THE MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION

ORDER

January 19, 2017

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Moscow

On approval of requirements to
the content of technical and operational documentation issued by
a producer (manufacturer) of a medical device

Pursuant to Article 38 of the Federal Law dated November 21, 2011 No.323-FZ “On the Basics of Health Protection of the Citizens in the Russian Federation” (Collection of Legislative Acts of the Russian Federation, 2011, No.48, Article 6724; 2013, No.48, Article 6165; 2015, No.1, Article 85; No.27, Article 3951) and subparagraph 5.2.192(1) of the Regulations on the Ministry of Health of the Russian Federation approved by Decree of the Government of the Russian Federation dated June 19, 2012 No.608 (Collection of Legislative Acts of the Russian Federation, 2012, No.26, Article 3526; 2013, No.16, Article 1970; No.20, Article 2477; No.22, Article 2812; No.33, Article 4386; No.45, Article 5822; 2014, No.12, Article 1296; No.37, Article 4969; 2015, No.2, Article 491; No.12, Article 1763; 2015, No.23, Article 3333; 2016, No.2, Article 325; No.9, Article 1268; No.27, Article 4497; No.28, Article 4741; No.34, Article 5255; No.49, Article 5255), I hereby order that:

1. The attached requirements to the content of technical and operational documentation issued by a producer (manufacturer) of a medical device be approved.

2. The provision be established that the requirements approved by Paragraph 1 of this Order shall apply to technical and operational documentation issued by producers (manufacturers) of medical devices, applications for state registration whereof have been submitted to the Federal Service for Surveillance in Health Care, after this Order takes effect.

Minister

/signature/

V.I. Skvortsova
Requirements to
the content of technical and operational documentation issued by
a producer (manufacturer) of a medical device

I. General provisions

1. These Requirements determine the list of information to be included in the technical and operational documentation issued by a producer (manufacturer) of a medical device.

2. A producer (manufacturer) of a medical device shall develop technical and (or) operational documentation in accordance with which the medical device shall be produced, manufactured, stored, transported, installed, commissioned, applied, operated, including maintenance and repair, disposed of or destroyed.

3. These Requirements shall not apply to medical devices that are custom-made for patients, which shall meet specific requirements as regards to the appointment of medical staff and which are intended solely for the personal use by an individual patient, as well as medical devices intended for use in an international medical cluster.

II. Requirements to the content of technical documentation for a medical device
issued by a producer (manufacturer)

4. Technical documentation for a medical device (hereinafter - technical documentation) provided by the producer (manufacturer) of a medical device or an authorized representative of the producer (manufacturer) of a medical device as part of the registration dossier of the medical device, shall contain:

1) name of a medical device, and other information allowing for a medical device to be identified, for example, the model number, the modifications (versions) of a medical device;

2) intended use of a medical device and its operation principles;

3) indications and contraindications for the use of a medical device;

4) information on potential consumers of a medical device;

5) description of the main functional elements of a medical device, which may be accompanied by diagrams, photographic images, drawings, charts and other explanations;

6) description of components (parts) of a medical device (if available);

7) description of supplies, medical devices or devices that are not medical, but are intended for use in combination with a given medical device (if available);

8) list and description of the materials of a medical device that come into direct or indirect contact with a patient's body (the human body);

9) data on labeling a medical device and its packaging;

10) list of risks identified in the risk analysis process and description of methods to manage these risks to reduce them to an acceptable level (if available);
11) information on verification and validation of a medical device, which was used to prove compliance with medical device requirements, including the results of:

a) tests in test laboratories (centers);

b) laboratory and (or) factory tests, including results of tests under conditions simulating operational use;

c) laboratory tests on animals to validate the concept of finished medical devices;

12) list of materials of animal and (or) human origin, stating information on their biological compatibility and safety, selection of sources (donors), sampling, processing, storage and handling of these materials (if available);

13) information on testing, test protocols, analysis of the data obtained;

14) links to the previous modifications of a medical device or similar modifications of a medical device in circulation, in the case of use in the technical documentation of information on these or previous modifications of the medical device to prove compliance with the medical device safety and effectiveness regulations;

15) information on the main stages of design of a medical device and production processes, which may be accompanied by diagrams, photographic images, drawings, charts and other explanations;

16) information per the data specified in the State Register of Medicines for Medical Use on whether or not the medical device contains:

medicine for medical use, including the name (international nonproprietary name, or modified, or chemical and trade name), name of the manufacturer of a medicine for medical use, the date and number of the registration certificate of a medicine for medical use;

pharmaceutical substance, including the name (international nonproprietary name, or modified, or chemical and trade name), name of the manufacturer of a pharmaceutical substance, the date and number of registry entry in the State Register of Medicines for Medical Use;

17) description of the method of sterilization, information on the methods of validation in respect of the sterilization process (including biological load testing, the presence of pyrogenic substances, the presence of residual amounts of sterilizing substances) and the validation of packaging process (in the case of a medical device being supplied in a sterile form);

18) information on the process of design, development and validation of the software used in the finished medical device (in case of presence in a medical device of software to ensure its correct operation and (or) intended use);

19) requirements to the maintenance and repair of a medical device;

20) procedure and conditions for the disposal or destruction of a medical device.

5. Technical documentation for a medical device to conduct in vitro diagnostics, in addition to the information specified in paragraph 4 of these Requirements, shall contain:

1) description of the intended use of a medical device, including:

a) description of the target analyte, information on its scientific validity, indicating the qualitative, semi-quantitative or quantitative analyte type;

b) functional purpose (e.g. screening, monitoring, diagnostics or a diagnostics auxiliary tool);
c) a specific pathology, condition or a risk factor which the medical device is intended to detect, define or differentiate in the course of in vitro diagnostics;

d) type of the sample analyzed;

e) population, demographic aspects of the use of a medical device;

2) specification of the professional level of a potential end-user (e.g., physician at a clinical diagnostics laboratory, medical laboratory technician (paramedic assistant), another specialist);

3) description of the principle of the analytical method or principle of operation of a medical device for analytical equipment - appropriate technical specifications;

4) description of transportation conditions;

5) data on analytical sensitivity (detection limit), analytical specificity, diagnostic sensitivity and diagnostic specificity;

6) description of measurement procedures, metrological traceability of calibrator values and control materials;

7) data on the stability of a medical device, confirming the declared shelf life, stability during use and stability during transportation.

III. Requirements to the content of operational documentation issued by a producer (manufacturer) of a medical device

6. Operational documentation for a medical device (hereinafter - operational documentation) provided by the producer (manufacturer) or an authorized representative of the producer (manufacturer) as part of the registration dossier of the medical device, shall contain:

1) name of a medical device;

2) in respect of the producer (manufacturer) of a medical device - full and (if available) abbreviated name, including company name, legal entity’s incorporation form, location address or surname, name and (if available) patronymic, identity document details, residence address of the individual entrepreneur, and also phone numbers and (if available) email address of the legal entity or individual entrepreneur;

   in respect of authorized representative of the producer (manufacturer) of a medical device - full and (if available) abbreviated name, including company name, legal entity’s incorporation form, address (location) and phone numbers and (if available) email address of the legal entity;

3) the intended use of a medical device, indicating a potential consumer (e.g., healthcare worker);

4) functional characteristics and intended use of a medical device;

5) risks associated with the use of a medical device, contraindications, expected and predictable side effects related to the intended use of a medical device;

6) technical characteristics of a medical device;

7) description of facilities, medical devices or products that are not medical but are intended for use in combination with a given medical device (if available);

8) information on the presence in the medical device of a medicine for medical use, materials of animal and (or) human origin;
9) information on the procedure for installation, assembly, setup, calibration, and other steps required to put the medical device in operation;

10) requirements to the premises on which installation (assembly) of a medical device is scheduled, and requirements to training or qualifications of persons engaged in the installation (assembly) of a medical device (if available);

11) information to check the correctness of installation (assembly) of a medical device and its readiness for safe working operation, including:

a) contents and frequency of maintenance, including cleaning and disinfection of a medical device;

b) list of data, keys, passwords, programs, needed for installation, setup, operation and maintenance of the medical device provided by the producer (manufacturer);

c) list of consumables (components, reagents) and procedure for their use and replacement;

d) the need for calibration to ensure proper and safe operation of a medical device during its service life;

e) methods to reduce the risks associated with installation, calibration or maintenance of a medical device;

f) information on the installation, commissioning, configuration, calibration and other activities required for entering a medical device into operation and its correct operation (application);

g) information on the list of main characteristics of exploitation (use), transportation and storage (e.g. temperature and humidity, illumination and other characteristics) of a medical device;

h) list of national standards used by the producer (manufacturer) of a medical device.

12) information on a sterile condition of a medical device, sterilization method and the procedure in case of violation of the sterile packaging (if a medical device is supplied in a sterile form) or, if a medical device is supplied sterile, an indication of obligatory sterilization before use;

13) information on the processing of a medical device for reuse including cleaning, disinfection, packaging and, if necessary, the method of re-sterilization (if a medical device is reusable), as well as the criteria of unfitness of a medical device for use;

14) information necessary for the identification of a medical device with the aim of obtaining safe combinations, and information on known restrictions on the use of a medical device (for medical devices intended for use together with other medical devices and (or) facilities);

15) information on the nature, type and (if necessary) intensity and distribution of radiation (electromagnetic, ionizing and other) of a medical device and methods of consumer and third party protection from unintended radiation during the operation process of a medical device (if the medical device creates dangerous or potentially dangerous levels of radiation when used as intended);

16) information on the precautions to be taken in case of:

a) malfunction of a medical device, a failure in its operation or deviations in functioning, which may affect the safety of a medical device, including those identified by external signs;

b) impact on the functioning of a medical device by environmental factors associated with the use of a medical device in combination with other medical devices and (or) equipment, or such predictable factors as external electromagnetic fields, electrostatic discharges, radiation (electromagnetic, ionizing, otherwise), atmospheric pressure and its fluctuations, humidity and air temperature;
c) risk of electromagnetic interference creating by a medical device to other medical devices, equipment and means of communication in conducting and evaluating the results of diagnosis, treatment or use (e.g. electromagnetic radiation of a medical device affecting other equipment);

17) warning and (or) precautions to be taken by the consumer when using a medical device containing a medicine for medical use, material of animal and (or) human origin, materials that are carcinogenic, mutagenic or toxic, which possible leaching leads to sensitization, allergic reactions or adversely affects the reproductive function;

18) warning and (or) precautions to be taken by the consumer when disposing a medical device, supplies and consumables to be used together (if available), including information on infectious, microbial, environmental or physical hazard medical devices;

19) information on the circumstances under which the consumer shall consult a health worker;

20) information on the initial release or the latest revision of operational documentation;

21) procedure and conditions for the disposal or destruction of a medical device.

7. Operational documentation of a medical device for in vitro diagnostics, in addition to the information specified in paragraph 6 of these Requirements, shall contain:

1) information on the purpose of a medical device:

a) description of the target analyte, indicating a qualitative, semi-quantitative or quantitative form;

b) specific disorder, condition or risk factor to detect, define or differentiate which the medical device is intended for;

c) type of the sample analyzed;

2) information on the purpose of clinical laboratory diagnostics;

3) description of test procedure with the use of a medical device, and the description of reagents, calibrators and control materials;

4) list of materials and special materials required for testing (analysis), but are not in the scope of delivery of the medical device;

5) information to identify medical devices with the aim of obtaining safe combinations and (or) information on the known restrictions on the use of a medical device as intended (for medical devices intended for use in combination with other medical devices, including medical devices for in vitro diagnostics);

6) information on the stability characteristics of a medical device (e.g., storage conditions, shelf life after opening the immediate packaging);

7) customer information of a medical device about precautions to be taken in case of need, as well as on precautionary measures and (or) the measures taken in respect of potentially infectious material contained in the medical device;

8) information on the purpose of the medical device for single use only, by appointment;

9) information necessary for processing medical device for the purposes of re-use, including cleaning, disinfection, packaging and, if necessary, the method of re-sterilization (if the medical device is intended for reusable use);
10) information on the conditions necessary for the collection, processing and preparation of samples, data on the stability of analyzed samples, including storage conditions and duration, transportation conditions, freezing (thawing) cycle limits;

11) information on preparing for the use and operation of a medical device;

12) information on the traceability of values assigned to calibrators or control materials, which are ensured through the available reference measurement techniques (methods) and (or) standards;

13) description of the test procedure including calculations and interpretation of test results and, if necessary, information on the feasibility of confirmatory tests;

14) analytical performance characteristics: sensitivity, specificity, accuracy, repeatability, reproducibility, detection limit and measurement range, including information on the influence of known interferents, limitations of the method and the use of available reference materials and methods of analysis;

15) clinical effectiveness features: diagnostic sensitivity and diagnostic specificity;

16) biological reference interval of application of a medical device;

17) information on interfering substances or limitations associated with the sample, which may affect the study result;

18) prevention and (or) special precautions in relation to the safe disposal of a medical device and its accessories which shall describe:

a) infectious or microbial risks, including the possibility of contamination of consumables by infectious agents of human origin;

b) environmental risks associated with potentially hazardous materials and substances;

c) physical risks, including the possibility of an explosion or fire;

19) in relation to a medical device intended for self-testing by the consumer, the following information shall be specified:

a) testing procedure (preparation of reagents, sample selection (preparation), procedure and interpretation of test results);

b) description of consumer’s actions in the case of a positive, negative, or uncertain test result;

c) test errors and the possibility of obtaining false-positive or false-negative test results, as well as the factors that affect the testing result;

d) on avoidance of medical decision making by a consumer, based on test results without prior consultation with a medical professional.

8. Operational documentation shall be provided by a producer (manufacturer) for familiarization purposes to a consumer on paper (attached to the medical device or separately) and in an electronic form by placing it on the Internet.

Operational documentation may be provided to a consumer for familiarization purposes in the form of electronic document by placing it on the screen which is a part of a medical device.

In relation to medical devices of potential application risk classes 1 and 2a, operational documentation may be provided to a consumer for familiarization purposes in an abbreviated form on condition that the
scope of information is sufficient to use a medical device for the intended purpose and its safe usage is guaranteed.