REPUBLIC OF SERBIA
AUTONOMOUS PROVINCE OF VOJVODINA
CITY OF KIKINDA
CITY ADMINISTRATION
SECRETARIAT FOR PROJECTS
NUMBER: III-09-510-2/2018-17
DATE: 11.05.2023.
K I K I N D A

OBJECT OF THE PROCUREMENT: Procurement of ambulance vehicles and medical equipment
REFERENCE NUMBER: RORS 284/CityofKikinda/TD2
CONTRACTING AUTHORITY: City of Kikinda
LAUNCHING DATE OF THE PROCUREMENT: 12/04/2023
PROCEDURE: International Open
performed under:
PROGRAMME: Interreg-IPA Cross-border Cooperation Romania-Serbia Programme
PROJECT TITLE: „Banat 112 – fast response to a unique challenge“
EMS CODE: RORS 284

CLARIFICATION 1

According to the Point 13. of the Instruction to tenderers, published under procurement procedure, ref. no. RORS 284/CityofKikinda/TD2, City of Kikinda, as a Contracting Authority, by this Clarification 1 provides answers to all questions duly submitted up to the date of this document.

Clarification contains 1 (one) question/clarification request and 1 (one) answer of the Contracting Authority. Question is presented in its original text.

-

QUESTION

1. We are working on these tender specifications. We noticed the issue below. In the Item number 1 of the technical specifications, it is stated '"*all installed and attached medical equipment in the vehicle must be certified/registered in accordance to the national "Law on Medical Devices" and "Rulebook on registration of medical device" of the Republic of Serbia*''.

According to the ''Law on medical devices'' if an ambulance vehicle is delivered from a foreign country, medical equipment inside the vehicle must be registered in that country. A lot of ambulances delivered as donations to Serbian hospitals from foreign companies are delivered according to this rule. We suppose that the condition of registration of medical devices in Technical specification does not affect foreign companies because since this is an international public procurement, it would automatically eliminate all foreign companies and allow only local companies to participate. We need your clarification on this issue''.

ANSWER

Public procurement procedure, ref. no. RORS 284/CityofKikinda/TD2, launched by the City of Kikinda under the project "Banat 112 - fast response to a unique challenge", eMS Code: 284, foreseen purchase of ambulance vehicles and medical equipment for the work of the "Medical

Emergency Service" of "Dom zdravlja Kikinda" (health institution founded by the City of Kikinda). The subject of the supply procedure has been divided into two lots, as stated in Contract Notice and Instruction to tenderers. Since clarification request did not precisely determine the lot it referred, from the content of the submitted question Contracting Authority concludes that it is about the Lot no. 1 – "Ambulance vehicles with installed and attached medical equipment".

In Annex II+III (Technical specifications + Technical offer) of Lot 1, Contracting Authority numbered and marked all the goods that are the subject of this procurement, as well as set minimum technical criteria for each of them. Ambulance vehicles have been marked under item numbers 1 and 2, and attached medical equipment under item numbers from 1.1 up to 1.10. Also, Contracting Authority defined that "medical equipment from points 1.1 to 1.10 must be supplied in vehicles from point 1". It means that two ambulance vehicles (item point 1) should be offered/tendered and delivered with that attached equipment, but not the vehicle from item point 2. On the other hand, medical devices mentioned in vehicle's patient compartment should be installed in all vehicles from item points 1 and 2, since they are standard for this type of vehicles.

Having in mind that goods from 1.1 to 1.10, as well as equipment mentioned in vehicle's patient compartment, are medical devices, Contracting Authority defined that it must be certified/registered according to the national legislation. Circulation, placing on market and usage of medical devices are regulated by the legislation of the Republic of Serbia, so for that reason, City of Kikinda, as a Contracting Authority, is obliged to respect national legislation requirements when composing the procurement specifications and purchasing those kinds of goods in order to ensure their unhindered and legal usage. At this point City of Kikinda would like to emphasize the **Article 70.** of the Law on medical devices of the Republic of Serbia ("Official gazette RS", 105/2017) which states that "**the provisions of this law and the by-laws adopted for its implementation, which regulate the wholesale circulation of the medical devices, are accordingly applied to the wholesale of medical devices from donations or humanitarian aid**". Also, Contracting Authority would like to emphasize **Article 4.** of Annex IV (General conditions) of the "Financing Agreement for Interreg – IPA CBC Romania – Serbia Programme 2014 – 2020", which said: **"Operations supported by IPA II assistance shall comply with applicable Union law and national law relating to its application ("applicable law")"**. In that sense, the provision of the Technical specification that clarification request refers to does affect all tenders nevertheless the origin of the tenderer, since relevant national legislation set rules regarding certification or registration of medical devices (depending on the detailes of every concrete case).

Contracting Authority draws attention of all tenderers to the Article 27. point 1(b) and (e) of the „Framework Agreement between the Republic of Serbia and the European Commission on the arragements for implementation of the Union financial asisstance to the Republic of Serbia under the Instrument for pre-accession assistance (IPA II)". In that light, for all the detailes on certification and/or registration regime, as well as other aspects of supply/circulation, placing on the market, import and usage of medical devices, we refer to national legislation documents, especially:

- Law on Medical Devices („Official gazette of RS", No. 105/2017)
- Law on Medicinal Products and Medical Devices („Official gazette of RS", No. 30/2010; 107/2012 and 113/2017-other law)
- Rulebook on Essential Requirements for medical devices ("Official Gazette of RS", No. 65/2018)
- Rulebook on Registration of a medical devices ("Official Gazette of RS ", No. 84 of November 2, 2018)
- Rulebook on Import of unregistered medical devices ("Official Gazette of RS", No. 39/2018)
- Rulebook on the wholesale trade of medical devices ("Official Gazette of the RS", No. 84/2018)

Complete overview can be found on the website of the Medicines and Medical Devices Agency of Serbia: https://www.alims.gov.rs (Serbian) or ALIMS – Medicines and Medical Devices Agency of Serbia (English).

Regarding the claim that "according to the *the ''Law on medical devices'' if an ambulance vehicle is delivered from a foreign country, medical equipment inside the vehicle must be registered in that country",* City of Kikinda, as a Contracting Authority, is not familiar (now, nor at the moment of the Contract Notice publishing) that the mentioned law contains such a provision or that some provisions can be interpreted in such a way. If the above-mentioned claim was the case under some other donations that the question implies, that does not mean it is relevant for this procedure, or for the projects implementing under the Interreg-IPA Cross-border Cooperation Romania-Serbia Programme.

As for the terms of participation, it has been stipulated in point 8. of the Contract Notice, which said that „all natural persons or all legal persons from any country can participate in this public procurement procedure, and all goods can originate from any country". Beside, point 16. of the Contract Notice, as a one of the selection criteria, set that the tenderer must be „registred or authorized to trade goods that are the subject of this contract in accordance with the national legislation of the country of the delivery". Those provisions, along with all other provisions of the tender dossier, equally apply on all potential tenderers, nevertheless the origin.