorized body of the Member State in whose territory the undesirable event occurred, the justification that this event is not an adverse event (incident).

18. The notice of the medical product safety is sent by the manufacturer of medical products or his authorized representative using information and telecommunications means, ensuring its receipt by concerned organizations with the confirmation of receipt.

19. For medical products of class 3 of the potential risk of use, as well as implantable medical products of class 2b of the potential risk of use, the manufacturer of medical products or his authorized representative is obliged to conduct post-authorization clinical monitoring of safety and efficacy of medical products (hereinafter referred to as the post-authorization clinical monitoring) and annually, within 3 years, submit reports on the post-authorization clinical monitoring to the authorized authority of the reference state.

The initial, subsequent and final reports on post-authorization clinical monitoring are submitted to the authorized authority of the reference state by the manufacturer of medical products or his authorized representative not later than on February 1, starting from the year following the year of receipt of the registration certificate.

20. Post-authorization clinical monitoring is conducted in accordance with the plan included in the report on clinical evidence of efficacy and safety of the medical product, submitted by the manufacturer of the medical product or his authorized representative as part of the registration dossier when registering the medical product.

21. The post-authorization clinical monitoring plan should contain:

a) purposes and tasks of post-authorization clinical monitoring, taking into account available clinical data, specific features and risk factors associated with the medical product;

b) the scheme of post-authorization clinical monitoring, including justification of methods (ways) of receipt and statistical analysis of clinical data, selection of the test population, inclusion (exclusion) criteria and the minimum number of subjects in the test group and, where applicable, the need to include comparison groups into the study.

22. Reports on post-authorization clinical monitoring of safety and efficacy of medical products in accordance with Annex No. 5 are submitted by the manufacturer of medical products or his authorized representative to the authorized authority of the reference state using the information resource of the authorized authority of the reference state in the Internet.

23. The authorized authority of the reference state has a right to involve an expert organization to analyze reports on post-authorization clinical monitoring. On the basis of the expert opinion, the authorized authority of the reference state has a right to take a decision on the need to take corrective actions by the manufacturer of medical products.

24. Reports on post-authorization clinical monitoring are sent for examination by the authorized authority of the reference state to the expert organization.

25. The expert organization sends an opinion on possibility (impossibility) of completion of post-authorization clinical monitoring to the authorized authority of the reference state within at most 20 working days from the date of receipt of the report on post-authorization clinical monitoring.

26. On the basis of the expert opinion, the authorized authority of the reference state takes one of the following decisions:

a) on completion of post-authorization clinical monitoring;

b) on extension of post-authorization clinical monitoring with indication of an additional period if the data obtained is not sufficient to confirm safety and efficacy of the medical product or the manufacturer of medical products did not take necessary corrective actions based on the data obtained;

c) on suspension of the registration certificate of the medical product and extension of post-authorization clinical monitoring with indication of the additional period;

d) on cancellation (revocation, withdrawal) of the registration certificate and, if necessary, withdrawal of the medical product from circulation.

27. The authorized authority of the reference state should notify the manufacturer of medical products about the decision within at most 10 working days from the date of its adoption in accordance with paragraph 26 of these Rules.

28. In case the manufacturer of medical products or his authorized representative became aware of an adverse event (incident), but he did not inform about this the competent authority of the Member State of the Union in the territory of which the adverse event (incident) occurred, or violated the deadlines established for the records, then the said authorized authority has the right to suspend validity of the registration certificate of the medical product issued to them and to conduct its own investigation of an adverse event (incident) to suspend or prohibit the use of the medical product in the territory of its state.

29. In case the manufacturer of medical products or his authorized representative did not submit a subsequent or final incident report to the authorized authority of a Member State of the Union in the territory of which an adverse event (incident) occurred, the authorized authority, after notification of the manufacturer of medical products or his authorized representative of this violation has a right to suspend validity of the registration certificate issued by it or to take a decision on the start of the procedure for its cancellation (revocation, withdrawal) not earlier than in 30 working days from the date of the relevant notice of the manufacturer of medical products or his authorized representative either to suspend or prohibit the use of the medical product in the territory of the state.

30. In case the manufacturer of the medical product or his authorized representative did not submit an initial, subsequent or final report on post-authorization clinical monitoring to the authorized authority of the reference state, the said authorized authority, after notifying the manufacturer of the medical product or his authorized representative of this violation, can suspend the registration certificate of the medical product or take a decision to start the procedure for its cancellation (revocation, withdrawal) not earlier than in 30 working days from the date of the relevant notification of the manufacturer of medical products or his authorized representative.

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ANNEX No. 1
to the Rules for the monitoring of
safety, quality and efficacy
of medical products

FORM
of the report on the adverse event (incident)

<table>
<tr><td colspan="2">1. Administrative information</td></tr>
<tr><td>Authorized authority[1,2,3]</td><td rowspan="2">Place for a mark of
the authorized authority
(incoming date, registration number)</td></tr>
<tr><td>Address of the authorized 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) (assigned by the manufacturer)[1,2,3]</td></tr>
<tr><td colspan="2">Registration number of the adverse event (incident) (assigned by the authorized authority)[1,2,3]</td></tr>
<tr><td colspan="2">Does an adverse event (incident) pose serious threat to public health?[1,2,3]
☐ Yes
☐ No</td></tr>
<tr><td colspan="2">Incident classification[1,2,3]
☐ Death
☐ Unpredictable serious health deterioration
☐ Other criteria</td></tr>
<tr><td colspan="2">Other authorized authorities to which the report was sent</td></tr>
<tr><td colspan="2">2. Data on the person who submits the report</td></tr>
<tr><td colspan="2">Status of the person submitting the report[1,2,3]
☐ Manufacturer
☐ Authorized representative</td></tr>
<tr><td colspan="2">3. Data on the manufacturer</td></tr>
<tr><td colspan="2">Name of the manufacturer[1,2,3]</td></tr>
<tr><td colspan="2">Surname, name, patronymic (if any) of a contact person[1,2,3]</td></tr>
<tr><td colspan="2">Address[1,2,3]</td></tr>
<tr><td>Zip code[1,2,3]</td><td>City[1,2,3]</td></tr>
<tr><td>Telephone[1,2,3]</td><td>Fax (if any) [1,2,3]</td></tr>
<tr><td>E-mail[1,2,3]</td><td>Country[1,2,3]</td></tr>
</table>

4. Data of the authorized representative (if any)	
Name of the authorized representative[1,2,3]	
Surname, name, patronymic (if any) of a contact person[1,2,3]	
Address[1,2,3]	
Zip code[1,2,3]	City[1,2,3]
Telephone[1,2,3]	Fax (if any) [1,2,3]
E-mail[1,2,3]	Country[1,2,3]
5. Data on the medical product	
Class of the potential risk of use of the medical product[1,2,3] ☐3 ☐2b ☐2a ☐1	
Code of the type of the medical product in accordance with the nomenclature of medical products used in the Eurasian Economic Union[2,3]	
Unique device identifier (UDI) (if any) [1,2,3]	
Medical product name[1,2,3]	
Model (if applicable) [2,3]	Catalogue number (if applicable)[2,3]
Serial number (if applicable) [2,3]	Batch (lot) number (if applicable) [2,3]
Software version (if applicable)[2,3]	
Date of release[2,3]	Expiration date (if applicable)[2,3]
Date of implantation (only for implants)[2,3]	Date of explantation (only for implants)[2,3]
Duration of implantation (it is completed if the exact date of implantation or operation start is known)[2,3]	
Accessories and (or) jointly used medical products (if applicable) [1,2,3]	
Number of the registration certificate in the unified register of medical products, registered within the Eurasian Economic Union[1,2,3]	
Number of the registration certificate in the national register of the registered medical products (if any) [2,3]	
6. Data on the adverse event (incident)	
Date of the adverse event (incident) occurrence[2,3]	
Adverse event (incident) description[1,2,3]	
Number of the report of the medical organization-user (if applicable) [2,3]	
Data of receipt of the information on adverse event (incident) by the manufacturer[1,2,3]	
Number of the patients involved (if known)	Number of the medical products involved (if

[2,3]	known) [2,3]
Location of the medical product at this moment (if known) [1,2,3]	
Who used the medical product at the moment of the adverse event (incident) (choose one) [2,3] ☐Medical personnel ☐Patient ☐Other	
Use of the medical product (choose one) [2,3] □ primary use □ repeated use of a single-use medical product □ repeated use of a multiple-use medical product □ medical product after maintenance or repair □ other □ the problem was detected prior to the use	
7. Data on the patient	
Description of a patient's problem[2,3]	
Code and term of a patient's problem with regard to adverse event (incident) in accordance with the International Statistical Classification of Diseases and Related Health Problems of 10th revision (ICD-10)[3]	
Country of adverse event (incident) occurrence[1,2,3]	
Actions and help rendered to the patient by the medical organization[2,3]	
Gender (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. Data on the medical organization (if applicable)	
Medical organization name[1,2,3]	
Surname, name, patronymic of a contact person of the medical organization[2,3]	
Address[1,2,3]	
Zip code[1,2,3]	City[1,2,3]
Telephone[1,2,3]	Fax (if any) [1,2,3]
E-mail[1,2,3]	Country[1,2,3]
Preliminary opinion of the manufacturer (for initial/subsequent report)	
Preliminary analysis performed 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, taken by the manufacturer[1,2]
Provisional date of the next report[1,2]
10. Results of the final investigation of the manufacturer (for a final report)
Results of the analysis performed 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 action for safety in situ[3]
Period of implementation of the specified arrangements[3]
Final remarks of the manufacturer
Does the manufacturer know about similar adverse events (incidents) with the same type of medical products with the same main problem?[3] ☐Yes ☐No If yes, indicate in what countries and indicate numbers of adverse events (incidents)
Number of similar adverse events (incidents)[3]
The medical product was distributed in the following states (if any)[3] □ Republic of Armenia □ Republic of Belarus □ Republic of Kazakhstan □ Kyrgyz Republic □ Russian Federation □ Other states (indicate)

[1] Mandatory field in case of the initial report
[2] Mandatory field in case of the subsequent report
[3] Mandatory field in case of the final report

Note. This report is not admission of responsibility of the manufacturer or his authorized representative for occurred adverse event (incident) and its consequences, the information contained in it can be incomplete and inaccurate. This report is also not an admission that the medical product described in the report was defective and that the medical product caused supposed health deterioration or death of a person or contributed to it.

I confirm that, to the best of my knowledge, the presented information is correct.

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

_____ "____", 20_____

ANNEX No. 2
to the Rules for the monitoring of
safety, quality and efficacy
of medical products

FORM
of the report on corrective actions
for medical product safety

1. Administrative information	
Authorized authorities to which a report is sent[1,2,3]	Place for mark of the authorized authority (incoming date, registration number)
Report type[1,2,3]: ☐Initial report ☐Subsequent report ☐Final report	
Report date[1,2,3]	
Registration number of the report on corrective actions (assigned by the manufacturer)[1,2,3]	
Registration number of the report on corrective actions (assigned by the authorized authority)[2,3]	
Registration number of the report on corrective actions (assigned by the authorized authority)[2,3]	
Name of a coordinating authorized authority (if applicable)	
2. Data on the person who submits the report	
Status of the person submitting the report[1,2,3] ☐ Manufacturer ☐ Authorized representative	
3. Data on the manufacturer	
Name of the manufacturer[1,2,3]	
Surname, name, patronymic (if any) of a contact person[1,2,3]	
Address[1,2,3]	
Zip code[1,2,3]	City[1,2,3]
Telephone[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 a contact person[1,2,3]	
Address[1,2,3]	
Zip code[1,2,3]	City[1,2,3]
Telephone[1,2,3]	Fax (if any) [1,2,3]

E-mail[1,2,3]	Country[1,2,3]
5. Data on the medical product	
Class of the potential risk of use of the medical product[1,2,3] ☐3 ☐2b ☐2a ☐1	
Code of the type of the medical product in accordance with the nomenclature of medical products used in the Eurasian Economic Union[2,3]	
Unique device identifier (UDI) (if any) [1,2,3]	
Medical product name[1,2,3]	
Model (if applicable) [2,3]	Catalogue number (if applicable)[2,3]
Serial number (if applicable) [2,3]	Batch (lot) number (if applicable) [2,3]
Software version (if applicable)[2,3]	
Date of release[2,3]	Expiration date(if applicable)[2,3]
Date of implantation (only for implants)[2,3]	Date of explantation (only for implants)[2,3]
Accessories and (or) jointly used medical products (if applicable) [2,3]	
Number of the registration certificate in the unified register of medical products, registered within the Eurasian Economic Union[1,2,3]	
Number of the registration certificate in the national register of the registered medical products (if any) [2,3]	
6. Data on corrective action for medical product safety	
General data and reason of corrective actions[1,2,3]	
Description and justification of corrective actions[1,2,3]	
Recommendations for users[1,2,3]	
Arrangements and deadlines of implementation of corrective actions[2,3]	
Annex to the report[1,2,3] □ Notice of medical product safety in Russian □ Notice of medical product safety in sate language of a Member State of the Eurasian Economic Union in the territory of which an adverse event (incident) occurred □ Other	
The medical product was distributed in the following states (if any)[3] □ Republic of Armenia □ Republic of Belarus □ Republic of Kazakhstan	

□ Kyrgyz Republic □ Russian Federation □ Other states (indicate)
7. Comments

[1] Mandatory field in case of the initial report
[2] Mandatory field in case of the subsequent report
[3] Mandatory field in case of the final report

Note. This report is not admission of responsibility of the manufacturer or his authorized representative for occurred adverse event (incident) and its consequences, the information contained in it can be incomplete and inaccurate. This report is also not an admission that the medical product described in the report was defective and that the medical product caused supposed health deterioration or death of a person or contributed to it.

I confirm that, to the best of my knowledge, the presented information is correct.

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

_____ "____", 20_____

ANNEX No. 3
to the Rules for the monitoring of
safety, quality and efficacy
of medical products

FORM
of the notification of an adverse event (incident)
associated with the medical product use

1.	a) name of a person (subject of circulation of medical products), sending a notice	
	b) address	
	c) contact phone, fax	
2.	a) medical product name	
	b) model	
	d) serial number	
	e) batch or lot number	
	f) 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) contacts (address, phone)	
5.	Date of medical product manufacture (day/month/year)	
6.	Expiration date (day/month/year) (if information is available)	
7.	Date of expiration of guarantee or operational period established by the manufacturer (day/month/year) (if information is available)	
8.	Date of detection of serious and (or) unforeseen adverse reactions, adverse events, defects, malfunctions or incompliances (day/month/year)	
9.	Category of the adverse event (incident) associated with the use of the medical product (chose the necessary): □ serious and (or) unforeseen adverse reaction not specified in the instruction for use or operational manual of the medical product □ adverse event when using the medical product □ properties of interaction of medical products □ inadequate quality of the medical product □ circumstances, creating threat to life and health of the population and medical workers when using and operating medical products □ other cases of adverse event (incident)	
10.	Measures to eliminate adverse event (incident) taken by the user or medical organization	
11.	Damaged caused	
12.	Note	

I guarantee the reliability of the information contained in this notification.
Annex: copies of documents confirming adverse event (incident), on _____ sheets in 1 counterpart.

The person sending the notification:

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

L. S. (if any)

_____ "____", 20_____

ANNEX No. 4
to the Rules for the monitoring of
safety, quality and efficacy
of medical products

FORM
of medical product safety notice

NOTICE ON MEDICAL PRODUCT SAFETY	
No._____	Date:_____
Type of the corrective action: □ Suspension of medical product use □ Replacement of the medical product by the manufacturer or his authorized representative □ Return of the medical product to the manufacturer or his authorized representative □ Medical product in situ modernization □ Medical product destruction □ Change of instructions for use or operational manual of the medical product □ Software updating □ Other	
Medical product name Version/model/serial number, catalogue number (if applicable):	
Registration certificate number:	
Problem description:	
Description of actions which should be taken by the user of the medical product	
An indication on the need to send a notice to persons who need to be informed about the problem and (or) should take corrective actions:	
An indication on the need to provide the manufacturer (the authorized representative of the manufacturer) with information on medical products sent to other organizations and transfer of the notice (if any) to these organizations:	
Contact information	
Surname, name, patronymic (if any) of the person sending a notice[1,2,3]	
Address[1,2,3]	
Zip code[1,2,3]	City[1,2,3]
Telephone[1,2,3]	Fax (if any) [1,2,3]
E-mail[1,2,3]	Country[1,2,3]

I confirm that the relevant authorized authority has been informed of this problem and of this notice on the medical product safety.

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

L. S.

_____ "____", 20_____

ANNEX No. 5
to the Rules for the monitoring of
safety, quality and efficacy
of medical products

FORM
of the report on post-authorization clinical monitoring
of safety and efficacy of the medical product

<table>
<tr><td colspan="2">1. Administrative information</td></tr>
<tr><td>Authorized authority
Address of the authorized authority</td><td>Place for a mark of
the authorized authority
(incoming date, registration number)</td></tr>
<tr><td colspan="2">Report type
☐Initial report
☐Subsequent report
☐Final report</td></tr>
<tr><td colspan="2">Report date</td></tr>
<tr><td colspan="2">Registration number of the report (assigned by the manufacturer)</td></tr>
<tr><td colspan="2">Registration number of the report (assigned by the authorized authority)</td></tr>
<tr><td colspan="2">2. Data on the person who submits the report</td></tr>
<tr><td colspan="2">Status of the person submitting the report
☐ Manufacturer
☐ Authorized representative</td></tr>
<tr><td colspan="2">3. Data on the manufacturer</td></tr>
<tr><td colspan="2">Name of the manufacturer</td></tr>
<tr><td colspan="2">Surname, name, patronymic (if any) of a contact person</td></tr>
<tr><td colspan="2">Address</td></tr>
<tr><td>Zip code</td><td>City</td></tr>
<tr><td>Telephone</td><td>Fax (if any)</td></tr>
<tr><td>E-mail</td><td>Country</td></tr>
<tr><td colspan="2">4. Data of the authorized representative (if any)</td></tr>
<tr><td colspan="2">Name of the authorized representative</td></tr>
<tr><td colspan="2">Surname, name, patronymic (if any) of a contact person</td></tr>
<tr><td colspan="2">Address</td></tr>
<tr><td>Zip code</td><td>City</td></tr>
<tr><td>Telephone</td><td>Fax (if any)</td></tr>
<tr><td>E-mail</td><td>Country</td></tr>
</table>

5. Data on the medical product
Class of the potential risk of use of the medical product ☐3 non-implantable ☐3 implantable ☐2b implantable
Code of the type of the medical product in accordance with the nomenclature of medical products used in the Eurasian Economic Union
Medical product name
Versions (modification) of the medical product
Number of the registration certificate in the unified register of medical products, registered within the Eurasian Economic Union
6. List of the identified residual risks associated with the medical product
7. Purposes and tasks of the post-authorization clinical monitoring of safety and efficacy of the medical product
8. Scheme of the post-authorization clinical monitoring of safety and efficacy of the medical product
9. Clinical data, obtained for the reporting period
10. Evaluation of clinical data obtained for the reporting period
11. Evaluation of all clinical data obtained during post-authorization clinical monitoring of safety and efficacy of the medical product
12. Opinion on the need (no need) to correct a plan of post-authorization clinical monitoring of safety and efficacy of the medical product
13. Conclusion on the need (no need) to implement corrective actions for medical product safety
14. Description of corrective action for medical product safety (if any)
15. Conclusion (justification) on clinical safety and efficacy of the medical product (if any)
16. Conclusion on the need (no need) to extent a cycle of post-authorization clinical monitoring of safety and efficacy of the medical product (for the final report)
17. Comments

I confirm that, to the best of my knowledge, the presented information is correct.

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

L. S.

_____ "____", 20_____