



**Technical Regulations
of Common Economic Space of the Republic of
Belarus, Kazakhstan and Russian Federation
"On Medical Products Safety".**

(at the suggestion of the Committee for Technical Regulations, Sanitary, Veterinary and Phytosanitary Measures in Trade under the Integration Committee of the Eurasian Economic Community; twenty fifth session, clause 3.6)

“On Medical Products Safety”



Foreword

These Technical Regulations have been prepared in accordance with the Recommendations for Technical Regulations Standard Structure by Eurasian Economic Community approved by the Resolution of the Interstate Council of Eurasian Economic Community (hereinafter referred to as “the EurAsEC) No. 321 as of October 27, 2006.

These Technical Regulations are based on provisions set forth by: Agreement on the Fundamental Principles of EurAsEC member states’ Technical Regulations Harmonization as of March 24, 2005; Agreement on Concerted Policy with Respect to Technical Regulation, Sanitary and Phytosanitary Measures as of January 25, 2008; Agreement on Circulation of Products Subject to Obligatory Assessment (Confirmation) of Conformity in the Customs Territory of the Customs Union as of December 11, 2009; Agreement on Mutual Recognition of Accreditation of Certification Authorities (Assessment (Confirmation) of Conformity) and Test Laboratories (Centers) Performing Assessment (Confirmation) of Conformity as of December 11 2009; Agreement on the Customs union Committee as of October 6, 2007.

These Technical Regulations are meant for intensification of integration processes in the Customs Union and development of the Common Economic Space, as well as safe and free circulation of medical products in the Republic of Belarus, Kazakhstan and the Russian Federation.

These Technical Regulations are also based on principles and provisions set forth in the European Economic Community Directives with regard to medical products, founded on the “new approach” to technical harmonization and standardization, as well as Global Harmonization Task Force documents related to medical products.



Article 7. Registration of Medical Products and Persons Responsible for their Safety upon their Release into Free Circulation.

1. Any manufacturer releasing products into circulation under its own name shall submit the following information to the corresponding healthcare body of executive power of a Customs Union member state, where it performs its activities:

- registration address of natural person or legal entity according to the laws of the Customs Union member state;
- place of business;
- list of products distributed by it with a brief description of intended use and area of application.

The Customs Union member state's healthcare regulatory body shall be entitled, with respect to any products distributed in its territory, to require information regarding identification of such products together with the marking (label) and application data sheet (instructions).

2. In case the manufacturer distributing products under its own name is not a resident of the Customs Union member states, then it shall assign a single authorized representative responsible for the distribution of the products in the territory of the Customs Union member states. The authorized representative shall submit information specified in the first paragraph of clause 1 of this Article to a healthcare body of power in the territory where it performs its business.

3. Based on the request, healthcare regulatory bodies shall submit information specified in the first paragraph of clause 1 of this Article to other healthcare regulatory bodies of the Customs Union member states, as well as to the Committee founded pursuant to Article 11.

4. The manufacturer shall inform its authorized representative regarding all supplies of its medical products to the territory of the Customs Union member states.

5. The authorized representative shall prepare and regularly update the list of importers supplying the products to the Customs union member states it is responsible for, and, upon a request, submit the corresponding information to healthcare regulatory bodies.

V. Unified Rules for Identification of Medical Equipment and Medical Products, Procedure, Forms and Schemes for Confirmation of Medical Products Conformity, Including Methods of Conducting and Means of Confirmation, Declaration, and Obligatory Certification.

Article 12. Medical Products Identification Rules

1. Medical products identification shall be performed by the manufacturer via establishing conformity of identified objects to essential features of "Medical Products" term specified in clause 2 paragraph 1 on the basis of evidence (clinical data) available to the manufacturer.

2. Identification of a medical product being an object of the technical regulation shall be performed in the course of the following processes:



- a) assessment (confirmation) of medical products conformity, in the form of declaration made by the manufacturer or its authorized representative prior to release or putting into operation;
- b) assessment (confirmation) of medical products conformity in the form of certification done by an appointer certification body prior to the release;
- c) state control (supervision) over the compliance with the requirements of these Technical Regulations at the stage of distribution.

Article 13. Classification of Medical Products

1. In order to determine forms and schemes for the confirmation of conformity with the requirements of these Technical Regulations the Products are divided into classes according to the potential risk of use.
2. Depending on the level of potential risk of use, the products are divided into the following classes: 1, 2a, 2b and 3. The higher the class number, the higher the potential risk. Classification is based on the rules set forth in Schedule 2 of these Technical Regulations.
3. Disputes arising between the manufacturer and the appointed certification body due to the application of classification rules shall be settled by the healthcare regulatory body of the Customs Union member state, where the appointed certification body is registered, or NKMI.
4. For the purposes of products classification and differentiation between medical and other products, the appointed certification body shall be entitled to make a request for explanations to the healthcare regulatory body of the Customs Union member state where it is registered.

Article 14. Amendments And Exceptions form the Classification Rules.

1. In the event healthcare regulatory bodies of the Customs Union member states believe that:
 - a) application of classification rules set forth in Schedule 2 require a specific decision for the classification of a product belonging to a particular type or a category of products;or
 - b) product, or a group of products in question, contrary to the classification rules set forth in Schedule 2 shall be assigned to a different class; or
 - c) assessment of the product or group of products' conformity shall be established via determining a single suitable procedure of Article 15, or a modified procedure, then they shall be entitled to submit a justified request to the Committee to take the necessary measures.
2. The Committee shall inform the healthcare regulatory body of the Customs union member state of its decision.



Article 15. Assessment (Confirmation) of Medical Products Conformity with the Requirements of these Technical Regulations (Conformity Assessment Procedures).

1. Assessment of Medical Products conformity with the requirements set forth in these Technical Regulations shall be performed in the form of obligatory confirmation of conformity and state control (supervision).

1.1 Confirmation of conformity with the requirements of these Technical Regulations shall be performed with respect to any medical products except for the products meant for clinical trials and products for personal use.

1.2 Products for clinical trials shall comply with the provisions of Article 17 and shall be accompanied by a set form (statement) pursuant to clause 3 of Schedule 3.

1.3 Products for personal use belonging to potential risk classes 2a, 2b and 3 shall be accompanied by a set form (statement) pursuant to Schedule 8. Upon a healthcare regulatory body of the Customs Union member state's request the manufacturer or its authorized representative shall submit the list of products that have already been put into operation in their territory.

2. Confirmation of products conformity with the requirements of these Technical Regulations shall be done in the form of a declaration of conformity (hereinafter referred to as "the Declaration of Conformity") or obligatory certification.

2.1 Every type or model of a medical product shall be provided by the manufacturer prior to its release into circulation with a consolidated set of technical documentation (technical file), prepared in compliance with Schedule 5. The manufacturer or its authorized representative shall maintain, update and submit such documentation to the state control (supervision) authorities upon their request for the fulfillment of these Technical Regulations requirements. Requirements of this clause shall not apply to products meant for clinical trials.

2.2 Confirmation of conformity of 1 potential application risk class, except for products distributed in sterile conditions, shall be performed in the form of the Declaration of Conformity. The procedure for Declaration of Conformity for class 1 products, except for products distributed in sterile conditions, is set forth in Schedule 6.

2.3 Confirmation of conformity of class 1 products distributed in sterile conditions, as well as class 2a, 2b and 3 products shall be performed in the form of obligatory certification.

The selection of procedures for confirmation of conformity in the form of obligatory certification shall be done by the manufacturer or its authorized representative based on the products classification by the degree of potential application risk and limitations imposed on such procedure.

2.4 Obligatory certification of class 2b and 3 products can be performed according to the procedure set forth in Schedule 9 (complete quality assurance) or in Schedule 7 (production quality assurance).

2.5 Obligatory certification of class 2a and 2b products, except for products distributed in sterile conditions, can be performed according to the procedure associated with testing of products samples selected on the basis of statistical acceptance control from the certified batch set forth in Schedule 10 (certification of homogeneous batch).



2.6 Obligatory certification of class 1 products distributed in sterile conditions, as well as class 2a products can be performed according to the procedure set forth in Schedule 7 (production quality assurance).

3. In the event the confirmation of products conformity with the requirements of these Technical Regulations provides for the participation of the appointed certification body, the manufacturer or its authorized representative shall be entitled to refer as an applicant to any appointed body entitled to confirm conformity with the requirements of these Technical Regulations.

Work performed by the appointed body with respect to obligatory confirmation of products' conformity with the requirements of these Technical Regulations shall be paid for on the basis of the corresponding agreement with the applicant.

4. In justified cases, taking into account the selected procedure, the appointed certification body shall be entitled to request any information or data required to confirm the conformity.

5. Certificates of conformity issued by the appointed certification bodies pursuant to Schedules 9 and 7 may be valid for maximum 5 years. Certificates of conformity issued by the appointed certification bodies pursuant to Schedule 10 shall be valid for the service life of the medical product.

Article 17. Clinical trials of Medical Products

1. If a product is designed for clinical trials, the manufacturer or its authorized representative shall fulfill requirements specified in Schedule 3, and notify in written form the healthcare regulatory body of the Customs Union member state where it is planned to perform the clinical trials.

2. In the event the product belongs to class 3, or it is an implantable or an invasive long term application class 2a or 2b product, the manufacturer shall be entitled to proceed to the corresponding clinical trials only a 60-day period has passed after the notification. Within this period the healthcare regulatory bodies shall be entitled to veto the planned clinical trials due to healthcare or social policy reasons.

Healthcare regulatory bodies may give the manufacturer their approval to proceed to the clinical trials prior to the expiration of the above mentioned 60-day period if the corresponding ethics committee has made a positive decision with respect to the clinical development program, including its analysis.

3. In the event the product is not covered by clause 2, the healthcare regulatory bodies may give the manufacturer their approval to proceed to the clinical trials immediately after the notification, if the corresponding ethics committee has made a positive decision with respect to the clinical development program, including its analysis.

4. Permission mentioned in the second paragraph of clause 2 and in clause 3 of this Article may be provided by an authority subordinate to the healthcare regulatory body, on the territory of which it is planned to perform the clinical trials.

5. Clinical trials shall be conducted in compliance with the provisions of Schedule 3.



6. Member states of the Customs Union shall implement a concerted policy with respect to clinical trials on the basis of healthcare needs and implemented social policy. In case a healthcare regulatory body of a Customs Union member state makes a decision to suspend clinical trials or veto them, it shall immediately notify other healthcare regulatory bodies of the Customs Union member states thereof, including the reasons for such a decision and their explanations.

7. The manufacturer or its authorized representative shall in written (official) form notify the healthcare regulatory body of the Customs Union member state where the clinical trials are performed of their completion, including reasons for an early completion. In case early completion is related to safety aspects, then the regulatory body receiving such notification shall immediately inform other healthcare regulatory bodies of the Customs Union member states thereof.

The manufacturer or its authorized representative shall keep the written report prepared according to clause 2.3.7 of Schedule 3 and submit it to healthcare regulatory bodies upon request.

8. Provisions of clauses 1 and 2 of this Article shall not apply if clinical trials are conducted with respect to products that have passed confirmation of conformity procedures set forth in Article 15 and have been marked with a uniform sign of distribution in the market, unless the objective of the trials is to expand the limits of intended use.

VII. Marking of Products with a Uniform Sign of Distribution in the Market.

Article 20. Marking of Products with a Uniform Sign of Distribution in the Marking

1. Products, except for products meant for individual use or clinical trials, may be released for distribution in a Customs Union member state in case they are marked with a uniform sign of distribution in the market that confirms the product have passed assessment (confirmation) of conformity procedures set forth by these Technical Regulations.

2. Uniform distribution marking shall be clearly visible, readable, inerasable and located on the product or, if possible, on the package and in the instructions for use. If possible the marking shall be applied on consumer and group package.

The marking shall be accompanied by an identification number of the appointed body that has performed the assessment (confirmation) of conformity with the requirements of these Technical Regulations.

3. It is prohibited to apply identification or inscriptions that can mislead consumers or third parties with respect to the meaning or graphical image of the uniform market distribution mark. It is allowed to apply any other marking on the product, package or instructions, provided that it will not have any adverse effects on visibility and readability of the uniform market distribution mark.

13. Information Provided by the Manufacturer

13.1. Each medical product shall be accompanied with the information required to ensure its safe operation, manufacturer and its authorized representative identification, if applicable, taking into



account the level of training and knowledge of prospective users. This information shall include data provided in the medical product marking and in operational documentation.

Information required to ensure safe operation of a medical product shall be applied directly on the medical product and/or individual package, and/or transport package, if possible. In case individual package of every medical product unit is not possible, such information shall be provided in a product insert supplied with one or more medical products.

In case a medical product has information inscriptions required for its operation, or operational or adjustment properties are displayed using visual means, such information shall be easy to understand by the user or patient, when applicable.

Each medical product shall be supplied with an operation manual (instructions).

It is acceptable to supply class I and IIa medical products without an operation manual, provided that the user can safely apply (operate) such medical product without the manual. At the same time, the necessary information shall be provided on the medical product or its marking.

Information provided in the marking shall be in the Russian Language. The specified information may be also provided in other languages, provided its contents are identical to the text in the Russian language.

13.2. Marking of a medical product may contain symbols. Any used symbol or identification color shall meet the requirements specified in standards related to these Technical Regulations. If standards are unavailable, description of such symbols and identification colors shall be provided in operational documents supplied together with the medical product.

13.3. Medical products mark shall contain the following information:

trade name (if available) and full name and identification of the medical product (type, grade, model);

name and address of the manufacturer;

name and address of the authorized representative (for imported medical products);

date (year and month) of the medical product manufacture;

service life or best before date of the medical product;

if information accompanying a medical product does not include indication of a service life or best before date, then the indication of the manufacture date (year, month) may be included in the serial or batch number of such medical product;

requirements to storage conditions of the medical product, special operation conditions specified by the manufacturer, if applicable;

indication with respect to sterility for sterile medical products;

identification of sterilization means;

batch (lot) number of the medical product or its serial number;



sterilization means for medical products subject to sterilization prior to their intended use;

identification, if the medical products are intended for a single use;

identification “product for personal use” for products intended for personal use;

identification “only for clinical trials” for products intended for clinical trials;

any other instructions of the manufacturer with respect to the medical product;

any warnings and precautions necessary to comply with regarding the medical product;

intended use of the medical product and, in case it is not obviously users, type of patients the medical product is intended for;

information on substances contained in the medical product that were obtained from human blood or plasma (if available);

13.3.1. In the event a medical product (or its constituent parts) is intended to be inserted into a body or for excretion of medical drugs, body fluids, or for transportation and storage of such fluids or other substances, or contains hazardous substances belonging to class 1 and 2 of hazardous substances exhibiting carcinogenic, mutagenic or toxic properties endangering fertility, or contains phthalates, then such medical products shall be marked accordingly. The appropriate marking shall be applied on the medical product itself and on its packaging, or, if necessary, on its external packaging used for storage and transportation of the medical product.

13.4. Operation manual (instructions) to a medical product shall include:

information on the intended use and area of application of the medical product;

performance properties and characteristics;

rules and conditions for the safe operation of the medical product;

any side effects which appear or can appear during the intended use of the medical product;

rules and conditions for storage, transportation, realization, installation and disposal;

information on measures to be taken if the medical product is found to be faulty;

location of the manufacturer and its contact data;

name and location of the authorized representative (for imported medical products), and its contact data;

information or characteristics that allow identification of medical products for their safe installation and connection to other medical products, if such installation or connection is necessary to use the medical product as intended;

information necessary to check proper installation of the medical product and its correct and safe operation;



information on the scope and frequency of maintenance and adjustment necessary to ensure correct and safe operation of the medical product throughout the entire service life;

information required to exclude or minimize risk related to the medical product implantation (if applicable);

detailed information on the nature of generated emissions, means of patient or user protection against direct and/or indirect factors of such emission (for medical products generating emission);

necessary instructions in case of damage of the sterile package and data on subsequent sterilization, if required;

information on the appropriate treatment of medical products prior to their reuse for multiple-use medical products, including cleaning, disinfection and packaging, specifying if necessary the allowed number of reuses and means of sterilization of the medical product subject to subsequent sterilization;

information on actions to be performed prior to use of the medical product (sterilization, final assembly, connection of accessories, connection of power and substance sources);

information on the nature, type, intensity and distribution of emission (for medical products generating emission for medical or diagnostics purposes);

information on the conformity of the medical product with the requirements of these Technical Regulations;

13.4.1. The operation manual (instructions) shall contain information to be provided to the patient by medical personnel with regard to counter-indications and precautions to be taken. Such information shall include:

precautions to be taken in case of any changes in the medical product operation;

precautions to be taken upon exposure to magnetic field, electrostatic charges, acceleration, pressure, increased temperature or pressure and temperature fluctuations;

information with respect to drugs or substances, medias and materials the medical product is intended for, including any limitations on selection of substances to be applied;

precautions to be taken with respect to a specific or non-typical risk related to the usage and/or disposal of the medical product;

accuracy of measurements (readings) a product with a measuring function shall insure;

14. Evaluation of Performance Properties Based on Clinical Appraisal.

14.1 In case conformity of a product with the requirements of Section I shall be based in clinical data, then such data shall be obtained pursuant to requirements set forth by the Council on Healthcare under the Integration Committee of EurAsEC.



Clinical trials on humans shall be performed in compliance with the Declaration passed in Helsinki (Finland) during the 18 Global Medical Assembly taking place in Hong Kong in 1989. All measures related to the safety of human health shall be taken according to the Declaration passed in Helsinki. This applies to all stages of clinical trials starting from the initial decision on the trials' necessity and legal basis, and ending with the publication of its results.



Schedule 2

MEDICAL PRODUCTS CLASSIFICATION

I. TERMS, DEFINITIONS AND PROCEDURE FOR THE CLASSIFICATION RULES APPLICATION

1. Terms and Definitions Used in the Classification Rules

1.1 *Time of Application*

Short-term

In normal conditions the product is intended to be continuously used for less than 60 minutes

Temporary

In normal conditions the product is intended to be continuously used for less than 30 days

Long-term

In normal conditions the product is intended to be continuously used for more than 30 days

1.2 *Invasive Products*

Invasive product

A product that completely or partially penetrates inside a human body either through an anatomical foramina or through body surface.

Anatomical foramina

Any natural foramina in a body, external surface of the eyeball, and also any constant foramina of an artificial origin, e.g. stoma.

Surgically invasive product

Invasive product which is entered into a body through the surface by means of a surgical intervention or in connection with it.

For purposes of this Law any products which cause penetration into a body not through an existing anatomic foramina shall be also considered as invasive.

Implanted products

Any product intended to be either completely implanted into a human body, or for the replacement of epithelial or eye surface in the course of surgical intervention, whereas the product shall remain in the place of introduction after the procedure. Any product intended to be partially implanted into a human body in the course of a surgical intervention and which shall remain in the place of implantation for a period at least 30 days after the procedure, shall be also considered as implanted.

1.3 *Multiple-use surgical instrument*



A tool intended for surgical application for cutting, drilling, sawing, scrubbing, strangulation, diversion, clipping or similar procedures without being connected to any active medical product and which can repeatedly be applied after carrying out the corresponding procedures.

1.4 *Active medical product*

Any medical product depending on a source of electric energy or any energy source, other than directly generated by the human body or gravity, and which operates due to transformation of such energy. Medical products intended for the transmission of energy, substances or other elements between an active medical product and the patient without their essential change, shall not be considered as active medical products.

Separately used software shall be deemed an active medical product.

1.5 *Active therapeutic product*

Any active medical product intended to be used both separately and together with other medical products for the purposes of maintaining, changing, replacing or restoring biological functions or structures in the course of treatment of an illness, trauma or physical disability, or to relieve their course.

1.6 *Active diagnostics product*

Any active medical product intended to be used both separately and together with other medical products for the purposes of obtaining information for the detection, diagnosing, supervision over physiological conditions (for example, state of health, diseases or congenital defects) or information for treatment thereof.

1.7 *Central blood circulation system*

In this Law the term “central blood circulation system” includes the following blood vessels:

arteriae pulmonales, aorta ascendens, arcus aorta, aorta descendens вплоть до *bifurcatio aortae* включительно, *arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior, vena cava inferior.*

1.8 *Cerebrospinal nervous system*

In this Law the term “cerebrospinal nervous system” includes brain, brain tunic and spinal medulla.

2. **Classification rules application**

2.1 The application of classification rules shall be determined by the intended use of the product.

2.2 In case a product is intended for joint use with another product, then classification rules shall be applied to each product separately. Accessories shall be classified separately from the product with which they are applied.

2.3 Software that controls a product and influences its use shall be automatically delegated to the same class as the product.



2.4 If a product is not intended to be used exclusively or mainly on a certain part of a body, it shall be considered and classified on the basis of the most critical intended use.

2.5 In the event the operational properties established by the manufacturer give the grounds for the application of several classification rules to the same product, the rule setting the highest class shall be applied.

2.6 When determining application duration, continuous application means “continuous direct intended use of the product”. At the same time, if product use is interrupted for an immediate replacement of the product by the same or identical following product, the application duration shall be deemed prolonged for the period of use of the following product.

II. CLASSIFICATION RULES

1 Non-invasive Products

1.1 Rule 1

All non-invasive product shall belong to class I, unless any of the rules provided below can be applied to it.

1.2 Rule 2

All non-invasive products intended for transmission or storage of blood, body fluids or tissues, fluids or gases with the purposes of subsequent infusion or administration into a body shall belong to Class IIa if they:

- can be connected to a Class IIa (or higher) active medical product,
- are intended to transmit or store blood or other body fluids, or to store viscera, parts of viscera or body tissues.

In all other cases such products belong to Class I.

1.3 Rule 3

All noninvasive products intended to change biological or chemical compound of blood, other body fluids or other liquids intended for administration into a body belong to the class IIb, except for cases when the compound change is due to filtration, centrifugation, gas or heat exchange, in which case the products shall belong to the class IIa.

1.4 Rule 4

All non-invasive products that contact damaged skin:

- shall belong to Class I if they are not intended to be used as a mechanical barrier, for compression and for exudate absorption,
- shall belong to Class IIb if they are mainly intended for wounds associated with dermal breach, and the cicatrization of which may be considered only as an auxiliary objective of the product use,



- shall belong to Class IIa in all other cases, including products intended mainly to regulate wound microenvironment.

2. Invasive Products

2.1 Rule 5

All invasive products which are not surgically invasive and are not intended to be connected to Class IIa (and higher) active products, depending on anatomic foramen shall belong to:

- Class I if they are intended for a short-term use,
- Class IIa if they are intended for a temporary use, except for cases when they are used in the oral cavity down to the throat, in the ear cavity down to the eardrum or in the nasal cavity, in which case the products shall belong to the Class I,
- Class IIb if they are intended for a long-term use, except for cases when they are used in the oral cavity down to the throat, in the ear cavity down to the eardrum or in the nasal cavity, in which case the products shall belong to the Class IIa,

All invasive products which are not surgically invasive and are intended to be connected to Class IIa (and higher) active products shall belong to Class IIa.

2.2 Rule 6

All surgically invasive products intended for short-term use shall belong to Class IIa, except for cases when they:

- are specially designed for diagnostics, monitoring or correction of heart or central blood circulation system deficiency by direct contact with these body parts, in which case they shall belong to Class III,
- are multiple-use surgical instruments, in which case they shall belong to Class I,
- are specially designed for direct contact with cerebrospinal nervous system, in which case they shall belong to Class III,
- are designed to provide energy in the form of ionizing radiation, in which case they shall belong to Class IIb,
- are designed to provide biological exposure, or complete or primary absorption, in which case they shall belong to Class IIb,
- are intended for administration of medical substances through a delivery system, when the administration means represent a potential danger taking into account the mode of application, in which case they shall belong to Class IIb.

2.3 Rule 7

All surgically invasive products intended for temporary use shall belong to Class IIa, except for cases when they:

- are specially designed for diagnostics, monitoring or correction of heart or central blood circulation system deficiency by direct contact with these body parts, in which case they shall belong to Class III,



- are specially designed for direct contact with cerebrospinal nervous system, in which case they shall belong to Class III,
- are designed to provide energy in the form of ionizing radiation, in which case they shall belong to Class IIb,
- are designed to provide biological exposure, or complete or primary absorption, in which case they shall belong to Class III,
- undergo chemical change in the body and, are not installed on the teeth, in which case they shall belong to Class IIb,
- are intended for administration of medical drugs, in which case they shall belong to Class IIb.

2.4 Rule 8

All implanted and surgically invasive products intended for long-term use shall belong to Class IIb, except for cases when they:

- are active implanted products, in which case they shall belong to Class III, or they are intended:
- to be installed on the teeth, in which case they shall belong to Class IIa,
- to be used in a direct contact with the heart, central blood circulation system or cerebrospinal nervous system, in which case they shall be long to Class III,
- to provide biological exposure, or complete or primary absorption, in which case they shall belong to Class III,
- to provide exposure via chemical change in the body and not to be installed on the teeth, in which case they shall belong to Class III,
- for administration of medical drugs, in which case they shall belong to Class III.

3. Additional Rules applied to Active Products

3.1 Rule 9

All active therapeutic products intended to provide or exchange energy shall belong to the class IIa, except for cases when. due to their characteristics, they can provide or exchange energy with the human body in a potentially dangerous mode taking into account the energy type, intensity and place of energy application, in which case the products shall belong to Class IIb.

All active products intended to control and monitor operation of active therapeutic products, belonging to Class IIb, or intended to render direct influence on operation of such products, shall belong to Class IIb.

3.2 Rule 10

Active diagnostics products shall belong to Class IIa, if they:



- are intended to supply energy, which will be absorbed by the human body, except for products used for the exposure of the patient body to a radiation in a visible part of the spectrum, are intended *in vivo* display of radiopharmaceutical,

- are intended for direct diagnostics or registration of vital physiological processes, except for the cases when they are specially intended for registration of vital physiological parameters, the change of which indicates a direct threat for the patient's health, e.g. changes in the performance of heart, breath, cerebrospinal nervous system, in which case they shall belong to Class IIb.

Active products intended to generate ionizing radiation, as well as for diagnostic and therapeutic invasive radiology, including products designed to control and monitor such products, or intended to directly influence operation of such products, shall belong to Class IIb.

Rule 11

All active products intended for administration and/or removal of medical drugs, body fluids or other substances, shall belong to Class IIa, except for cases when the administration/removal of substances is carried out in a potentially dangerous mode taking into account the compound of used substances, the place of administration/removal and the application method, in which case the products shall belong to Class IIb.

3.3 Rule 12

All other active products shall belong to Class I.

4 Special Rules

4.1 Rule 13

All products containing as an integral part a substance, which, when applied separately, can be deemed as a medical product, and which influences human body being auxiliary in relation to the influence rendered by products, shall belong to Class III. All products containing human blood by-products as their integral part shall belong to Class III.

4.2 Rule 14

All products used for the purposes of contraception or protection against transmission of sexually transmitted diseases, shall belong to Class IIb, except for cases when they are implanted or invasive products for long-term application, in which case the products shall belong to Class III.

4.3 Rule 15

All products specially designed for disinfection, cleaning or rinsing, or hydration of contact lenses, if applicable, shall belong to Class IIb. All products specially intended to clean or disinfect medical products shall belong to Class IIa, except for cases when they are specially intended to disinfect invasive products, in which case they shall belong to Class IIb. This rule shall not apply to agents intended for cleaning medical products via physical action, except for agents for contact lenses.

4.4 Rule 16

Products especially designed to record X-ray diagnostics images shall belong to Class IIa.



4.5 Rule 17

All products made with use of animal tissues or their abiotic derivatives shall belong to Class III, except for cases when such products are intended to be in contact only with intact skin.

5. Rule 18

Blood and blood component containers shall belong to Class IIb.

Schedule 3. Clinical Appraisal

1. General Provisions

1.1. Assessment of conformity with the requirements related to the functioning and operational properties of the products set forth in clauses 1 and 3 of Schedule 1, under normal conditions of use, as well as assessment of side effects and admissibility of the risk/benefit ratio specified in clause 6 of Schedule 1, shall be based on clinical data. Analysing clinical data, one shall take into account any applicable standards and follow a particular methodological procedure based:

1.1.1. On comparison of the appropriate available scientific literature with respect to the safety, operational properties, designed (expected) characteristics and the intended use of the product, with a critical evaluation of such comparison in cases when:

- data shows equivalency of the examined product and the product these data relate to, and
- data is sufficient to demonstrate the applicable significant requirements have been met.

1.1.2. Or on the analysis of results of all performed clinical trials (tests) with a critical evaluation of such analysis.

1.1.3. Or on the analysis of aggregated clinical data obtained pursuant to clauses 1.1.1. and 1.1.2.

1.2. Clinical trials of Class 3 and implanted products shall be performed only if the available clinical data are not sufficient.

1.3. Clinical appraisal and its results shall be documented. Such documentation shall be kept in the technical file for the product or shall be specified in the form of references.

1.4. The clinical appraisal and the corresponding documentation shall be updated as new data become available after the distribution of the product or its putting into operation. Non-collection of such data shall be justified and documented.

1.5. If the manufacturer considers that demonstration of the conformity with the requirements specified in clause 3 of Schedule 1, based on the clinical data, is not applicable, then the justification of such exclusion shall be based on the output data of risk management performed by the manufacturer, as well as examination of specific features of the product's interaction with the human body, intended use and mode of functioning.

Sufficiency of demonstration of conformity with the essential requirements only by the appraisal of performance properties, field tests and preclinical appraisal shall be justified.



1.6. All data shall meet the requirements of confidentiality.

2. Clinical Trials

2.1. Objective.

Clinical trial objectives:

- verify that under normal conditions of use operational properties of the product meet the requirements set forth in clause 1 of Schedule 1; and
- define any adverse side effects under normal conditions of use, and evaluate acceptability of risks, taking into account functional properties of the product (risk/benefit ratio).

2.2. Ethical aspects

Clinical trials shall be performed according to the Helsinki Declaration and applicable standards related to these Regulations. All measures related to protection of test subjects shall be taken according to the Helsinki Declaration. It applies to each stage of clinical trials from the consideration and justification of need in the trials to the publication of results.

2.3. Methods

2.3.1. Clinical trials shall be conducted according to the appropriate study plan designed in such a way so that to confirm or disprove statements of the manufacturer concerning clinical efficiency of the product. Such trials shall include a sufficient number of observations to ensure scientific credibility of results.

2.3.2. Trial procedures shall correspond to the investigated product.

2.3.3. Clinical trials shall be performed in conditions equivalent to those that will be present during normal use of the product.

2.3.4. All features shall be examined, including those related to the safety and performance properties of the product, and its influence on patients.

2.3.5. All serious adverse effects shall be registered in detail and immediately communicated to the healthcare regulatory body.

2.3.6. All trials shall be performed under the responsibility of an expert doctor or another authorized qualified person in appropriate clinical conditions.

The expert doctor or any other authorized person shall have access to technical and clinical data related to the product.

2.3.7. The written report signed by the responsible expert doctor or another authorized person shall include critical evaluation of all data collected during the trial.

3. Products intended for clinical trials shall be accompanied by a set form (statement), prepared by the manufacturer or its authorized representative, containing the following information:



- data providing the identification of the examined product,
 - clinical trial plan,
 - investigator's brochure
 - proof of test subjects' insurance,
 - form of informed consent documents.
 - statement specifying that among the integral parts of the product there is a substance or human blood by-products, as specified in Schedule 1, clause 7.4., if applicable
 - statement specifying that the product contains biological substances of animal origin, if applicable.
 - opinion of the corresponding ethics committee, if necessary.
 - data on the doctor or any other authorized person, as well as medical institution(s) responsible for the trials,
 - data with regard to the place and date of the trials start, expected duration of the trials.
 - statement that the examined product meets essential requirements of this Technical Regulations, except for the clauses the trials relate to, and also that with respect to such clauses all precautions for the protection of health and safety of the subjects have been made.
4. Upon a request the manufacturer shall provide the healthcare regulatory body of the Customs Union member state in which it is planned to conduct the trials, with the following documents:
- name of the product and general description of the intended use and area of application.
 - general drawings, general description of flow processes, description of sterilization method (if applicable) etc.,
 - descriptions and explanations necessary to understand the above mentioned drawings, as well as description of the product's mode of functioning,
 - Results of risk assessment and the list of all used standards, both related and not related to the requirements of the Regulations, as well as all other applied means to ensure conformity with the requirements of Schedule 1 of these Technical Regulations.
 - data regarding the performed trials with respect to the safety, quality and efficiency of the substance or human blood by-products (if among integral parts of the product there is a substance or human blood by-products, as specified in Schedule 1, clause 7.4.), taking into account the intended use of the product.
 - measures taken by the manufacturer as a result of risk management in order to reduce risk of infection (if the product is made of or contains biological substances of animal origin).
 - results of calculations made in the course of designing, tests and verifications executed in the course of manufacturing, and other relevant data, if required.



The manufacturer has to take all the necessary actions (measures) to ensure the production process consistently provides products complying with the documentation specified in this clause. The manufacturer shall perform or ensure the appraisal or audit of such actions (measures) efficiency.

Schedule 5.

The List of Documents Included into the Technical File Prepared by the Manufacturer for Every Type or Model of Medical Products

To do a conformity assessment, the manufacturer shall create a technical file on the basis of available technical documentation for the product. The technical file shall contain documents with regard to the manufacture of a particular medical product, or provide references to such documents, and shall include:

- a) general description of the type, including definition of all standard sizes, design and configuration options, indicating the corresponding intended use and area of application;
- b) description of the mode of functioning;
- c) potential risk class and applied classification rules;
- d) general and assembly drawings, structural and functional flow diagrams, control systems operational algorithms;
- e) list of materials and parts with detailed description of all medical drugs, human blood by-products and materials of animal origin;
- f) list of all applied standards, both related and not related to the Regulations requirements, as well as all other applied means to evaluate the product;
- g) the list of technical solutions used in the product and meant to ensure the level of safety according to the applicable requirements of Schedule 1;
- h) results of the risk analysis, simulation and design calculations, as well as tests to prove the fulfillment of applicable requirements of Schedule 1;
- i) clinical data, results of clinical appraisal, preclinical and clinical trials;
- k) description of the manufacturing process including detailed description and protocols of the sterilization process validation, if applicable, as well as other specific processes;
- l) description of products' identification and tracing system;
- m) description of acceptance rules and test methods, including with respect to the declared and metrological properties;
- n) approved designs of marking, labels, and accompanying documentation;
- o) package description.



Documents included into the technical file shall be in the Russian language. Manufacturer documentation in a foreign language shall be translated into Russian and approved by the authorized representative, and the initial manufacturer documentation shall be attached to the translation.

The manufacturer or its authorized representative shall ensure updates of the technical file and submit it to state control (supervision) authorities during state control (supervision).

Schedule 6.

The Procedure for the Declaration of Conformity for Class 1 Products, Except for Products Distributed Sterile.

1. The procedure for the Declaration of Conformity shall include:

- preparation of technical documentation for a particular type or model of the declared medical product according to Schedule 5 of these Technical Regulations;
- acceptance of the Declaration of Conformity;
- registration of the Declaration according to the established procedure;
- registration as a person responsible for the safety of the declared medical product during its launch, according to Article 7;
- marking of products with a uniform market distribution sign.

2. the Declaration of Conformity shall be in the Russian language and shall contain:

- name and location of the declarant;
- name and location of the manufacturer (in case the declarant is an authorized representative);
- data providing identification of the product;
- indication that the declared medical product belongs to Class 1 of potential risk of use and the applied classification rule;
- name of these Technical Regulations, the conformity with the requirements of which shall be confirmed;
- data on trials (tests) and measurements, both own and performed in the accredited test laboratories, which have formed the base for the Declaration of conformity of the product to the requirements of these Technical Regulations;
- Declaration of the product safety in the course of its application according to the intended use, and measures taken to ensure conformity of declared products to the requirements of these Technical Regulations during the valid period of the declaration;
- Declaration of Conformity valid period;



The manufacturer or its authorized representative shall keep the technical documentation set, including the Declaration of Conformity, for five years since manufacturing the last product.

Schedule 7

Production Quality Assurance

1. The manufacturer shall ensure conformity of the product to the applicable essential (basic) safety requirements set forth in Schedule 1 of these Technical Regulations, and prepare the technical file confirming such conformity, the scope and contents of which shall correspond to Schedule 5 of these Technical Regulations.

2. The manufacturer shall issue and introduce a quality assurance system, including production conditions, as well as production quality monitoring and measurement methods ensuring conformity of each released product to its characteristics according to the technical file for the product and to the requirements of Schedule 1.

The quality system shall be documented and its application shall include:

a) quality related objectives, including declaration of the manufacturer on the admissible probability of releasing inconsistent products;

b) production management, including:

- organizational structure of production, including functions and authority of persons responsible for the quality of manufacture and distribution of the products into the market;

- methods of regular monitoring and the analysis of process efficiency in the quality assurance system, including its ability to achieve the required quality of production and control inconsistent products;

- in cases when production and/or acceptance control and products testing or their elements are performed by a third party, the methods of regular monitoring and analysis of process efficiency in the quality assurance system, taking into account the type and degree of control, shall be applied to the third party, including the requirements to the traceability of the products and transfer of data on the products quality;

c) requirements to the incoming control of materials, semi-finished products and component parts;

d) description of the production methods, processes and techniques, including requirements to procurement, validation of special software, and requirements to the validation of special processes, sterilization in particular, including records based on the validation results;

e) control and quality assurance methods at all production stages, including:

- processes and procedures to be applied, and in particular related to sterilization, procurement and required documents;

- requirements to the identification of products sufficient for the definition of the products conformity with design, technological and other required documentation at each stage of



production, including the status of production with respect to the performed monitoring and measurement procedures;

- requirements to monitoring and measurements at all stages of production, including controlled parameters, monitoring and measurement methods, criteria of acceptance, as well as applied means of measurement and testing; requirements to monitoring and measurement records, including the assurance of a possibility to obtain information on the status of the used measuring and testing equipment regarding its validation and verification (calibration).

3. The manufacturer shall submit to one of the assigned regulatory bodies, which area of accreditation covers the specified procedure of conformity confirmation and corresponding medical products, a certification application containing:

- a) name and address of the manufacturer;
- b) technical file for the declared product;
- c) written statement specifying that a certification application for the same product has not been filed to any other assigned body;
- d) quality assurance system documents;
- e) written statement specifying that the manufacturer undertakes to fulfill the requirements set forth in the quality assurance system documentation and to maintain efficiency of the quality assurance system ;
- f) written statement specifying that the manufacturer undertakes to find, update and carry out regular procedure for the analysis of data on the market application of the product, planning and performing necessary correcting actions, including the obligatory notification of the assigned body confirming conformity of the product, and healthcare regulatory bodies in cases provided in Article 5 of these Regulations;
- g) written statement specifying that the manufacturer undertakes to provide the assigned body with all information related to the declared products and required to evaluate fulfillment of these Regulations requirements.

4. The assigned body shall:

- a) perform audit of the manufacturer's quality assurance system with regard to its conformity with the requirements of clause 3 of this Schedule, provided the group of auditors includes at least one expert experienced in the evaluation of production technology used by the manufacturer;
- b) for class 1 products distributed in sterile conditions, and class 2a products: perform an analysis of the technical file's conformity to the requirements of Schedule 5 for one representative product from each species group of the products taking into account differences and similarity of the intended use, design of the products, manufacturing techniques, including the method of sterilization, as well as taking into account the results of previous technical files analyses; the assigned body shall issue a justification of technical files verification scope and procedure and keep it to provide to the assigning authorities;



c) for class 2b products: perform an analysis of the technical file's conformity to the requirements of Schedule 5 for each type of the products, and, taking into account differences and similarity of the intended use, design of the products, manufacturing techniques, including the method of sterilization, as well as perform for one representative product from each species group of the products technical tests and verification of fulfillment of all applied standards, both harmonized and not harmonized with the Regulations requirements, taking into account the results of previous technical files analyses, as well as all the other techniques for evaluation of the product applied by the manufacturer; the assigned body shall issue a justification of technical files verification scope and procedure and keep it to provide to the assigning authorities;

d) for class 3 products: perform an analysis of the technical file's conformity to the requirements of Schedule 5 for each product, and also perform technical tests and verification of fulfillment of all applied standards, both harmonized and not harmonized with the Regulations requirements, as well as all the other techniques for the evaluation of the product applied by the manufacturer;

the assigned body shall issue a justification of technical files verification scope and procedure, as well as technical tests and verifications scope and procedures, and keep it to provide to the assigning authorities;

e) provide the manufacturer with reports based on the performed audits of the quality assurance system and technical files analysis;

f) in the event of a positive result of the audit, technical file analysis, technical tests and verification of the product, issue the certificate of the product conformity to the requirements of these Technical Regulations;

g) perform annual inspections of the manufacturer's quality assurance system.

Schedule 8.

Products for Personal Use

1. Each Class 1 product for personal use shall be accompanied by the information containing:

- name and location of the declarant;
- name and location of the manufacturer (in case the declarant is an authorized representative);
- data providing identification of the particular product for personal use, specifying that the product is intended exclusively for a particular patient;
- identification of the particular patient (by name, numerical or alphabetical code);
- identification that the product meets the requirements of these Technical Regulations.

The above information shall be kept by the representative, as well as by the qualified medical specialist, and shall be available to healthcare regulatory bodies for five years.



2. The manufacturer, or the authorized representative, shall be registered as the person responsible for the safety of the medical product by its distribution according to Article 7, and provide the list of types of distributed products for personal use.

3. Besides the information specified in clause 1, each Class 2a, 2b and 3 product for personal use, released to circulation and/or put in operation, shall be accompanied by the set form (statement) prepared by the manufacturer or its authorized representative containing the following information:

- Identification of the qualified medical specialist who has made the order (established special requirements and parameters for designing or manufacturing) for the specified product, specifying his/her place of work.

- reference to the established requirements to the product, i.e. the written instruction or other material designation (the recipe, letters prepared in any form with the description of the requirements parameters, model from any material, die mold, any digital information carrier and etc.).

- statement that the product complies with all applicable requirements of Schedule 1 of these Regulations, and, in case it is impossible to identify applicable requirements, statement that the product is safe for use.

4. The manufacturers has to ensure reliability of the above mentioned information, hence it shall:

- a) keep and, upon a request, provide the documents to a healthcare authority ensuring the understanding of the development, manufacturing and working operational properties of the product, including expected performance data, in order to enable the evaluation of conformity.

- b) take all necessary measures to ensure that the products are manufactured in compliance with the applied documents.

5. The scope of the required documents depends on the type of a product and shall be determined by the manufacturer. The manufacturer does not have to use a quality assurance system. Nevertheless, the manufacturer has to develop, issue and apply a procedure for control of documents and records to ensure conformity with all established requirements imposed on this type of the product. Such documents may contain a review of the order, manufacturing process, verification and tests.

The documents shall be kept for 5 years since the date of the product distribution.

Schedule 9

Complete Quality Assurance

1. The manufacturer shall ensure conformity of the product to the applicable essential (basic) safety requirements set forth in Schedule 1 to these Technical Regulations, and prepare the technical file confirming such conformity, the scope and contents of which shall correspond to Schedule 5 of these Technical Regulations.

2. The manufacturer shall issue and introduce a quality assurance system, including product design and production procedure, production conditions, as well as production quality monitoring and



measurement methods ensuring conformity of each released product to its characteristics according to the technical file for the product and to the requirements of Schedule 1.

The quality system shall be documented and its application shall include:

a) quality related objectives, including declaration of the manufacturer on the admissible probability of releasing inadequate products;

b) production management, including:

- organizational structure of production, including functions and authority of persons responsible for the quality of manufacture and distribution of the products into the market;

- methods of regular monitoring and the analysis of process productivity in the quality assurance system, including its ability to achieve the required quality of production and control inadequate products;

- in cases when production and/or acceptance control and products testing or their elements are performed by a third party, the methods of regular monitoring and analysis of process efficiency in the quality assurance system taking into account the type and degree of control shall be applied to the third party, including the requirements to the traceability of the products and transfer of data on the products quality;

c) procedure for the design and production of the certified product, including description of measures for verification and validation of the project (development), as well as an analysis system with respect to the stages of design and development, in particular:

- general description of the product and planned options;

- requirements to the project, including standards to be applied and results of the risk analysis, as well as the results of made decisions for the fulfillment of essential (basic) requirements applied to the products if the standards specified in Article 5 are not applied in full;

- clinical data, results of clinical appraisal, requirements to which are specified in Article 15;

- design of the marking and instructions for use, if applicable.

c) requirements to the incoming control of materials, semi-finished products and component parts;

d) description of production methods, processes and techniques, including requirements to procurement, validation of special software, and requirements to validation of special processes, sterilization in particular, including records based on validation results;

e) control and quality assurance methods at all production stages, including:

- processes and procedures to be applied, and in particular related to sterilization, procurement and required documents;

- requirements to identification of products sufficient for the definition of the products' conformity with design, technological and other required documents at each stage of production, including the status of production with respect to the performed monitoring and measurement procedures;



- requirements to monitoring and measurements at all stages of production, including controlled parameters, monitoring and measurement methods, criteria of acceptance, as well as applied means of measurement and testing; requirements to monitoring and measurement records, including the assurance of a possibility to obtain information on the status of the used measuring and testing equipment regarding its validation and verification (calibration).

3. The manufacturer shall submit to one of the assigned regulatory bodies, which area of accreditation covers the specified procedure of conformity confirmation and corresponding medical products, a certification application containing:

a) name and address of the manufacturer;

b) technical file for the declared product;

c) written statement specifying that the certification application for the same product has not been filed to any other assigned body;

d) quality assurance system documentation;

e) written statement specifying that the manufacturer undertakes to fulfill the requirements set forth in the quality assurance system documentation and to maintain efficiency of the quality assurance system ;

f) written statement specifying that the manufacturer undertakes to found, update and carry out regular procedure for the analysis of data on the market application of the product, planning and performing necessary correcting actions, including the obligatory notification of the assigned body confirming conformity of the product, and healthcare regulatory bodies in cases provided in Article 5 of these Regulations;

g) written statement specifying that the manufacturer shall provide the assigned body with all information related to the declared products and necessary to evaluate the fulfillment of these Regulations requirements including changes introduced into an approved project in all cases when such changes can influence the conformity to the essential (basic) requirements of these Regulations, or previously described conditions of the product use.

4. The assigned body shall:

a) audit the manufacturer's quality assurance system with regard to its conformity with the requirements of clause 3 of this Schedule, while group of auditors shall include at least one expert experienced in the evaluation of production technology used by the manufacturer;

b) for class 1 products distributed in sterile conditions, and class 2a products: perform analysis of the technical file's conformity to the requirements of Schedule 5 for one representative product from each type of the products, taking into account differences and similarity of the intended use, design of the products, manufacturing techniques, including the method of sterilization, as well as taking into account the results of previous technical files analyses; the assigned body shall issue a justification of technical files verification scope and procedure and keep it to provide to the assigning authorities;

c) for class 2b products: perform analysis of the technical file's conformity to the requirements of Schedule 5 for one representative product from each type of the products taking into account



differences and similarity of the intended use, design of the products, manufacturing techniques, including the method of sterilization, as well as taking into account the results of previous technical files analyses; the assigned body shall issue a justification of technical files verification scope and procedure and keep it to provide to the assigning authorities;

d) for Class 3 products: taking into account differences and similarity of the intended use, design of the products, manufacturing techniques, including the method of sterilization, as well as taking into account the results of previous technical files' analyses and projects expert evaluation, perform analysis of conformity of the technical file to the requirements of Schedule 5 for one representative product from each type of the products, procedure and results of design and development of the certified product pursuant to clause 2 c) of these Regulations, as well as verification of fulfillment of all applied specialized standards requirements, both harmonized and not harmonized with the requirements of the Regulations, as well as all the other techniques for the evaluation of the product applied by the manufacturer;

the assigned body shall issue a justification of technical files verification scope and procedure, as well as expert evaluation of the project, and keep it to provide to the assigning authorities;

e) provide the manufacturer with reports based on the performed audits of the quality assurance system, technical files analysis, and project expert evaluation;

f) in the event of a positive result of the audit, technical file analysis, technical tests and verification of the product, issue the certificate of the product conformity to the requirements of these Technical Regulations;

g) perform annual inspections of the manufacturer's quality assurance system.

Schedule 10

Certification of Homogeneous Batch

1. The manufacturer shall ensure conformity of the product to the applicable essential (basic) safety requirements set forth in Schedule 1 of these Technical Regulations, and prepare the technical file confirming such conformity, the scope and contents of which shall correspond to Schedule 5 of these Technical Regulations, and issue the production process ensuring the homogeneity of the declared products. The batch shall contain products of the same type and model. The number of products in the homogeneous batch declared for the certification shall not exceed 200. This certification procedure may not be applied to Class 3 products, as well as sterile products of any potential risk of use class.

2. The manufacturer shall submit to one of the assigned regulatory bodies, which area of accreditation covers the corresponding medical product, a certification application containing:

a) name and address of the manufacturer;

b) technical file for the declared product;

c) written statement specifying that a certification application for the same product has not been filed to any other assigned body;



d) documents on the declared batch ensuring unique identification of the products included in the batch, specifying the quantity of products, serial numbers and/or batch number with the picture of each product, date and location of manufacture, documents for the batches of source materials and component parts;

e) documents on the production process ensuring the homogeneity of the products batch declared for the certification with respect to the production technology, production medium, test methods and acceptance rules;

f) written statement specifying that the manufacturer undertakes to carry out procedure, as described in the technical file, for analysis of data on market application of the product, planning and performing necessary corrective actions, including the obligatory notification of the assigned body confirming the conformity of the product, and healthcare regulatory bodies in cases provided in Article 5 of these Regulations;

g) written statement specifying that the manufacturer undertakes to provide the assigned body with all information related to the declared products and required to evaluate the fulfillment of these Regulations requirements.

3. The assigned body shall:

a) perform analysis of the technical file conformity to the requirements set forth in Schedule 5;

b) taking into account the results of the technical file analysis, determine the sample size for statistical acceptance control of the batch, taking into account the admissible level of AQL, and perform a randomized selection of the batch products to perform control in the amount complying with the sample size plus one reference product; the assigned body shall issue a justification of the volume and procedure for selecting products from the batch to perform quality control and keep it to provide to the assigning authorities

c) for each product from the sample: perform technical tests and verify fulfillment of all applied standard requirements, both harmonized and not harmonized with the Regulations requirements, as well as all the other techniques for the evaluation of the product applied by the manufacturer; the assigned body shall issue a justification of the scope and procedure for technical tests and verification of the products; the assigned body shall keep products that have passed quality control and one reference product to provide to the assigning authorities;

d) provide the manufacturer with reports on the results of performed technical tests and verifications of batch products quality, and analysis of technical files;

e) in the event of a positive result of technical tests and batch products quality verification, as well as results of technical files analysis, the body shall issue a certificate of the products batch conformity to the requirements of these Technical Regulations.