

GOVERNMENT OF THE RUSSIAN FEDERATION

RESOLUTION

No. 102 of February 5, 2015

MOSCOW

Establishing Market Entry Restrictions for Individual Types of Medical Devices Originating from Foreign Countries in the Context of Procurement for State and Municipal Needs

Pursuant to Part 3, Article 14 of the Federal Law *On the Contracting System in the Field of Procurement of Goods, Work, and Services for State and Municipal Needs*, the Government of the Russian Federation **r e s o l v e s** :

1. To approve the enclosed List of Individual Types of Medical Devices Originating from Foreign Countries Subject to Market Entry Restrictions in the Context of Procurement for State and Municipal Needs (hereinafter referred to as “the List”).

2. To establish that, when procuring individual types of medical devices included in the List, the buyer shall reject all offers to supply medical devices originating from foreign countries, other than the Republic of Armenia, the Republic of Belarus, or the Republic of Kazakhstan, provided that at least two bids satisfying the requirements of procurement documentation have been submitted for the supplier selection process, which meet all of the following requirements:

contain offers to supply one or several types of medical devices included in the List, which originate from

the Russian Federation, the Republic of Armenia, the Republic of Belarus, or the Republic of Kazakhstan;

do not contain offers to supply one and the same type of medical device from one manufacturer.

3. Proof of the country of origin of medical devices included in the List shall be a certificate of the origin of goods issued by an authorized agency (organization) of the Russian Federation, the Republic of Armenia, the Republic of Belarus, or the Republic of Kazakhstan in the format established by the Rules for Determining the Country of Origin of Goods, which make an integral part of the Agreement on the Rules for Determining the Country of Origin of Goods in the Commonwealth of Independent States of November 20, 2009, and in accordance with the criteria for determining the country of origin of goods specified in said Rules.

4. The market entry restrictions for individual types of medical devices included in the List, which are established by this Resolution, shall not apply in the following cases:

procurement notices for individual types of medical devices included in the List have been published in the unified procurement information system and/or invitations to participate in a non-public supplier selection process have been sent before the effective date of this Resolution;

procurement of individual types of medical devices included in the List by diplomatic offices and consular institutions of the Russian Federation, trade missions of the Russian Federation, and official missions of the Russian Federation at international organizations, which perform such procurement for the purposes of supporting their own operations in the territory of a foreign country.

Dmitry
Medvedev

APPROVED
by Russian Government Resolution No.
102 of February 5, 2015

L I S T
of Individual Types of Medical Devices Originating from Foreign Countries
Subject to Market Entry Restrictions in the Context of Procurement for State
and Municipal Needs

Code per the All-Russia Product Classification by Type of Business (OKPD) OK 034-2007	* Description of the type of medical device
18.21.11.111	Medical outfits
18.21.21.111	
18.21.30.411	
18.21.30.412	
24.41.60.330	Kits of reagents for detecting infectious agents by polymerase chain reaction method
24.41.60.363	Kits of reagents for quantitative and qualitative assay
24.41.60.364	of immunoglobulins / antigens of infectious agents by immunoferment analysis method
24.41.60.384	Kits of reagents for quantitative and qualitative assay of
24.41.60.391	hormones by immunoferment analysis method
24.41.60.395	Kits of biochemical reagents for assay of blood-coagulation factors

Code per the All-Russia Product Classification by Type of Business (OKPD) OK 034-2007	Description of the type of medical device*
24.41.60.399	Kits of reagents for detecting infectious agents by polymerase chain reaction method
24.42.12.120	Alcohol antiseptic wipes
24.42.12.131	
24.42.13.391	Kits (sets) of reagents for blood analyzers
24.42.23.110	Kits of reagents for blood typing and Rh factor determination
24.42.23.111	Kits of biochemical reagents for assay of ferments
24.42.23.111	Kits of biochemical reagents for assay of blood-coagulation factors
24.42.23.119	Kits of reagents for human blood phenotyping according to Rhesus, Kell, Kidd blood group systems
24.42.24.140	Special-purpose disposable sterile surgical products from
24.42.24.141	non-woven materials for protection of patients and
24.42.24.142	medical personnel
24.42.24.143	
24.66.42.140	Selective and non-selective nutritive media
24.66.42.310	Kits of biochemical reagents for assay of substrates
24.66.42.341	Kits of biochemical reagents for assay of ferments

Code per the All-Russia Product Classification by Type of Business (OKPD) OK 034-2007	* Description of the type of medical device
24.66.42.389	Kits (sets) of reagents for blood analyzers
25.22.14.210	Polymer containers for bio samples
29.23.13.331	Combined laboratory refrigerators; pharmaceutical
29.23.13.335	refrigerators; medical freezers
29.23.13.990	
33.10.11.111	Computer tomographic scanners with 1 to 64 slices
33.10.11.140	Single-photon emission computed tomography systems (gamma chambers)
33.10.11.112	X-ray diagnostic complexes with 2 workstations; X-ray
33.10.11.113	diagnostic complexes with 3 workstations; X-ray diagnostic complexes based on a remotely controlled tripod table; fluorographs; mammographs; mobile X-ray machines for use inside wards
33.10.12.111	Electrocardiographs
33.10.12.126	Bedside cardiac monitors; daily ECG monitoring complexes
33.10.12.126	Glucose analyzers
33.10.13.119	Root canal needles
33.10.15.110	Dental air micromotors for handpieces; handpieces for micromotors; turbine dental handpieces
33.10.15.120	Surgical needles

Code per the All-Russia Product Classification by Type of Business (OKPD) OK 034-2007	Description of the type of medical device*
33.10.15.121	Reusable and disposable medical injection syringes, with or without injection needles
33.10.15.134	Micro surgery scissors
33.10.15.136	Hard-alloy dental burs
33.10.15.152	Micro surgery forceps
33.10.15.154	Micro surgery needle holders
33.10.15.213	Micro surgery instruments for ophthalmology
33.10.15.430	Device for transfusion of blood, blood substitutes, and infusion solutions, including devices with a micro filter
33.10.15.610	Containers for collecting, storing, and transporting blood; devices with a leukocyte filter; devices for infusion of blood substitutes and infusion solutions
33.10.15.614	Polymeric gynecological Cusco vaginal specula; disposable sterile gynecology inspection kits
33.10.16.150	Medical outfits
33.10.17.415	Osteosynthesis implants
33.10.18.110	Individual hearing aids

Code per the All-Russia Product Classification by Type of Business (OKPD) OK 034-2007	Description of the type of medical device*
33.20.53.145	Devices for electrophoresis of blood serum proteins on cellulose acetate films
33.20.53.310	Blood clotting analyzers
33.20.53.311	Bilirubin analyzers; urine protein analyzers; semi-automatic biochemical analyzers
33.20.53.311	Hemoglobinometers
33.20.53.320	Individual blood glucose meters
33.20.53.332	Detecting amplifiers for real-time polymerase chain reaction assays

* In applying this List, one shall be guided both by the code per the All-Russia Product Classification by Type of Business (OKPD) OK 034-2007 and the name of the type of medical device corresponding to the specified code.