Coat of Arms of the Russian Federation
MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION
(MINZDRAV)

Coat of Arms of the Russian Federation
Ministry of Justice of the Russian Federation
REGISTERED
Registration No. *45896*
Dated *March 10th, 2017*

ORDER

January 19th, 2017 No. 11n

Moscow

On approval of the requirements for the content of technical and operational documentation of the medical product manufacturer (producer)

Under Article 38 of the Federal Law No. 323-FZ dated November 21st, 2011 "On fundamental healthcare principles in the Russian Federation" (Collected Legislation of the Russian Federation, 2011, No. 48, Article 6724; 2013, No. 48, Article 6165; 2015, No. 1, Article 85; No. 27, Article 3951) and under Subparagraph 5.2.192 (1) of the Charter of the Ministry of Health of the Russian Federation, approved by the Decree of the Government of the Russian Federation No. 608 dated June 19th, 2012 (Collected Legislation 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 6922), I hereby order:

1. To approve the attached requirements for the content of technical and operational documentation of the medical product manufacturer (producer).
2. To find that the requirements approved by paragraph 1 of the present Order are applied to the technical and operational documentation of medical products manufacturers (producers); and the applications for state registration of which are submitted to the Federal Service for Surveillance in Healthcare after the entry into legal force of this Order.

Minister */signature/* V.I.Skvortsova

APPROVED
by the Order of the Ministry of Health
of the Russian Federation
No. 11n dated January 19th, 2017

Requirements
for the content of technical and operational documentation of the medical product manufacturer (producer)

I. General Provisions

1. The present Requirements define the list of information to be specified in the technical and operational documentation of the medical product manufacturer (producer).
2. The manufacturer (producer) of the medical product develops technical and (or) operational documentation, according to which he carries out the production, manufacturing, storage, transportation, installation, adjustment, use, operation, including maintenance, as well as repair, utilization or destruction of a medical product.
3. The present Requirements do not apply to patients custom-designed medical products, which are applied to special requirements as per the medical professionals orders and which are intended only for personal use by a particular patient; as well as the present Requirements do not apply to the medical products intended for use in the territory of the international medical cluster.

II. Requirements for the content of the manufacturer's (producer's) technical documentation for the medical product

4. The manufacturer (producer) technical documentation for the medical product (hereinafter referred to as the technical documentation) provided by the medical product manufacturer (producer) or by the authorized representative of the medical product manufacturer (producer) as part of the Common Technical Document for the medical product shall contain:
   1) the name of a medical product, other information allowing to identify the medical product, for example, the model number, modifications (versions) of the medical product;
   2) the purpose of a medical product and the principles of action;
   3) indications and contraindications for use of a medical product;
   4) information on potential consumers of a medical product;
   5) description of the main functional elements of the medical product, which may be

provided with diagrams, photographic images, figures, charts and other illustrations;

6) description of components (units) of a medical product (if any);
7) description of accessories, medical products or products that are not medical, but intended for use in combination with the stated medical product (if any);
8) the list and description of the materials of a medical product making direct or indirect contact with the patient's body (human body);
9) data on marking of a medical product and its package;
10) the list of risks identified in the risk assessment process and the description of these risks control method in order to reduce them to the tolerable level (if any);
11) information on the verification and validation of a medical product that was used in order to prove the compliance of the medical product with the applicable requirements, including the results:
    a) tests in testing laboratories (centers);
    b) laboratory and (or) factory tests, including test results under conditions simulating the operational ones;
    c) laboratory animal tests in order to confirm the accuracy of the concept of the finished medical product;
12) the list of animal test materials and (or) human origin materials with specifyication of the information on their biological compatibility and safety, on the selection of sources (donors), sampling, processing, storage and handling of these materials (if any);
13) information on the tests carried out, test reports, data analysis;
14) references to the previous modifications of the medical product or similar modifications of current medical products in case of using the information on similar or previous versions of the medical product in the technical documentation in order to prove the medical product compliance with the safety and efficiency requirements;
15) information on the main design stages of medical products and information about the production processes, which may be provided with diagrams, photographic images, figures, charts and other illustrations;
16) information in accordance with the data of the state register of medicinal products for human use about the contained in a medical product:

    medicinal product for human use, including the name (international non-proprietary, or grouping, or chemical and commercial name), the name of the manufacturer of the medicinal product for human use, the date and number of the marketing authorization of the medicinal product for human use;

    pharmaceutical substance, including the name (international non-

proprietary, or grouping, or chemical and commercial name) the name of the manufacturer of the pharmaceutical substance, the date and number of the registry entry of the State Register of Medicines for human use;

17) description of the sterilization method, information on validation methods concerning sterilization process (including bioburden tests, tests for pyrogenic agents availability, tests for residual quantity of sterilizing agent) and information on validation of the packaging process (if the medical product is delivered sterile);
18) information on the process of design, engineering and validating of the software used in the finished medical product (upon the existence of software in the medical product that ensures its proper operation and (or) intended application);
19) requirements for maintenance and repair of medical products;
20) the procedure and circumstances for disposal or destruction of a medical product.

5. Technical documentation of the medical product for in vitro diagnostic, in addition to the information specified in paragraph 4 of these Requirements, shall contain:
   1) description of purpose of the medical product, including:
      a) description of the target analyte, information on its scientific validation, specifying of the qualitative, semiquantitative or quantitative analyte type;
      b) functional purpose (for example, screening, monitoring, diagnostics or auxiliary in diagnostics);
      c) specific pathology, condition or risk factor for the detection, definition or differentiation of which a medical product for in vitro diagnostics is intended;
      d) the analytical sample type;
      e) population, demographic aspects of the medical product use;
   2) specification of the professional level of potential users (for example, a pathologist, a medical laboratory technician (medical technologist), another specialist);
   3) description of the principle of the analytical method or the medical product operating principle, for analytical equipment - the corresponding technical specifications;
   4) description of transportation conditions;
   5) information on analytical sensitivity (detection threshold), analytical specificity, diagnostic sensitivity and diagnostic specificity;
   6) description of measuring procedures, metrological traceability of values of calibrators and control materials;
   7) data on the medical product stability, confirming the stated expiration date, usage stability and transportation stability.

III. Requirements for the content of the manufacturer's (producer's) operational documentation for the medical product

6. The operational documentation of the manufacturer (producer) for the medical product (hereinafter referred to as the operational documentation) provided by the medical product manufacturer (producer) or by the authorized representative of the medical product manufacturer (producer) as part of the Common Technical Document for the medical product shall contain:
   1) name of a medical product;
   2) concerning the medical product manufacturer (producer) full and (if available) abbreviated name, including the company name, legal entity form, place of business address or last name, first name and (if available) patronymic, details of the identity document, residential address of the self-employed entrepreneur, as well as phone numbers and (if available) the e-mail of the legal entity or self-employed entrepreneur;

      concerning the authorized representative of the medical product manufacturer (producer), the full and (if available) abbreviated name, including the company name, legal entity form, address (location), telephone numbers and (if available) the e-mail of the legal entity;
   3) the purpose of the medical product with specifying the potential consumer (for example, it is a health professional);
   4) functional specifications and purpose of the medical product;
   5) risks of using the medical product, contraindications, expected and predictable side effects connected with the medical product intended application;
   6) technical specifications of the medical product;
   7) description of accessories, medical products or products which are not medical, but intended for use in combination with a medical product (if any);
   8) information on the medicine for human use existence in the medical product, animal materials and (or) human origin materials;
   9) information on the installation procedure, assembling, adjustment, calibration and other actions necessary to put the medical product into operation;
   10) requirements for locations wherein the medical product installation (mounting) is assumed to be, as well as the requirements for the training or qualification of persons who install (mount) the medical product (if any);
   11) information for verifying the correctness of the installation (mounting) of the medical product and its readiness for safe operation, including:
      a) maintenance and service frequency, including cleaning and disinfection of the medical product;
      b) provided by the medical product manufacturer (producer) list of information,

keys, access passwords, programs required for installation, commissioning, operation and maintenance of the medical product;

c) list of consumable products (components, reagents), as well as the procedure for their use and replacement;

d) need for calibration for ensuring appropriate and safe operation of the medical product during its lifetime;

e) methods of risks reduction associated with the installation, calibration or maintenance of medical products;

f) information on mounting, adjustment, setting up, calibration and other actions necessary for putting the medical product into operation and its proper operation (application);

g) information on the list of the main characteristics of the operation (application) of the medical product, transportation and storage conditions (for example, temperature and humidity, lighting and other characteristics);

h) the list of national standards applied by the manufacturer (producer) of the medical product.

12) information on the sterile condition of the medical product, its sterilization method and the plan of action in case of the sterile package violation (if the medical product is delivered sterile) or, if the medical product is supplied non-sterile, the instruction on need of its sterilization before use;

13) information on the medical product treatment procedure for its repeated use, including cleaning, disinfection, packaging and, if necessary, the resterilization method (if the medical product is non-disposable), as well as the criteria for the medical product unfitness for use;

14) the information necessary for medical products identification in order to obtain a safe combination, and information on known joint use restrictions of medical products (for medical products intended for use with other medical products and (or) accessories);

15) information on the nature, type, and also (if necessary) on the intensity and distribution of radiation (electromagnetic, ionizing, other) of the medical product and information on ways of consumers and third parties protection from unintentional radiation during the medical product operation (if the medical product the dangerous or potentially dangerous radiation level when used as intended);

16) information on precautionary measures taken in the event of:

a) malfunctions of the medical product, failure in his work or deviations in functioning that may affect the medical product safety, including malfunctions determined by outward signs;

b) external factors impact on the medical product functioning connected with the medical product use in combination with other medical products and (or) equipment, or such predictable factors as external electromagnetic fields,

electrostatic discharges, radiation (electromagnetic, ionizing, other), atmospheric pressure and its differences, humidity and air temperature;

c) risk of electromagnetic interference created by the medical product for other medical products, equipment and communication equipment during the carrying out and evaluating the results of diagnostics, treatment, or when used for its intended purpose (for example, electromagnetic radiation from the medical product affecting other equipment);

17) prevention and (or) precautions taken by the consumer when using a medical product containing medicinal product for human use, animal material and (or) human origin material, materials which are carcinogenic, mutagenic or toxic, the possible discharge or washout of which leads to sensitization, allergic reaction or negatively affects reproductive function;

18) prevention and (or) precautions taken by the consumer when disposing of the medical product, accessories and consumable materials used with it (if any), including information on the infectious, microbial, environmental or physical hazard of the medical product;

19) information on circumstances under which the consumer should consult a healthcare professional;

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

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

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

1) information on the medical product intended use:

a) description of the target analyte with a qualitative, semi-quantitative or quantitative indication;

b) specific disorder, condition or risk factor for detection, definition or differentiation of which the medical product is intended

c) test portion type;

2) information on the intended for clinical laboratory diagnostics purpose;

3) description of the testing procedure with use of the medical product, description of reagents, calibrators and control materials;

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

5) information for the medical products identification for the purpose of safe combination obtaining and (or) information on known restrictions on the medical products joint use for their intended use (for medical products intended

for use in combination with other medical products, including medical products for in-vitro diagnostics);

6) information on the stability characteristics of the medical product (for example, storage conditions, in-use stability after the opening of the primary package);
7) information for the medical product consumers on precautionary measures taken when necessary, as well as on precautions and (or) measures taken concerning potentially infectious material contained in the medical product;
8) information on the purpose of the single-use medical product;
9) information on the necessary treatment of the medical product for the purpose of its repeated use, including cleaning, disinfection, packaging and, if necessary, the method of repeated sterilization (if the medical product is intended for repeated use);
10) information on the conditions necessary for the collecting, processing and preparation of samples, data on the stability of the analyzed samples, including conditions and storage period, transport conditions, restrictions on freezing (defrosting) cycles;
11) information on the preparing for intended use, for the operation of the medical product;
12) information on the values traceability set for calibrators or control materials, which is provided by available reference measurement techniques and (or) standards;
13) description of testing procedure, including calculation and interpretation of test results and, if necessary, information on the futility of carrying out confirmatory tests;
14) analytical performance characteristics: sensitivity, specificity, correctness, repeatability, reproducibility, detection limit and range of measurement, including information on the effect of known interference, on limitations of the method and information on the use of available reference materials and analysis methods;
15) clinical efficacy characteristics: diagnostic sensitivity and diagnostic specificity;
16) biological reference interval of use of the medical product;
17) information on interfering substances or on limitations associated with the sample, which may affect the result of the study;
18) prevention and (or) special precautions for the safe disposal of a medical product and its accessories, which should describe:
    a) infectious or microbial risks, including the possibility of infection of consumables with infectious agents of human origin;
    b) environmental risks connected with potentially hazardous materials and substances;

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

19) concerning the medical product intended for self-testing by the consumer, the following information should be specified:

a) about the testing procedure (preparation of reagents, sampling (sample preparation), procedure and test results interpretation);

b) description of the consumer's actions in case of positive, negative or inconclusive test result;

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

d) about the inadmissibility of making medical decisions by the consumer according to the test results without preliminary consultation with a health professional.

8. The operating documentation is provided by the manufacturer (producer) to the consumer for information purpose as hard copies (with the medical product or separately from it) and in the electronic document format by means of posting on the Internet, the information and telecommunication network.

The operational documentation can be provided to the consumer for information purpose in the electronic document format by displaying on the screen that is part of the medical product.

Concerning medical products of 1 and 2a classes of their use potential risks, the operational documentation can be provided to the consumer in short, on the condition that the amount of information provided is sufficient to the medical product intended application and such application is safe.