



**MINISTRY OF HEALTH  
OF THE RUSSIAN FEDERATION**

**(Minzdrav of Russia)**

**ORDER**

***9 January 2014***

***No. 2n***

Moscow

**On Approval of the Procedure for Medical Device Conformity Assessment in the Form of Technical Trials, Toxicological Studies and Clinical Trials for Medical Device State Registration Purposes**

In accordance with Article 38, Federal Law No. 323-FZ of November 21, 2011, “On Fundamentals of Public HealthCare in the Russian Federation” (Collection of Laws of the Russian Federation, 2011, No. 48, Art. 6724; 2012, No. 26, Art. 3442, Art. 3446; 2013, No. 27, Art. 3459, Art. 3477; No. 30, Art. 4038; No. 39, Art. 4883; No. 48, Art. 6165) and par. 5.2.187 of the Regulations on the Ministry of Health of the Russian Federation approved by the Russian Federation Government Resolution No. 608 of June 19, 2012 (Collection of Laws of the Russian Federation, 2012, No. 26, Art. 3526; 2013, No. 16, Art. 1970; No. 20, Art. 2477; No. 22, Art. 2812; No. 33, Art. 4386; No. 45, Art. 5822), it is ordered as follows:

Approve the Procedure for Medical Device Conformity Assessment in the Form of Technical Trials, Toxicological Studies and Clinical Trials for Medical Device State Registration Purposes as set out in the Appendix hereto.

Minister

V.I. Skvortsova

Appendix  
to Order of the Ministry of Health of  
the Russian Federation  
No. 2n of January 9, 2014

**Procedure for Medical Device Conformity Assessment in the Form of Technical Trials,  
Toxicological Studies and Clinical Trials for Medical Device State Registration  
Purposes**

I. General

1. This Procedure sets out requirements to medical device conformity assessment in the form of technical testing, toxicological studies and clinical trials for the purpose of state registration of medical devices (hereinafter “conformity assessment”, “technical trials”, “toxicological studies” and “clinical trials”, respectively).

2. Medical device technical trials, toxicological studies and clinical trials shall be performed in accordance with this Procedure and subject to the requirements of the Russian Federation applicable laws on medical device circulation, standards and technical documentation of the medical device manufacturer, and national (international) standards<sup>1</sup> setting out rules and methods of medical device studies (tests) and measurements.

3. Assessment results shall form the basis for issuing:

- a) the medical device technical trials report according to the Form provided in Annex 1 hereto;
- b) the in-vitro diagnostics medical device technical testing report according to the Form provided in Annex 2 hereto;
- c) the medical device toxicological study report according to the Form provided in Annex 3 hereto;
- d) the medical device clinical trial report according to the Form provided in Annex 4 hereto;
- e) the in-vitro diagnostics medical device clinical trial report according to the Form provided in Annex 5 hereto.

The test, study and trial results shall be kept in the manner provided for by the Russian Federation laws on archiving.<sup>2</sup>

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<sup>1</sup> Federal Law of December 27, 2002, No. 184-FZ “On Technical Regulation” (Collection of Laws of the Russian Federation. 2005, No. 19, Art. 1752; 2007, No. 19, Art. 2293; No. 49, Art. 6070; 2008, No.30, Art. 3616; 2009, No. 29, Art. 3626; No.48, Art. 5711; 2010, No.1, Art. 5, 6; No.40, Art. 4969; 2011, No.30, Art. 4603; No.49, Art. 7025; No.50, Art. 7351; 2012, No.31, Art. 4322; No.50, Art. 6959; 2013, No.30, Art. 4071).

<sup>2</sup> Federal Law of October 22, 2004, No.125-FZ “On Archiving in the Russian Federation” (Collection of Laws of the Russian Federation, 2004, No.43, Art. 4169; 2006, No.50, Art. 5280; 2007, No.49, Art. 6079; 2008, No.20, Art. 2253; 2010, No.19, Art. 2291; 2010, No.31, Art. 4196; 2013, No.7, Art. 611).

4. The medical device manufacturer or its authorized representative (hereinafter the “Applicant”) shall, at its discretion, select a testing organization to perform technical trials and toxicological studies, subject to its accreditation, and a medical organization to perform medical device clinical trials.

## II. Conformity assessment in the form of medical device technical trials

### Medical device conformity assessment

5. Medical device technical testing shall be performed in the form of tests and/or data evaluation and analysis (hereinafter “tests” and “data evaluation and analysis”, respectively) to verify the medical device quality and safety when used for its designated purpose set forth in the manufacturing documentation.

6. Technical trials in the form of data evaluation and analysis shall cover only the medical devices, which require obtaining permits (licenses) for their installation (putting in operation), creating special environment, erecting standalone capital structures, and additional staff training (and in some cases, visiting the medical device manufacturing site).

7. Data evaluation and analysis shall comprise:

- a) Review of technical publications and information related to safety, operational and design characteristics, as well as the intended medical device use;
- b) Analysis of the medical device testing results;
- c) Analysis of the medical device manufacturing conditions.

8. If the data evaluation and analysis fails to validate the medical device quality and safety, the medical device shall undergo technical testing in the form of tests.

9. For the purpose of technical trials, the Applicant shall provide the testing organization with:

- a) The medical device technical testing application;
- b) Sample(s) of the medical device along with the accessories necessary for its intended use (in testing);
- c) Copies of the medical device preliminary testing reports (if any);
- d) Copies of reports on the medical device technical testing outside the Russian Federation (if any);
- e) Data on the medical device regulatory documents;
- f) The medical device manufacturing documentation, both technical and operational;
- g) Photographs of the medical device general view with its accessories necessary for the medical device intended use (the min. size shall be 18x24cm);
- h) Detail drawings, tables and diagrams required for the technical testing, if included in the operational manufacturing documentation;
- i) Special equipment developed by the manufacture for technical testing of a particular medical device and specified in the technical manufacturing documentation (if any);
- j) Documents prepared by the manufacturer in the process of use risk analysis (risk management file) (if any);

k) Information on the medical device clinical use for medical purposes outside the Russian Federation (if any).

If the original documents are executed in a foreign language, they shall be accompanied with a certified translation into Russian.

10. Medical device technical trials shall be performed by a testing organization within 30 working days from the date the Applicant provides the testing organization with the documents, sample(s), special equipment (if any) and the medical device specified in par. 9 hereof. Upon agreement with the Applicant, the testing organization manager may extend the technical trials period for not more than twenty working days.

11. Technical trials shall include:

- a) Medical device identification;
- b) Defining of the medical device type and the potential use risk class in accordance with the Medical Device Nomenclature Classification approved by the Ministry of Health of the Russian Federation<sup>3</sup> and agreement thereupon with the Applicant;
- c) Review of the medical device technical manufacturing documentation;
- d) Drafting a technical testing program (for tests);
- e) Testing of the medical device sample(s) (for tests);
- f) Evaluation and analysis of the medical device data for its quality and safety verification;
- g) Updating of the medical device technical and operational documentation issued by the manufacturer based on the technical testing results (when necessary) as to:  
Completeness and adequacy of the requirements ensuring the medical device quality and safety;  
Compliance of the requirements listed in the medical device manufacturing documentation with the requirements of applicable national (international) standards;
- h) Preparation and delivery (by hand or by registered mail with a receipt) of the medical device technical testing report to the Applicant.

12. The technical testing program shall be drawn up together with the Applicant. The testing organization manager shall approve the program and method of technical trials.

13. Technical trials shall verify:

- a) The medical device compliance with the requirements of applicable national (international) standards as well as regulatory documents, technical and operational documents issued by the manufacturer;
- b) Compliance of the documentation submitted by the Applicant with the requirements of the applicable national (international) standards and the medical device regulatory documents;
- c) Completeness and fairness of the characteristics specified by the manufacturer in the technical documentation, which are subject to technical trials verification, as well as the methods of trials;

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<sup>3</sup> Order of the Ministry of Health of the Russian Federation of June 6, 2012, No.4n, "On Approval of the Medical Device Nomenclature Classification" (registered by the Ministry of Justice of the Russian Federation on July 9, 2012, Registration No.24852).

d) Possibility to use the operational manufacturing documentation in using the medical device for its intended purpose;

e) Quality and safe usage of the medical device.

14. The technical trials results shall be deemed unsatisfactory in one or more of the following cases:

a) The medical device sample(s) provided together with its accessories required for its use as intended do not comply with the requirements of the regulatory documentation, technical and operational manufacturing documentation;

b) The medical device information specified in the technical and operational documentation submitted by the manufacturer does not prove its quality and safety;

c) The required technical trials cannot be performed using special technical trials equipment developed by the manufacturer for a particular medical device and specified by the manufacturer in the draft technical documentation.

15. The technical trials results, except for the cases specified in par. 14 hereof, shall be deemed satisfactory and validating the medical device quality and safety.

#### Conformity Assessment of In-vitro Diagnostics Medical Devices

16. Technical trials of in-vitro diagnostics medical devices (devices, equipment, reagent kits, chemical agents, reagents, test-systems, control materials, calibrators, and growth media) shall be performed to verify in-vitro diagnostics medical device performance for assessment of their quality and safety when used as intended by the manufacturer.

Technical trials of in-vitro diagnostics medical devices in the form of closed analytical systems, as performed for the medical device and its accessories, reagent kits and calibrators required for the medical device use for its intended purpose, may be conducted within one technical test.

17. Technical trials of in-vitro diagnostics medical devices shall be based on:

a) Review of scientific and technical literature related to safety, efficiency, functionality, as well as the in-vitro diagnostics medical device intended use pursuant to the regulatory documentation and the technical and operational manufacturing documentation;

b) Analysis of the in-vitro diagnostics medical device test results.

18. The Applicant shall provide the testing organization with the following documents to perform the in-vitro diagnostics medical device technical trials:

a) The in-vitro diagnostics medical device technical trials application;

b) Sample(s) of the in-vitro diagnostics medical device with its accessories (devices, equipment, reagent kits, chemical agents, reagents, test-systems, control materials, calibrators, and growth media) required for its intended use (in the quantity sufficient for the in-vitro diagnostics medical device technical testing according to the requirements of the regulatory documents and the agreed testing program);

c) Copies of the medical device preliminary trials reports (if any);

d) Copies of the in-vitro diagnostics medical device reports on trials outside the Russian Federation (if any);

- e) Information on the in-vitro diagnostics medical device regulatory documents;
- f) The in-vitro diagnostics medical device technical and operational manufacturing documentation;
- g) Photographs of the in-vitro diagnostics medical device general view with the accessories required for its intended use (the min. size shall be 18x24cm);
- h) Tables and diagrams, software required for the in-vitro diagnostics medical device technical trials, if the tables, diagrams and software are included or referenced in the operational manufacturing documentation;
- i) Special equipment for the medical device operation verification or support, as specified in the technical manufacturing documentation (if any and when necessary);
- j) Set of documents developed by the manufacturer in the process of use risk analysis (risk management file) (if any).

If the original documents are executed in a foreign language, they shall be submitted with a certified translation into Russian.

19. In-vitro diagnostics medical device technical trials shall be performed by a testing organization within 30 working days from the date the Applicant provides the testing organization with the medical device documents and sample(s) specified in par. 18 hereof. Upon agreement with the Applicant, the testing organization manager may extend the in-vitro diagnostics medical device technical trials period for not more than twenty working days.

Technical trials of the in-vitro diagnostics medical devices for especial danger infections shall be performed by the testing organization authorized to work with group I-II pathogenic microorganisms.

20. In-vitro diagnostics medical device technical trials shall include:

- a) Medical device identification;
- b) Defining of the medical device type and the potential use risk class in accordance with the Medical Device Nomenclature Classification approved by the Ministry of Health of the Russian Federation<sup>4</sup> and agreement thereupon with the Applicant;
- c) Review of the medical device technical manufacturing documentation;
- d) Drafting a technical trials program;
- e) Technical trials of the sample(s) of the in-vitro diagnostics medical device with its accessories, reagent kits and calibrators required for its intended use to verify the medical device performance (analytical sensitivity, specificity, reproducibility, linear and other characteristics) specified in the technical and operational manufacturing documentation;
- f) Evaluation and analysis of the medical device data for its quality and safety verification;
- g) Updating of the medical device draft technical and operational manufacturing documentation based on the results of the trials (when necessary);

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<sup>4</sup> Order of the Ministry of Health of the Russian Federation of June 6, 2012, No.4n, "On Approval of the Medical Device Nomenclature Classification" (registered by the Ministry of Justice of the Russian Federation on July 9, 2012, Registration No.24852).

h) Preparation and delivery (by hand or by registered mail with a receipt) of the in-vitro diagnostics medical device trials report to the Applicant.

21. The in-vitro diagnostics medical device technical trials program shall be drawn up together with the Applicant. The manager of the testing organization performing the testing shall approve the program and method of technical trials.

22. Technical trials shall verify:

a) The medical device compliance with the requirements of applicable national (international) standards, as well as regulatory documents, technical and operational documents issued by the manufacturer;

b) Compliance of the documentation submitted by the Applicant with the requirements of the applicable national (international) standards and the medical device regulatory documents;

c) Completeness and fairness of the characteristics specified by the manufacturer in the technical documentation, which are subject to technical trials verification, as well as the testing methods;

d) Possibility to use the operational manufacturing documentation in using the medical device for its intended purpose;

e) Quality and safe usage of the medical device.

23. The in-vitro diagnostics medical device technical trials results shall be deemed unsatisfactory, if:

a) Provided sample(s) of the in-vitro diagnostics medical device and its accessories (devices, reagent kits, chemical agents, reagents, test-systems, control materials, calibrators, and growth media) required for its intended use do not comply with the requirements of the regulatory documents, technical and operational manufacturing documents.

b) The required technical tests cannot be performed using special technical trials equipment developed by the manufacturer for a particular in-vitro diagnostics medical device and specified by the manufacturer in the draft technical documentation.

24. The in-vitro diagnostics medical device technical trials results, except for the cases specified in par. 23 hereof, shall be deemed satisfactory and validating the in-vitro diagnostics medical device quality and safety.

### III. Conformity assessment in the form of medical device toxicological studies

25. The toxicological study shall be performed for the medical device intended to contact the human body during its use.

a) Medical device and/or its accessories, contacting human body surface;

b) Externally attached medical device;

c) Medical device implantable in the human body.

26. The medical device toxicological study shall be performed to assess its biological effect on the human body and include verification of the following parameters:

a) Physicochemical;

b) Sanitary and chemical;

c) Biological in-vitro and in vivo.

27. The Applicant shall provide the testing organization with the following documents for toxicological studies:

- a) Application for toxicological studies;
- b) Sample(s) of the medical device or its accessories, contacting the human body surface, or materials the medical device and its accessories, contacting the human body surface, are made of;
- c) Information on the medical device regulatory documents;
- d) Technical and operational manufacturing documentation with the list of national (international) standards the medical device complies with (if applied by the manufacturer);
- e) Information on regulatory documents for the materials the medical device and/or its accessories, contacting the human body surface, are made of (if any);
- f) Pharmacopeial monograph number or, in case of its absence, the number of the regulatory documentation or document for the pharmaceutical substance or drug included in the State Register of Medicines (if the above is used in the medical device);
- g) Documents specifying the composition of the materials the medical device and/or its accessories, contacting the human body surface, are made of;
- h) Copies of the reports of the medical device toxicological studies (biocompatibility tests) performed outside the Russian Federation (if any).

If the original documents are executed in a foreign language, they shall be submitted with a certified translation into Russian.

28. The medical device toxicological studies shall be performed by the testing organization within 30 working days from the date the Applicant provides the testing organization with the medical device documents and sample(s) specified in par. 27 hereof. Upon agreement with the Applicant, the testing organization manager may extend the technical testing period for not more than twenty working days.

29. Toxicological studies shall include:

- a) Medical device (material) identification;<sup>5</sup>
- b) Medical device classification;<sup>6</sup>
- c) Determination of the duration of the medical device contact with the human body;
- d) Analysis of the medical device documentation submitted;
- e) Development of a toxicological study program;
- f) Holding of the medical device toxicological studies;
- g) Preparation and delivery (by hand or by registered mail with a receipt) of the medical device toxicological study report to the Applicant.

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<sup>5</sup> Federal Law of April 12, 2010, No.61-FZ, "On Drug Circulation" (Collection of Laws of the Russian Federation, 2010, No.16, Art.1815; No.31, Art.4161; No.42, Art.5293; No.49, Art.6409; 2011, No.50, Art.7351, 2012, No.26, Art.3442, Art.3446; No.53, Art.7587; 2013, No.27, Art.3477).

<sup>6</sup> Order of the Ministry of Health of the Russian Federation of June 6, 2012, No.4n, "On Approval of the Medical Device Nomenclature Classification" (registered by the Ministry of Justice of the Russian Federation on July 9, 2012, Registration No.24852).



30. The toxicological study program shall be drawn up by the testing organization together with the Applicant and approved by the manager of the testing organization performing the toxicological studies.

31. Single use (disposable) medical devices that are produced sterile shall be sterility tested, subject to the positive result of analysis of sterilization methods and conditions, as well as of methods of their validation and control by the manufacturer.

32. Medical devices contacting blood and its components, as well as substances for intravascular administration, shall be subject to toxicological studies for pyrogenicity and hemocompatibility.

33. Toxicological studies shall verify:

a) Medical device compliance with the requirements of the applicable national (international) standards, regulatory documents, technical and operational manufacturing documents;

b) Compliance of the documentation provided by the Applicant with the requirements of the applicable national (international) standards and the medical device regulatory documentation;

c) Completeness and fairness of the characteristics specified by the manufacturer in the technical and operational documentation, which are subject control in the medical device toxicological studies, as well as the study methods;

d) Safety of the medical device use.

34. The toxicological study results shall be deemed unsatisfactory in the following cases:

a) Provided sample(s) of the medical device or its accessories, contacting the human body surface, or the materials the medical device and its accessories, contacting the human body surface, are made of do not comply with the requirements of the regulatory documents, technical and operational manufacturing documents;

b) Provided technical and operational manufacturing documentation does not prove safety of the medical device use.

35. The toxicological study results, except for the cases specified in par. 34 hereof, shall be deemed satisfactory, subject to the systematic approach with due account for the characteristics of all materials the medical device and/or its accessories, contacting the human body surface, are made of, and shall validate safety of the medical device use.

#### IV. Conformity assessment in the form of medical device clinical trials

##### Medical device conformity assessment

36. Medical device clinical trials shall be performed in the form of studies (hereinafter referred to as “analysis and evaluation of clinical data”) and trials, including human ones (hereinafter referred to as “human trials”), held to assess medical device safety and efficiency.

37. Medical devices human trials shall be carried out in the following cases:

a) New medical device type;

b) Application of new complex and/or unique and/or special methods for prevention, diagnostics and treatment of diseases and conditions, as well as application of new complex medical technologies;

c) Failure to verify the medical device efficiency and safety by clinical data analysis and evaluation.

In other cases, medical device clinical trials shall be performed in the form of clinical data analysis and evaluation.

38. To hold clinical trials, the Applicant shall provide the medical organization with:

a) Application for clinical trials;

b) Sample(s) of the medical device (excluding medical devices, which require obtaining permits (licenses) for their installation (putting in operation), creating special environment, erecting standalone capital structures, and additional staff training (and in some cases, visiting the medical device manufacturing site));

c) Clinical trial authorization issued by the Federal Service on Healthcare Surveillance in the Russian Federation (Roszdravnadzor);<sup>7</sup>

d) Medical device technical testing report with the documents supporting the technical testing results;

e) Medical device toxicological study report with the documents supporting the toxicological study results (for medical devices intended to contact the human body when used);

f) Results of testing to verify metering equipment types (in respect of the medical devices referred to the metering devices in the state regulation of uniformity of measurements, the list of which is approved by the Ministry of Health of the Russian Federation);<sup>8</sup>

g) Information on the medical device regulatory documents with the list of national (international) standards the medical device complies with (if applied by the manufacturer);

h) The medical device technical and operational manufacturing documentation;

i) Photographs of the general view of the medical device with its accessories required for its intended use (the min. size shall be 18x24cm);

j) Documents (materials) containing data on the medical device clinical use, including outside the Russian Federation, reviews, scientific reports, publications, presentations, use risk analysis, medical device application methods in particular (if any).

If the original documents are executed in a foreign language, they shall be submitted with a certified translation into Russian.

39. The medical device clinical trial program and duration shall be agreed upon examination of the medical device documents submitted. The clinical trial duration shall be determined by the medical device intended use and complexity. The clinical trial program

<sup>7</sup> The Russian Federation Government Regulation of December 27, 2012, No.1416, "On Approval of the Medical Device State Registration Rules" (Collection of Laws of the Russian Federation, 2013, No.1, Art.14).

<sup>8</sup> Order of the Ministry of Health of the Russian Federation of August 15, 2012, No.89n, "On Approval of the Testing Procedure to Establish the Types of Metering Devices and the List of Medical Products Classified as Metering Devices in State Registration of Uniformity of Measurements and Tested to Establish the Types of Metering Devices" (registered by the Ministry of Justice of the Russian Federation on December 25, 2012, registration No.26328).

shall be developed by the Applicant together with the medical organization holding the medical device clinical trials, in compliance with the requirements specified in the technical and operational manufacturing documentation and the regulatory documents.

40. In case of human trials, the medical device clinical trial program approved by the manager of the medical organization carrying out the medical device clinical trials, accompanied with the documents specified in subparagraphs “d”-“j” of par. 38 hereof, shall be submitted by the Applicant to the Board of Ethics in Medical Device Circulation of the Ministry of Health of the Russian Federation<sup>9</sup> (hereinafter referred to as the Board of Ethics).

The Board of Ethics shall issue a clinical trial ethicality opinion within 30 working days from receipt of the documents for their consideration.

41. Medical device human clinical trials shall be held upon a favourable opinion of the Board of Ethics.

In case of the medical device failure or the patient’s condition deterioration during the medical device clinical trials, the manager of the medical organization, which carries out the medical device clinical trials, shall suspend or terminate the trials and notify the Applicant<sup>10</sup> thereof, stating the suspension or termination reasons.

42. If clinical data analysis and evaluation fails to verify the medical device efficiency and safety, the medical organization shall notify and refer the Applicant to the Board of Ethics in Medical Device Circulation of the Ministry of Health of the Russian Federation to obtain the human clinical trial ethicality opinion, as per par. 40 hereof.

43. Clinical trials shall include:

a) Analysis and evaluation of clinical data of the documents and materials submitted by the Applicant under par. 38 hereof;

b) Evaluation of data on clinically significant corrective actions, including the medical device application suspension, withdrawal from circulation and recall;

c) Analysis of scientific publications and/or data on file and communications related to the studied medical device intended use specified by the manufacturer and its proposed use;

d) Development of a clinical trial program;

e) Trials involving the medical device sample(s), in case of human trials;

f) Updating of the medical device operational manufacturing documentation according to trial results (when necessary);

g) Preparation and delivery (by hand or by registered mail with a receipt) of the medical device clinical trial report to the Applicant.

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<sup>9</sup> Order of the Ministry of Health of the Russian Federation of February 8, 2013, No.58n, “On Approval of the Regulation on the Board of Ethics in Medical Device Circulation” (registered by the Ministry of Justice of the Russian Federation on June 5, 2013, registration No.28686).

<sup>10</sup> Order of the Ministry of Health of the Russian Federation of June 20, 2012, No.12n, “On Approval of the Procedure for Disclosure by Pharmaceutical Entities of All Instances when the Side Effects not Specified in the Medical Device Leaflet / User Manual Are Detected, of Adverse Effects Associated with the Medical Device Application, of the Particular Features of Medical Devices’ Interaction, of the Facts and Circumstances Threatening Life and Health of Patients and Medical Professionals in Application/ Operation of Medical Devices” (registered by the Ministry of Justice of the Russian Federation on July 20, 2012, registration No.24962).

44. Clinical trials shall verify:

- a) Conformity of the medical device to regulatory documents, technical and operational manufacturing documentation;
- b) Conformity of the documents provided by the Applicant to the intended use and the indications for use set by the manufacturer;
- c) Completeness and accurateness of the medical device characteristics set by regulatory documents, technical and operational manufacturing documentation;
- d) Quality of the medical device, efficiency and safety of its use, including the expected therapeutic effect in respect of the therapeutic medical devices.

45. The medical device clinical trial results shall be considered unsatisfactory in the following cases:

- a) Medical device does not comply with its intended use and indications for use set by the manufacturer in the medical device operational documentation;
- b) Any side effects, other than those specified in the medical device leaflet or user manual, or any adverse effects are revealed in its use;
- c) Any facts and circumstances threatening life and health of patients and medical professionals are found in medical device use and operation.

46. Except for the cases specified in par. 45 hereof, the medical device clinical trial results shall be deemed satisfactory and shall verify the medical device conformity to the safety and efficiency requirements according to the use intended by the manufacturer.

#### Conformity assessment of in-vitro diagnostics medical devices

47. In-vitro diagnostics medical device clinical trials shall be performed in laboratory conditions, using patients' biomaterial samples taken during their diagnostics and treatment (hereinafter referred to as "clinical laboratory trials") to verify the medical device performance and/or efficiency in its use as intended by the manufacturer.

In-vitro diagnostics medical device clinical laboratory trials of new infectious diseases or rare feral herd infectious diseases shall be performed in laboratory conditions, using museum test-strains from state, national, research and other collections of pathogenic microorganisms.

In-vitro diagnostics medical device clinical laboratory trials in the form of closed analytical systems held in respect of the medical device with its accessories, reagent kits and calibrators required for its intended use may be carried out within one trial.

48. To hold in-vitro diagnostics medical device clinical laboratory trials, the Applicant shall provide the testing organization with:

- a) Application for in-vitro diagnostics medical device clinical laboratory trials;
- b) Sample(s) of the in-vitro diagnostics medical device with its accessories (equipment, reagent kits, **calibrators**, chemical agents, test systems, control materials, **calibrators**, and growth media) required for its intended use;
- c) The in-vitro diagnostics medical device technical testing report supporting the results of the in-vitro diagnostics medical device with its accessories (equipment, reagent

kits, **calibrators**, chemical agents, test systems, control materials, **calibrators**, and growth media) intended use;

d) Operational documentation for the in-vitro diagnostics medical device with its accessories (equipment, reagent kits, **calibrators**, chemical agents, test systems, control materials, **calibrators**, and growth media) required for its intended use (when necessary);

e) Documents (materials) with the medical device in-vitro application data analysis (if any);

f) Results of testing to verify metering equipment types (in respect of the in-vitro diagnostics medical devices referred to the metering devices in the state regulation of uniformity of measurements, the list of which is approved by the Ministry of Health of the Russian Federation)<sup>11</sup> (if any).

In case of original documents executed in a foreign language, they shall be submitted with a certified translation into Russian.

49. The in-vitro diagnostics medical device clinical laboratory trial program and duration shall be agreed upon examination of the in-vitro diagnostics medical device documents submitted. The clinical laboratory trial duration shall be determined by the in-vitro diagnostics medical device intended use and complexity.

The clinical laboratory trial program shall be developed by the Applicant together with the medical organization holding the medical device clinical laboratory trials, in compliance with the requirements specified in the technical and operational manufacturing documentation and the regulatory documents, and shall be approved by the manager of the medical organization holding the said trials.

50. The in-vitro diagnostics medical device clinical laboratory trials shall include:

a) Analysis of the in-vitro diagnostics medical device documents provided;

b) Development of a trial program;

c) Clinical laboratory trials of sample(s) of the in-vitro diagnostics medical device with its accessories (equipment, reagent kits, **calibrators**, chemical agents, test systems, control materials, **calibrators**, and growth media) required for its intended use;

d) Evaluation and analysis of the obtained data for compliance with the declared characteristics;

e) Updating of the in-vitro diagnostics medical device operational manufacturing documentation according to trial results (when necessary);

f) Preparation and delivery (by hand or by registered mail with a receipt) of the in-vitro diagnostics medical device clinical laboratory trial report to the Applicant.

51. Trials shall verify:

a) Conformity of the in-vitro diagnostics medical device to regulatory documents, technical and operational manufacturing documentation;

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<sup>11</sup> Order of the Ministry of Health of the Russian Federation of August 15, 2012, No.89n, "On Approval of the Testing Procedure to Establish the Types of Metering Devices and the List of Medical Products Classified as Metering Devices in State Registration of Uniformity of Measurements and Tested to Establish the Types of Metering Devices" (registered by the Ministry of Justice of the Russian Federation on December 25, 2012, registration No.26328).

b) Conformity of the in-vitro diagnostics medical device to its intended use and application methods proposed by the manufacturer;

c) Completeness and accurateness of the declared in-vitro diagnostics medical device safety and efficiency characteristics against those set by regulatory documents, technical and operational manufacturing documentation, according to the in-vitro diagnostics medical device intended use, including its diagnostic sensitivity, specificity and reproducibility specified in technical and operational manufacturing documentation.

d) Quality of the medical device, efficiency and safety of its use.

52. The medical device clinical laboratory trial results shall be deemed unsatisfactory in the following cases:

a) The studied medical device does not comply with its intended use and indications for use proposed by the manufacturer;

b) Any facts and circumstances making it inefficient for medical professionals to use and operate the medical device, and/or directly or indirectly threatening life and health of medical professionals using and operating the same, are established.

53. Except for the cases specified in par. 52 hereof, the in-vitro diagnostics medical device clinical laboratory trial results shall be deemed satisfactory and shall verify the medical device conformity to safety and efficiency requirements according to the use intended by the manufacturer.