

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

(as amended by Russian Government Resolutions N528 as of 02.06.2015, N337 as of 22.04.2016, N1268 as of 30.11.2016)

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 for purposes of procuring individual types of medical devices included in the list, the buyer shall reject all bids (final offers) to supply specific types of medical devices included in the list and originating from foreign countries (other than the member states of the Eurasian Economic Union), provided that at least two bids (final offers) satisfying the requirements of the procurement notice and/or procurement documentation have been submitted for the supplier selection process, which meet all of the following requirements:

contain offers to supply specific types of medical devices included in the list and originating only from the member states of the Eurasian Economic Union;
do not contain offers to supply one and the same type of medical device made by the same manufacturer or by manufacturers that belong to the same group of entities, which group meets the attributes indicated in Article 9 of the Federal Law *On the Protection of Competition*, when such bids (final offers) are compared.

2(1). If the bid (final offer) containing a proposal to supply specific types of medical devices included in the list and originating from foreign countries (other than the member states of the Eurasian Economic Union) has not been rejected in accordance with the restrictions established by this Resolution, the market entry clearance conditions shall apply for purposes of procurement of goods

originating from one foreign country or from a group of foreign countries, which conditions have been established by the Ministry of Economic Development of the Russian Federation.

2(2). To establish that for purposes of market entry restrictions for specific types of medical devices originating from foreign countries, medical devices that are included in the list and medical devices that are not included in the list may not be the subject of the same contract (the same lot).

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 member states of the Eurasian Economic Union in the format established by the Rules for Determining the Country of Origin of Goods, which form 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.

3(1). In performing a contract that has been awarded while rejecting (according to the restrictions established by this Resolution) bids (final offers) containing a proposal to supply specific types of medical devices included in the list and originating from foreign countries (other than the member states of the Eurasian Economic Union), it shall be prohibited to substitute the medical device with a medical device originating from a country other than a member state of the Eurasian Economic Union.

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 specific types of medical devices included in the list, by clients indicated in Part 1, Article 75 of the Federal Law On the Contracting System in the Field of Procurement of Goods, Work, and Services for State and Municipal Needs, in the territory of a foreign country for purposes of supporting their activities in that territory.

Prime Minister of the Russian Federation

Dmitry Medvedev

APPROVED by Russian Government
Resolution No. 102 as of February 5, 2015 (as
amended by Russian Government Resolution
No. 1268 of November 30, 2016)

LIST

of Specific 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	Code per the All-Russia Product Classification by Type of Business (OKPD2) OK 034-2014	* Description of the type of medical device
17.40.22.149	22.19.71.190	Orthopedic memory foam bed sore relief pillows
18.21.11.111 18.21.21.111 18.21.30.411 18.21.30.412 33.10.16.150	14.12.11 14.12.21 14.12.30.131 14.12.30.132 14.12.30.160	Medical outfits
18.21.30.530	14.12.30.170	Special-purpose fitness wear
21.22.12.350	17.22.12.130	Sanitation and hygiene products — absorbent underwear (diapers, swaddles)
24.20.14.190	20.20.14.000	Medical devices containing antiseptics or disinfectants
24.41.60.330 24.41.60.399	21.10.60.196	Kits of reagents for detecting infectious agents by polymerase chain reaction method
24.41.60.363 24.41.60.364	21.10.60.196	Kits of reagents for quantitative and qualitative assay of immunoglobulins or antigens of infectious agents by immunoferment analysis method

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24.41.60.384 24.41.60.391 24.66.42.341 24.66.42.342 24.66.42.344	20.59.52.199 21.10.60.196	Kits of reagents for newborn dried blood spot screening
24.41.60.384 24.41.60.391	21.10.60.196	Kits of reagents for quantitative and qualitative assay of hormones by immunoferment analysis method
24.41.60.395	21.10.60.196	Kits of biochemical reagents for assay of blood-coagulation factors
24.42.13.391	21.20.10.139	Kits (sets) of reagents for blood analyzers
24.42.23.110	21.20.23.111	Kits of reagents for blood typing and Rh factor determination
24.42.23.111	21.20.23.111	Kits of biochemical reagents for assay of ferments; Kits of biochemical reagents for assay of blood-coagulation factors
24.42.23.119	21.20.23.111	Kits of reagents for human blood phenotyping according to Rhesus, Kell, Kidd blood group systems
24.42.24.120	13.20.44.120	Bleached cotton gauze
24.42.24.120 24.42.24.131	21.20.24.160	Alcohol antiseptic wipes; sterile and non-sterile gauze wipes
24.42.24.120 24.42.24.139	21.20.24.150	Sterile and non-sterile gauze cloths cut to length; sterile medical bandage packs
24.42.24.127	21.20.24.131	Sterile and non-sterile gauze bandages
24.42.24.128 24.42.24.139	21.20.24.150	Sterile and non-sterile tampons, setons, wick drains, and

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		gauze balls
24.42.24.139	21.20.24.160	Wound bandages and dressings, saturated or covered with medicinal products
24.42.24.140 24.42.24.141 24.42.24.142 24.42.24.143	14.19.32.120	Special-purpose disposable sterile surgical products from non-woven materials for protection of patients and medical personnel
24.42.24.149	21.20.24.150	Sterile and non-sterile medical gauze masks
24.66.42.140	20.59.52.140	Selective and non-selective nutritive media
24.66.42.310	21.20.23.111	Kits of biochemical reagents for assay of substrates
24.66.42.341	20.59.52.199	Kits of biochemical reagents for assay of ferments
24.66.42.389	20.59.52.199	Kits (sets) of reagents for blood analyzers
25.22.14.210	22.22.14.000	Polymer containers for bio samples
29.23.13.331 29.23.13.335 29.23.13.990	28.25.13.111 28.25.13.115 28.25.13.119	Combined laboratory refrigerators; pharmaceutical refrigerators; medical freezers
29.23.14.110 29.23.14.113	28.25.14.110	Set of equipment for clean rooms; air filtration, decontamination, and/or purification equipment and apparatus

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30.02.13.110 30.02.13.120 30.02.13.190 30.02.14.110 30.02.14.120 30.02.14.123 30.02.14.124 30.02.14.129	26.20.13.000 26.20.14.000	Radiological information systems for obtaining, processing, transmitting, and archiving digital medical images
31.50.34.190	27.40.39.110	Surgical and medical examination lights
33.10.11.111	26.60.11.111	Computer tomographic scanners with 1 to 64 slices
33.10.11.112 33.10.11.113	26.60.11.112 26.60.11.113	X-ray diagnostic complexes with 2 workstations; X-ray 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
33.10.11.113	26.60.11.113	Mobile surgical X-ray machines (C-arm)
33.10.11.140	26.60.11.120	Single-photon emission computed tomography systems (gamma chambers)
33.10.12.110 33.10.12.119 33.10.12.125 33.10.15.320 33.10.15.329	26.60.11.113 26.60.12.110 26.60.12.129 32.50.1 32.50.21.112	Endoscopy systems
33.10.12.111	26.60.12.111	Electrocardiographs
33.10.12.123	26.60.12.123	Devices for studying sound oscillations in human organs
33.10.12.126	26.60.12.129	Bedside cardiac monitors; daily ECG monitoring complexes; glucose analyzers

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33.10.12.140	26.60.13	Neonatal phototherapeutic irradiators
33.10.13.119	32.50.11.000	Root canal needles
33.10.14.111	32.50.12.000	Steam sterilizers
33.10.15.110	32.50.13.190	Dental air micromotors for handpieces; handpieces for micromotors; turbine dental handpieces
33.10.15.120	32.50.13.110	Piercing instruments; surgical needles
33.10.15.121	32.50.13.110	Reusable and disposable medical injection syringes, with or without injection needles
33.10.15.130	32.50.13.190	Cutting and percussion instruments with a sharp (cutting) edge
33.10.15.134	32.50.13.190	Micro surgery scissors
33.10.15.136	32.50.13.190	Dental cutters; dental diamond points, including shaped dental points; hard-alloy dental burs
33.10.15.140	32.50.13.190	Retractors
33.10.15.144	32.50.13.190	Pulp extractors
33.10.15.150	32.50.13.190	Instruments for managing multiple surfaces
33.10.15.152	32.50.13.190	Micro surgery forceps
33.10.15.154	32.50.13.190	Micro surgery needle holders

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33.10.15.160	32.50.13.190	Bougie sounding instruments
33.10.15.180	32.50.13.190	Canal filling instruments; auxiliary instruments
33.10.15.190 33.10.15.513	32.50.1 32.50.13.190	Electrical surgical tools
33.10.15.212	32.50.13.120	Slit lamps
33.10.15.213	32.50.13.120	Ophthalmic kit of test eyeglass lenses; micro surgical instruments for ophthalmology
33.10.15.430	32.50.21.112	Devices for transfusion of blood, blood substitutes, and infusion solutions, including devices with a micro filter
33.10.15.441	32.50.21.121	Inhalational anesthetic equipment
33.10.15.512 33.10.15.619	26.60.13.190 32.50.13.190	Defibrillators
33.10.15.519 33.10.15.619	26.60.13.190 32.50.13.190	Neonatal heaters for babies; neonatal tables with automatically maintained heating temperature for newborns
33.10.15.610	32.50.13.190	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	32.50.13.190	Urogenital probes; colposcopes; polymeric gynecological Cusco vaginal specula; disposable sterile gynecology inspection kits
33.10.15.619	32.50.13.190	Nasal respiratory support apparatus for babies; intensive care incubators for newborns; medical modules with climate control (clean rooms)

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33.10.15.619	32.99.59.000	Medical gases and power feed consoles
33.10.16.122	32.50.21.112	Therapeutic equipment (hydraulic massage baths and shower cabins)
33.10.17.119	32.50.22.120	Bathroom and restroom handrails (straight, angular, right-hand, left-hand)
33.10.17.190	32.50.22.190	Silicon gel external chest (breast) prostheses
33.10.17.415	32.50.22.127	Osteosynthesis implants
33.10.17.610	32.50.22.129	Wheeled walkers; foldable and height-adjustable walking aids; supports (supporting walking aids, wheeled walkers); angular, straight (linear) and fold-away handrails (banisters) for unassisted ascent
33.10.17.710	32.50.22.152	Children's orthopedic footwear
33.10.18.110	26.60.14.120	Individual hearing aids
33.10.18.120	32.50.22.128	Crutches
33.10.18.242	32.50.23.000	Polyurethane foam prosthetic feet
33.10.18.313	32.50.23.000	Lower limb stump sheath; cosmetic sheaths for active upper limb prostheses
33.10.20.116	32.50.22.129	Toilet chairs
33.20.53.145	26.51.53.140	Devices for electrophoresis of blood serum proteins on cellulose acetate films

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33.20.53.310	26.51.53.190	Blood clotting analyzers
33.20.53.311	26.51.53.190	Bilirubin analyzers; urine protein analyzers; semi-automatic biochemical analyzers; hemoglobinometers
33.20.53.320	26.51.53.190	Individual blood glucose meters
33.20.53.332	26.51.53.190	Detecting amplifiers for real-time polymerase chain reaction assays
35.43.11	30.92.2	Wheelchairs
36.15.12.129	22.19.71.190	Orthopedic memory foam bed sore relief mattresses; bed sore relief mattresses with gel elements
36.63.31.120	32.99.21.120	Support canes

* In applying this List, one shall be guided both by the code per the All-Russia Product Classification by Type of Business (OKP and OKPD2) and the name of the type of medical device corresponding to the specified code.