

Client Update

List of Foreign Medical Devices State Procurement Restrictions Are Applied to Is Extended

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On December 16, 2016, the Decree of the Government of the Russian Federation No. 1268¹ (“Decree No. 1268”) came into effect. It extends the list of medical devices manufactured abroad in relation to which the Decree of the Government of the Russian Federation No. 102² (“Decree on limitation of access”) imposes restrictions with regard to the access to state and municipal procurement in case other bidders offer to supply similar medical devices manufactured in the Russian Federation, the Republic of Belarus, the Republic of Armenia, the Republic of Kazakhstan, and the Kyrgyz Republic (the “Eurasian Economic Union member states”).

Such restrictions apply to certain types of medical devices included in the list approved by Decree No. 1268 (the “Medical Devices” and the “List” respectively) and not manufactured in the Eurasian Economic Union member states³ (the “Foreign Medical Devices”).

¹ Decree of the Government of the Russian Federation No. 1268, dated November 30, 2016 “On amendments to the list of certain types of medical devices originating from foreign countries subject to restrictions for state and municipal procurement”.

² Decree of the Government of the Russian Federation No. 102 dated February 5, 2015 “On limitation of access and terms of access for certain types of medical devices originating from foreign countries for state and municipal procurement needs.”

³ The country of origin for the Medical Devices is confirmed by a certificate of origin issued by authorized bodies (organizations) of the Eurasian Economic Union member states (see Clause 3 of the Decree on limitation of access).

Decree No. 1268 is prepared in accordance with the Action Plan of the Government of the Russian Federation⁴ and aims at supporting the state import substitution policy⁵.

MEDICAL DEVICES SUBJECT TO RESTRICTIONS

Starting from December 16, 2016, the following Foreign Medical Devices, in particular, are also subject to restrictions:

- some types of diagnostic equipment (for instance, endoscopic devices and equipment for sound wave analysis in human organs);
- some types of physiotherapeutic equipment (for instance, neonatal phototherapy irradiators, hydro massage baths and shower booths);
- certain surgical and dental surgical instruments (for instance, pulp extractors, retracting instruments, instruments for multi-surface interaction, cutting instruments and chisels with sharp (cutting) edge);
- certain types of technical rehabilitation devices (for instance, breast forms based on silicone gel, disability armchairs with sanitary equipment, wheelchairs, medical polyurethane foam feet, orthopedic footwear for children, support canes and crutches);
- certain types of medical devices from the cotton-gauze group (like sterile and non-sterile bandages, tampons, setons, small narrow gauze tampons, sterile and non-sterile gauze balls);
- defibrillators;
- inhalation anesthetic machines;
- nasal devices for newborn respiratory support, neonatal intensive care units, medical climate modules; and

⁴ Clause 13 of the Action Plan of the Russian Government focuses on ensuring stable social and economic development of the Russian Federation in 2016 (approved by the Russian Government on March 1, 2016).

⁵ For instance, see Decree of the Government of the Russian Federation No. 1289, dated November 30, 2015 “On limitation access and terms of access for medicine originating from foreign countries included in the essential drug list for state and municipal procurement”; Decree of the Government of the Russian Federation No. 925, dated September 16, 2016 “On the priority of goods of Russian origin and works and services performed and rendered by Russian persons over goods originating in a foreign country and works and services performed and rendered by foreign entities” (in accordance with Clause 9 of the Decree it takes effect as of January 1, 2017).

- some other types of medical devices⁶.

LIMITATION OF ACCESS FOR FOREIGN MEDICAL DEVICES FOR STATE PROCUREMENT

The Decree on limitation of access expressly stipulates that combining medical devices stated in the List and medical devices not included in this List in one lot shall not be allowed.⁷

As before,⁸ in state and municipal procurement, the consumer is obliged to reject all bids (final proposals) for supply of the Foreign Medical Devices, provided that at least two bids (final proposals) were submitted which at the same time:

- satisfy the requirements of the procurement notice and (or) procurement documentation;
- contain proposals for supply of the Medical Devices originating only from the Eurasian Economic Union member states; and
- do not contain proposals for supply of one and the same type of a medical device of one manufacturer or manufacturers being a part of one group.

However, if any of the above conditions is not met, and the bid (final proposal) for supply of the Foreign Medical Devices is not to be rejected in accordance with the Decree on limitation of access, the price preferences provided to the bidders of certain medical devices originating from the Eurasian Economic Union member states on the basis of the Order of the Russian Ministry for Economic Development No. 155⁹ (the “Order on conditions of access”) should also be taken into account. In particular, the Order on conditions of access stipulates that in certain cases, such bidders shall be granted a 15% preference on the contract price.¹⁰

⁶ Decree on limitation of access and Decree No. 1268.

⁷ Clause 2(2) of the Decree on limitation of access.

⁸ Clause 2 of the Decree on limitation of access.

⁹ Order of the Ministry for Economic Development of the Russian Federation, dated March 25, 2014, No. 155 “On conditions of access for goods originating from foreign countries for the purpose of state and municipal procurement of goods, works and services.”

¹⁰ Clauses 3–7 of the Order on conditions of access. Such preference implies that (a) the bid of the bidder offering to supply medical devices originating from the Eurasian Economic Union shall be evaluated under the “contract price” criterion as if the offered price is 15% less (in the case such bidder wins, the state contract with such bidder will be made at the

The Order on conditions of access shall only apply¹¹ to the goods stated therein,¹² in particular, to “medicine and materials used for medical purposes” and “medical tools and equipment”, but not to all Medical Devices.

For example, (a) if, during the state and municipal procurement, only one bid that meets all of the above requirements of the Decree on limitation of access was submitted and (b) the subject of the procurement is a Medical Device which is not stated in the Order on conditions of access, the limitations of access stipulated in this Order and the Decree on limitation of access will not apply to the bids for supply of the Foreign Medical Devices.

Limitations stipulated in the Decree on limitation of access shall also not apply in the following cases:

- notices on procurement of the Medical Devices and (or) invitations to participate in the closed supplier selection bidding were placed / sent before February 14, 2015;¹³
- procurement of the Medical Devices by the respective consumers in the territory of a foreign state to maintain their activity in such territory.

The Decree on limitation of access also stipulates that it is not permitted (a) to replace the medical device of the Eurasian Economic Union member state origin with the medical device from a non-Eurasian Economic Union member state, and (b) to change the medical device manufacturer under the contract upon the conclusion of which the bids (final proposals) for supply of the Foreign Medical Devices were rejected.

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price initially proposed by that bidder); (b) if, subject to the preference stated in clause (a), several bidders offer the same contract price, the state contract will be made with the bidder entitled to the preference; and (c) if the winner of the procurement procedure is declared to be the bidder offering to supply medical devices originating from countries other than the Eurasian Economic Union member state, the state contract with such bidder will be made at the price offered by it reduced by 15%.

¹¹ Clause 8 of the Order on conditions of access stipulates cases in which the respective limitations do not apply.

¹² Clause 1 of the Order on conditions of access.

¹³ It is not entirely clear which date shall be taken into account in respect of the procurement of the Medical Devices not included in the list of certain types of medical devices approved by the Decree on limitation of access prior to the effective date of Decree No. 1268 (i.e., before December 16, 2016). In theory, such exclusion may also apply to the respective notices/invitations which were placed/sent prior to December 16, 2016. However, we advise to clarify the opinion of competent state authorities on this matter.

Please do not hesitate to contact us should you have any questions.