*/Logotype/*

**EURASIAN ECONOMIC COMMISSION**

**COUNCIL**

**DECISION**

February 12, 2016 **No. 42** city of Moscow

**On Approval of the List of Types of Medical Products**

**subject to Assignment to Measuring Instruments during Their Registration**

In accordance with Article 31 of the Treaty on the Eurasian Economic Union dated May 29, 2014, Article 4 of the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Medical Equipment) within the Eurasian Economic Union dated December 23, 2014, paragraph 110 of Annex No. 1 to the Rules of Procedure of the Eurasian Economic Commission approved by Decision No. 98 of the Supreme Eurasian Economic Council dated December 23, 2014, and by Decision No. 109 of the Supreme Eurasian Economic Council dated December 23, 2014 “On Implementation of the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Medical Equipment) within the Eurasian Economic Union”, the Council of the Eurasian Economic Commission **decided:**

1. To approve the attached list of types of medical products subject to assignment to measuring instruments during their registration.

2. This Decision shall enter into force after 10 calendar days have elapsed from the effective date of the Protocol, signed on December 2, 2015, on the accession of the Republic of Armenia to the Agreement on Common Principles and Rules for the circulation of medical products (medical devices and medical equipment) within the Eurasian Economic Union dated December 23, 2014, but not earlier than after 10 calendar days have elapsed from the date of the official publication of this Decision.

**Members of the Council of the Eurasian Economic Commission:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **For the Republic of Armenia**  Seal:  *Eurasian Economic Commission.*  *For documents* | **For the Republic of Belarus**  Seal:  *Eurasian Economic Commission.*  *For documents* | **For the Republic of Kazakhstan**  Seal:  *Eurasian Economic Commission.*  *For documents* | **For the Kyrgyz Republic**  Seal:  *Eurasian Economic Commission.*  *For documents* | **For the Russian Federation**  Seal:  *Eurasian Economic Commission.*  *For documents* |
| **V. Gabrielyan** | **V. Matyushevskiy** | **B. Sagintaev** | **O. Pankratov** | **I. Shuvalov** |

APPROVED

by Decision No. 42 of the Council of

the Eurasian Economic Commission

dated February 12, 2016

**LIST**

**of types of medical products subject to assignment to measuring instruments during their registration**

| Medical product type | Medical characteristics and values, determined by measurements | Name of measured values, units | Measurements | Measurement range | Maximum permissible error |
| --- | --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 | 6 |
| 1. Medical audiometer | characteristics of the auditory analyzer of the patient: the intensity of test tone sound signals of different frequencies for air and bone conduction | sound intensity (dB) | measurement of the intensity of test tone sound signals of different frequencies for air and bone conduction | from 125 to 4,000 Hz inclusive  more than 4,000 to 8,000 Hz | ± 3 dB  ± 5 dB |
| 2. Medical balance | human weight (mass) | mass (kg) | measurement of human mass | from 0.5 to 15 kg inclusive  more than 15 to 150 kg | ± 0.01 kg  ± 0.1 kg |
| 3.Medical dynamometer | force, developed by any group of human muscles | force (daN) | measurement of the force developed by any group of human muscles | from 5 to 500 daN | ± 5 % |
| 4. Clinical universal dosimeter for radiation therapy | dose characteristics of photon and electron radiation during radiation therapy | absorbed dose (Gy), absorbed dose rate (Gy/s), energy of radiation (MeV) | measurement of the absorbed dose in water, absorbed dose in biological tissue, air kerma during radiation therapy | from 0.5 to 10.0 Gy | ± 3 % during external radiation  ± 5 % during intra-tissue and cavernous radiation |
| 5. Clinical X-ray dosimeter | dose characteristics of radiation during radio-diagnostic studies | absorbed dose in the air (Gy), absorbed dose rate (Gy x cm2) | measurement of the absorbed dose during radio-diagnostic studies: in biological tissue, air kerma | from 5⋅10-6 to 0.2 Gy  from 1⋅10-6 to 10 Gy х m2  from 3⋅10-5 to 50 Gy х cm2 (for X-ray computed tomography) | ± 15% |
| 6. Photon radiation dosimeter for radiation control at workplaces of personnel | dose characteristics of photon radiation at workplaces of personnel | absorbed dose (Sv) of photon radiation | measurement of dose equivalents (ambient, directional) at workplaces of personnel and individual dose equivalent for personnel | from 1⋅10-6 to 10 Sv | ± 20% |
| 7. Medical products for examination of parameters of external respiration (spirographs, pneumotachographs, etc.) | air volumes and flow rates on inspiration (expiration) | gas volume (l)  gas flow rate (l/s) | measurement of inspired (expired) air volume  measurement of air quantity flow when breathing | from 0.2 to 8.0 l  from 0.4 to 12.0 l/s | ± 3%  ± 5% |
| 8. Medical products for examination of composition of inhalant and exhalant air (oximeters, capnometers, alcometers) | concentrations: oxygen (oximetry), carbon dioxide (capnometry), ethanol vapor (alcometry) | concentration (%) or mass content (mg/l) of the substance | Measurement of concentration or assay content of oxygen and carbon dioxide in inspired (or) expired air (artificial breathing gas mixture) under normobaric conditions:  oxygen  carbon dioxide  measurement of mass content of ethanol fumes in the expired air | from 5% to 25% inclusive  more than 25% to 100%  from 0% to 4%  inclusive  more than 4 % to 15 %  from 0 to 0,5 mg/l  inclusive  more than 0.5 to 0.95 mg/l | ± 1%  ± 3%  ± 0.01%  ± 0.5%  ± 0.05 mg/l  ± 10% |
| 9. Kit of trial spectacle lens | measurement of visual apparatus characteristics (myopia, hyperopia, heterotropia, astigmatism, etc.) | optical power (diopter) | measurement of changes of characteristics of visual apparatus by optical and physical characteristics of trial spectacle lens | optical power from -20.0 to +20.0 diopter  prismatic action from 0.05 to 10.0 diopter | 0.06…0.25 diopter  0.2…0.3 diopter |
| 10. Clinical radiometer | activity of radioactive products, used for medical and biological studies, diagnostics and treatments of the disease | radioactivity of radionuclides (Bq) | measurement of activity of radionuclides in products used for microbiological studies, diagnostics and treatment of diseases | from 103to 1010 Bq | ± 10% |
| 11. Medical height meter | human height | length (cm) | measurement of human height | from 30 to 200 cm | ± 0.5 cm |
| 12. Medical thermometer | human body temperature (oC) | | measurement of human body temperature | from 32 to 42 oC inclusive | ± 0.1 oC |
| 13. Medical tonometer except for patient state monitoring systems with integrated channel for blood pressure check | values of systolic and diastolic blood pressure | measurement of excessive air pressure in a compression wrap (mm Hg) | blood pressure check (non-invasive) | from 40 to 250 mm Hg | ± 3 mm Hg |
| 14. Medical photometer, spectrophotometer, photocolorimeter for clinical laboratory diagnostics | concentration of substances, activity of enzymes in liquid biological specimens | optical density of solutions of test substances (absorbance units) | measurement of optical density values followed by recalculation of the measured value into the required parameter in accordance with the test method | from 0 to 2 absorbance units inclusive  more than 2 to 4 absorbance units | ± 0.06 absorbance units  ± 0.6 absorbance units |
| 15. Medical ergometer | power-dosed physical load | mechanical power (W) | measurement of power-dosed physical load | from 7 to 100 W inclusive  more than 100 to 500 W inclusive  more than 500 to 1,000 W inclusive | ± 2%  ± 3%  ± 5% |

Note:

1. Medical products subject to tests for the approval of the type of measuring instruments should meet the requirements for the measurement range and maximum permissible error, taking into account their purpose.

2. The List of types of medical products subject to assignment to measuring instruments during their registration is updated on the basis of proposals of the authorized authorities of the Member States of the Eurasian Economic Union in accordance with the procedure established by the Rules of Procedure of the Eurasian Economic Commission approved by Decision No. 98 of the Supreme Eurasian Economic Council dated December 23, 2014.

\_\_\_\_\_\_\_\_\_\_\_\_\_

Seal:

*Eurasian Economic Commission. For documents*