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**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	For the Republic of Belarus	For the Republic of Kazakhstan	For the Kyrgyz Republic	For the Russian Federation
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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 cm ²)	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 x m ² from 3·10 ⁻⁵ to 50 Gy x cm ² (for X-ray computed	± 15%

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

tomography)

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 $1 \cdot 10^{-6}$ to 10 Sv	$\pm 20\%$
7. Medical products for examination of parameters of external respiration (spirographs, pneumotachographs, etc.)	air volumes and flow rates on inspiration (expiration)	gas volume (l)	measurement of inspired (expired) air volume	from 0.2 to 8.0 l	$\pm 3\%$
		gas flow rate (l/s)	measurement of air quantity flow when breathing	from 0.4 to 12.0 l/s	$\pm 5\%$
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	from 5% to 25% inclusive $\pm 1\%$ more than 25% to 100% $\pm 3\%$
				carbon dioxide	from 0% to 4% inclusive $\pm 0.01\%$ more than 4% to 15% $\pm 0.5\%$

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
			measurement of mass content of ethanol fumes in the expired air	from 0 to 0,5 mg/l inclusive more than 0.5 to 0.95 mg/l	± 0.05 mg/l $\pm 10\%$
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 10^3 to 10^{10} Bq	$\pm 10\%$
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 ($^{\circ}\text{C}$)		measurement of human body temperature	from 32 to 42 $^{\circ}\text{C}$ inclusive	± 0.1 $^{\circ}\text{C}$
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, photocolormeter 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

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
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	$\pm 2\%$ $\pm 3\%$ $\pm 5\%$

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.

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