Registered with the Ministry of Justice of the Russian Federation dated December 25, 2012, No. 26328

MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION

ORDER
dated 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 REGULATION OF UNIFORMITY OF MEASUREMENTS AND TESTED TO ESTABLISH THE TYPES OF METERING DEVICES

Pursuant to Article 38, Federal Law dated November 21, 2011, No. 323-FZ, *On Fundamentals of Public Health Protection in the Russian Federation* (Collection of Laws of the Russian Federation, 2011, No. 48, Article 6724; 2012, No. 26, Article 3442; 2012, No. 26, Article 3446) and Section 5.2.189 of the Regulations on the Ministry of Health of the Russian Federation, as approved by the Resolution of the Russian Federation Government dated June 19, 2012, No. 608 (Collection of Laws of the Russian Federation, 2012, No. 26, Article 3526), I order:

To approve:

The Testing Procedure to Establish the Types of Metering Devices for Medical Products Classified as Metering Devices in State Regulation of Uniformity of Measurements and Tested to Establish the Types of Metering Devices, according to Appendix 1;

The List of Medical Products Classified as Metering Devices in State Regulation of Uniformity of Measurements and Tested to Establish the Types of Metering Devices, according to Appendix 2.

Acting Minister
A.V. YURIN

Appendix 1
to Order No. 89n dated August 15, 2012,
of the Ministry of Health of the Russian Federation

TESTING PROCEDURE TO ESTABLISH THE TYPES OF METERING DEVICES FOR MEDICAL PRODUCTS CLASSIFIED AS METERING DEVICES IN STATE REGULATION OF UNIFORMITY OF MEASUREMENTS AND TESTED TO ESTABLISH THE TYPES OF METERING DEVICES

1. This Procedure for the purposes of state registration of medical products defines the Testing Rules to Establish the Types of Metering Devices for Medical Products Classified as Metering Devices in State Regulation of Uniformity of Measurements (hereinafter 'Tests to Establish the Type' and 'Medical Products', respectively) by the competent federal executive authority in state regulation of uniformity of measurements.

2. The subjects of tests to establish the type shall be the medical products included into the List of Medical Products Classified as Metering Devices in State Regulation of Uniformity of Measurements and Tested to Establish the Types of Metering Devices, as approved by this Order.

3. The applicants for tests to establish the type (hereinafter the 'applicant') shall be:

1) the medical product manufacturer;

2) the medical product manufacturer's authorized representative that is a legal entity registered in the Russian Federation, is authorized by the medical product manufacturer to represent the latter in connection with a medical product circulation in the Russian Federation, with the related conformity assessment and state registration procedures in particular, and in whose name the medical product

marketing authorization may be issued.

4. The tests to establish the type shall be carried out by the organizations accredited to test metering devices in accordance with Russian law on uniformity of measurements, the accreditation area of which includes tests to establish the type of metering devices for medical products (hereinafter the 'test operator').

Information on test operator accreditation areas shall be obtained by an applicant from the federal executive authority in charge of accreditation in uniformity of measurements or from the national register of accredited organizations supporting uniformity of measurements.

5. To arrange for the test to establish the type, the applicant shall send an application for the test to establish the type (hereinafter the 'application') as well as the documents indicated in Section 7 hereof to the test operator.

6. The application shall specify:-

1) the medical product name (indicating the accessories required for application of the medical product according to its intended purpose);

2) the application number;

3) information on the medical product manufacturer:

Full and (if any) abbreviated name, including the corporate name, the legal form of incorporation, its registered address as well as telephone numbers and (if any) email address of the legal entity;

4) information on the medical product manufacturer's authorized representative:

Full and (if any) abbreviated name, including the corporate name, the legal form of incorporation, its registered address as well as telephone numbers and (if any) email address of the legal entity;

5) medical product manufacturing site addresses;

6) purpose of the medical product established by the medical product manufacturer;

7) medical product type, in accordance with the nomenclature classification of medical products;

8) class of the potential risk associated with the medical product application, in accordance with the nomenclature classification of medical products;

9) medical product code under the All-Russian Classifier of Products.

7. The application shall be accompanied with:-

1) a duly certified copy of the document evidencing powers of the medical product manufacturer's representative;

2) regulatory documents for the medical product;

3) technical documents for the medical product;

4) maintenance documents for the medical product, including the medical product leaflet/ user manual;

5) photographic image of the general view of the medical product, together with its accessories required for the medical product intended application (dimensions: min. 18 cm x 24 cm);

6) documents evidencing the medical product technical test outcomes;

7) stated metrological and technical parameters of the medical product to be validated during tests to establish the type, including the precision indicators;

8) information on availability of a software product used for the medical product functioning and obtaining the measurement results;

9) information on statutory metrological and technical requirements to the medical product (if any).

The applicant shall be entitled to submit other documents and information to the test operator, at its own initiative.

8. All documents for tests to establish the type shall be submitted in Russian. If the original documents are drafted in a foreign language, they shall be submitted with the Russian translation certified in the established manner.

9. The test operator shall review the application and the attached documents, make a decision as to the feasibility of tests to establish the type and, within fourteen days from the application receipt:-

1) if the decision is positive, send the draft agreement (contract) for tests to establish the type to the applicant;

2) if the decision is negative (in case of a refusal to test to establish the type), send the letter substantiating the decision made to the applicant.

10. The non-conformity of the submitted documents to the provisions of Section 7 and 8 of this Procedure and to provisions of the Procedure for Testing Standard Samples or Metering Devices to Establish the Type, as approved by the Ministry of Industry and Trade of the Russian Federation on November 30, 2009, No. 1081 (registered with the Ministry of Justice of the Russian Federation on December 25, 2009, registration No. 15866) (hereinafter the 'Order of the Ministry of Industry and Trade of the Russian Federation dated November 30, 2009, No. 1081'), shall serve as grounds for the test operator's decision to refuse to test to establish the type.

11. The test operator shall, upon signature of the agreement (contract), develop, get approved by the applicant and authorize the program of tests to establish the type.

12. The program of tests to establish the type shall be elaborated in accordance with Section 24 of the Procedure for Testing Standard Samples or Metering Devices to Establish the Type, as approved by Order of the Ministry of Industry and Trade of the Russian Federation dated November 30, 2009, No. 1081.

13. The program of tests to establish the type shall envisage:-

1) definition of metrological features of a medical product, including the precision indicators in the form of units allowed for application in the territory of the Russian Federation;

2) validation of meeting the statutory metrological and technical requirements to a medical product (if any), including requirements to its components, software and operating conditions;

3) software identification (if any) and assessment of its impact on the medical product metrological features;

4) elaboration or selection of the calibration method and its testing;

5) determination of the need in regular calibration;

6) determination of the interval between regular calibrations;

7) design review of the tested medical product for any limitations to access to its certain parts (including software), to prevent unauthorized setting up and intervention, which may lead to distortion of measurements taken by the medical product.

14. The applicant shall submit the medical product samples to test to establish the type upon approval of the program of tests to establish the type.

15. The test operator shall carry out tests to establish the type in accordance with the program of tests to establish the type.

16. The outcomes of particular tests envisaged in the program of tests to establish the type shall be specified in the respective test protocols.

17. The test protocols shall indicate:-

1) the test protocol name;

2) information on the medical product samples submitted for tests (name of the medical product, manufacturer's numbers of the provided samples);

3) list of the tested items of the program of tests to establish the type;

4) test outcomes.

18. The test operator shall draft the certificate of tests to establish the type based on the test outcomes.

19. The certificate of tests to establish the type shall specify:-

1) medical product name;

2) signature date of the certificate of tests to establish the type, its registration number (if any);

3) information on conducted tests:

(a) applicant's name;

(b) test operator's name, indicating its accreditation certificate number;

(c) medical product manufacturer's name;

(d) timing for tests to establish the type;

(e) grounds for tests to establish the type, with the date and number of the application for tests to establish the type;

(f) venue for the tests to establish the type;

4) information on the medical product samples submitted for tests to establish the type:-

(a) name of the type of the tested medical product sample;

(b) manufacturer's numbers of submitted samples;

5) general information on outcomes of the tests to establish the type:-

(a) name of the program of tests to establish the type, according to which the tests have been conducted;

6) assessment of the test outcomes (positive or negative);

7) detailed information on the test outcomes:-

(a) established values of metrological and other technical features;

(b) practical calibration method testing, with information on it;

(c) recommended interval between calibrations;

8) draft description of the metering device type;

9) information on the compliance test outcomes for the statutory metrological and technical requirements to metering devices (when included in the test program).

Protocols of all conducted tests, a draft description of the metering device type and the calibration method shall form an appendix to the certificate of tests to establish the type and make an integral part thereof.

20. The certificate of tests to establish the type shall be issued on the test operator's letterhead, in two counterparts, signed by the CEO and representatives of the test operator's company (indicating the date) and certified with the test operator's official seal.

21. One copy of the certificate of tests to establish the type, with an appendix, shall be sent to the applicant within Three business days from its issue for filing with the federal executive authority of the Russian Federation in charge of state registration of medical products.

22. The metering device type shall be established, and the certificate of the metering device type shall be issued, in accordance with Order dated November 30, 2009, No. 1081, of the Ministry of Industry and Trade of the Russian Federation.

Appendix 2
to Order dated August 15, 2012, No. 89n
of the Ministry of Health of the Russian Federation

LIST OF MEDICAL PRODUCTS CLASSIFIED AS METERING DEVICES IN STATE REGULATION OF UNIFORMITY OF MEASUREMENTS AND TESTED TO ESTABLISH THE TYPES OF METERING DEVICES

s/r No.	Medical product names	Medical features and values determined using measurements	Names (units) of measured values
1	Medical thermometers	Human body temperature	Temperature(°C)
2	Medical scales	Human weight	Weight (kg)
3	Height meters	Human height	Linear size (cm)
4	Medical dynamometers	Force developed by any group of muscles	Strength(daN)
5	Medical ergometers	Physical exertion dosed by capacity	Mechanical output(W)
6	Medical pulsimeters	Values of systolic and diastolic blood pressure	Gas pressure in the air gasket, with recording of the pressure micropulsation intensity (mm Hg)
7	Medical products to test the external respiration parameters (spirographs, pneumotachographs etc.)	Volumes and flow speeds of inhaled/ exhaled air	Gas volume (ml) Gas flow speed (l/s)

8	Medical products to test the composition of inhaled/exhaled air (oximeters, carbonometers, alcohol testers)	Concentrations: oxygen (oxymetry), carbon dioxide (carbonometry), air ethanol (alcohol testing)	Percentage or quantitative content of oxygen, carbon dioxide, air ethanol in inhaled and/or exhaled air
9	Sets of spectacle lens	Impairment of vision (myopia, hyperopia, heterotropy, astigmia etc.)	Optical strength (diopter) and other optical and physical values
10	Medical audiometers	Acoustic analyzer parameters	Intensity of test aural tones (dB) of different frequency in air and bone conduction
11	Clinical multi-purpose dosimeters for X-ray therapy	Dose parameters of photon and electron emissions in X-ray therapy	Absorbed dose(Gr), dose rate (Gr/s), radiation energy (MeV)
12	Clinical X-ray dosimeters	Dose parameters of radiation in X-ray imaging	Absorbed dose (Gr), dose rate (Gr/s), the absorbed dose multiplied by the beam area (cGr/sGr x cm2)
13	Photon emission dosimeters for radiation control at personnel workstations	Dose parameters of photon emissions at personnel workstations	Absorbed dose (μSv), dose rate (μSv/h) of photon emission
14	Clinical radiometers	Activity of radioactive drugs used in medical biological tests, disease diagnosis and treatment	Radioactivity of gamma ray radionuclides (Bq, Cu)
15	Medical laboratory photometers, spectrophotometers, photocolorimeters	Concentration of substances and activity of ferments in liquid biological samples	Optical density of solutions of tested substances (units of optical density)