

# **DOCUMENTATION RELATED TO AWARDING A PUBLIC CONTRACT**

## **SUBJECT MATTER OF THE TENDER: SUPPLIES**

### **PERCUTANEOUS AORTIC VALVES**

**The public procurement was published on the public procurement portal on 18.11.2019 under the publication number JN008030/2019-B01 and in the Official Journal of the EU on 19.11.2019, publication number 2019/S 223-546545.**

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Invitation No.: 460-E-DS-609/19

Date: 13.11.2019

## **A) INVITATION TO TENDER**

You are invited to submit a tender for supply contracts:

### **PERCUTANEOUS AORTIC VALVES**

It is required to draw up the tender in accordance with the instructions of this documentation related to public procurement.

Public procurement:

**PERCUTANEOUS AORTIC VALVES**

**B) INSTRUCTIONS TO TENDERERS FOR THE  
DEVELOPMENT OF THE TENDER**

November 2019

## 1. GENERAL

### 1.1 Basic information

Subject matter of the tender:	<b>PERCUTANEOUS AORTIC VALVES</b>  The subject matter of the tender is defined in detail under the Specification of the tenderer requirements, in the Annex to the contracting party specifications in the Section 2.11 of these instructions.  <b>The tenderer may submit a tender for an individual type of goods.</b>
Type of procedure:	The contracting authority will submit this public procurement following the open procedure in compliance with the Article 40 of the Public Procurement Act (Official Journal of the Republic of Slovenia, No. 91/15 and 14/18, hereinafter referred to as ZJN-3), with the purpose of concluding the framework agreement in compliance with the Article 48 of ZJN-3.
Duration of procurement:	From 22 February 2020 to 21 February 2021
Deadline for submission of tenders:	The tenderers are required to submit a tender through the e-JN information system available at <a href="https://ejn.gov.si/eJN2">https://ejn.gov.si/eJN2</a> by <b>27.12.2019 until 12.00</b> (See Section 2.4 of these instructions).
Public tender opening:	Tender opening will be performed automatically within the e-JN information system on <b>27.12.2019</b> and will start at <b>13.00</b> at the following website <a href="https://ejn.gov.si/eJN2">https://ejn.gov.si/eJN2</a> (See Section 2.5 of these instructions).

As the financial assets for the relevant public procurement for the year 2020 are yet provided, the contracting authority will conclude framework agreement under a condition precedent. The framework agreement will enter into force when and if the funding will be provided.

In the event the contracting authority will receive tenders exceeding the provided funding, the contracting authority reserves the right:

- to award a tender only partially,
- not to award the tender for the section (individual type of goods) where the tender exceeds the provided funds,
- to decrease the amount of goods where the offered price exceeds the provided funds.

The contracting authority will conclude a framework agreement with the tenderer offering best value.

The documentation related to public procurement is written in the Slovene and English language. In the event of differences in the meaning (interpretation) of individual provisions, the Slovene language shall be taken into account, i.e. the documentation related to public procurement in the Slovene language.

### 1.2. Participation

Each legal or natural person registered to conduct activities, which are the subject matter of this public procurement and authorized to perform these activities, may compete in this procedure.

### 1.2.1 Foreign tenderers

For tenderers registered in a foreign country the contracting authority will establish the tenderer's eligibility as for all tenderers registered in Slovenia.

Foreign tenderers are required to provide supporting documents as listed in Section 2.10 of these instructions.

### 1.2.2 Joint tender

Groups of economic operators may submit a joint tender.

In the event that such group of tenderers will be selected for the performance of the relevant procurement, the contracting party may request from the selected group a submission of a relevant act on the joint performance of the procurement (e.g. cooperation agreement), clearly demonstrating at least the following:

- appointment of the manager for the performance of the procurement,
- type of contractual obligations implemented by an individual partner and his responsibilities,
- a statement that they are familiarized with the payment terms from the documentation regarding the award of public contract and a statement that they severally liable to the contracting party,
- authorization of the manager's partners for signing the framework agreement with contracting party.

In the event of joint tender, the legal persons should state in the ESPD form all those participating in this joint tender. The tenderers in the joint tender can state also one of the legal persons for communication with the contracting party until a decision on the tender is reached, otherwise the contracting party shall address all tenderers participating in the joint tender.

In the event of a joint tender, it is necessary for each of the participating economic operators to submit a separate uniform European document regarding the award of public procurement (herein referred to as ESPD)

In the event that a group of tenderers submits a joint tender, the contracting party will establish for each individual tenderer of the group the eligibility arising from Section 2.10 of these instructions, specifically:

- absence of reasons for exclusion,
- suitability to pursue the professional activity

If any reason for exclusion listed in section 2.10 of these instructions will be provided for any of the joint tenderers, the contracting authority will act in compliance with the provision of Paragraph 9, 10 and 11 of Article 75 of the Public Procurement Act-3

Financial insurance may be submitted by only one of the partners of the joint tender, whereby all requirements set out in these instructions must be met (height, validity, etc.).

### 1.3 Clarifications related to public procurement

Clarifications on the content of documentation related to public procurement may be requested only through the public procurement portal<sup>1</sup>. The clarifications will be **provided** on the public procurement portal.

If any tenderer requests any additional clarification related to the public procurement documentation or preparation of the tender, this should be requested **in a timely manner or** until **13.12.2019 12:00 AM** at the latest. The contracting authority will provide additional clarification six days prior to due date for public procurements at the latest, provided the request was submitted in a timely manner.

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<sup>1</sup> <http://www.enarocanje.si>

## 1.4 Modifications and amendments of the documentation related to public procurement

The contracting authority reserves the right to amend or modify the documentation related to public procurement. If the contracting authority modifies or supplements the documentation related to public procurement, they will publish these modifications or amendments on their website (<http://www.ukc-mb.si>) and the public procurement portal.

After the deadline for submission of tender, the contracting authority will not modify or amend the documentation related to public procurement.

If the contracting authority modifies or supplements the documentation related to public procurement 6 days or less prior to deadline set for submission of tender, they will accordingly extend the deadline for submission of tender based on the extent and content of these modifications.

By exceeding the deadline for submission of tender, the rights and obligations of the contracting authority and tenderer are subject to/linked to new deadlines arising from the extended deadline for submission of tender.

## II TENDER

### 2 1 Language

The tenderer must prepare the tender in the Slovenian language, with the exception of catalogues, brochures, technical documentation etc. which can be submitted in the English language.

### 2.2 Admissibility of tender

The tender is admissible if no grounds for exclusion of the tenderer submitting this tender exist and the tenderer meets the requirements for participation and their offer meets the needs and requirements of the contracting authority set out in the technical specifications and the public procurement documentation which was submitted in due time and no evidence exists of collusion or corruption related to the tender and the contracting party did not assess the tender as unusually low and the price does not exceed the contracting authority's funds provided.

### 2.3 Submission of tender

The tenderer is required to submit the following:

1. completed tender form (OBR-1);
2. completed framework agreement form (OBR-2);
3. consent from the tenderer for obtaining personal data (OBR-3);
4. completed Specifications of the contracting authority requirements form (**for all types of goods subject to tender**);
5. completed tender specifications form with prices (**for all types of goods subject to tender**);
6. completed ESPD form for all economic operators in the tender;
7. documents from the form »Annex to the Specification of the contracting authority requirements«.

Forms from Sections 1, 2, 3, 4, and 5 are an integral part of this public procurement documentation. The tenderer is required to complete, sign and stamp with a single stamp. The documents are completed and signed by a legal representative or his duly authorised representative.

**Signed and stamped documents have to be scanned to a PDF file, except the ESPD form (though preferred)**

**The tenderer uploads the entire tender in an electronic form to the e-JN information system under heading "Drugi dokumenti (Other documents)".**

**The tenderer is required to upload in the e-JN information system under the heading »Predračun (Quotation)« a completed form »Specifikacija ponudbe s cenami (Tender**

**specifications including prices) (for all types of tenderer goods)« in a PDF file, which will be accessible at the public tender opening.**

**The tenderer uploads their ESPD to »ESPD – ponudnik« tab, and the ESPD form of other participating tenderers to »ESPD – ostali sodelujoči« tab. The tenderer submitting a procurement in the e-JN system (public procurement portal), the electronically signed ESPD in the XML format or unsigned ESPD in the XML format, in which case the latter is regarded as a legally binding document in accordance with the General conditions of use of the public procurement portal, and having the same effect as the signed version.**

**The tenderer may submit a tender for an individual type of goods.**

In the specification of contracting authority requirements, it is compulsory for the tenderer to enter the following data for each type of goods:

- packing,
- manufacturer,
- protected name,
- catalogue number or any other identification mark of goods.

**As the contracting authority is tendering on a single ident different forms and dimensions of the same kind of goods, the tenderer is required to attach the specification with catalogue numbers for all the offered dimensions and forms.**

The tender specification with prices needs to include:

- price without VAT,
- tax rate (%).

If the tenderer will perform the contract with a joint tender, they are required to submit the following documents for each partner in a joint tender:

- completed tender form (OBR-1),
- ESPD form.

The age of the documents must not exceed the deadline as set out by the individual provisions of the public procurement documentation. In cases where the age of the documents is not defined, the document must demonstrate the legal relevant status of the economic operator on the day set for tender submission.

#### ESPD form

The ESPD form, which requires evidence that reasons for exclusion do not exist (Section 2.10.1. of these instructions) and evidence of eligibility defined in Section 2.10.2 of these instructions, includes an updated own statement by the economic operator as preliminary evidence that a specific economic operator is not in one of the positions defined in Article 75 of Law on public procurement (ZPJ-3) and meets the relevant criteria for participation, defined in this documentation.

The economic operator must enter in the ESPD form all data based on which the contracting authority will obtain the certificates or other information from the national database and the submit consent within the relevant form for the contracting authority to obtain the supporting documents.

If the economic operator submits the supporting documents regarding the statements from the ESPD form, the contracting authority reserves the right to verify the authenticity of the submitted supporting evidence with the signatory of this supporting evidence.

The economic operator is required to save the tenderer's ESPD form (XML file) into their computer and then export it to the public procurement portal) choose the ESPD tab and then mark "Economic operator"). When saving the file, you are not allowed to change the file extension. This document must be completed, printed, signed and attached to the tender.

The economic operator may re-utilize the ESPD used in the previous public procurement procedure, if they can confirm that the information in it is still accurate.

## 2.4 Manner and deadline for tender submission

Tenderers must submit their tenders to the e-JN information system available at [https://ejn.gov.si/ponudba/pages/aktualno/vstopna\\_stran.xhtml](https://ejn.gov.si/ponudba/pages/aktualno/vstopna_stran.xhtml) in accordance with point 3 of the Instructions on how to use the e-JN information system for e-submissions of tenders: TENDERERS (hereinafter referred to as e-JN Instructions), which forms a part of these documentation relating to the award of contract and published at: [https://ejn.gov.si/documents/10193/191051/ejn\\_Navodila\\_za\\_uporabo\\_ponudniki.pdf](https://ejn.gov.si/documents/10193/191051/ejn_Navodila_za_uporabo_ponudniki.pdf).

Before submitting a tender, the tenderer needs to register at [https://ejn.gov.si/ponudba/pages/aktualno/vstopna\\_stran.xhtml](https://ejn.gov.si/ponudba/pages/aktualno/vstopna_stran.xhtml) in accordance with e-JN Instructions. If already registered, a login is required at the same address.

The user of the tenderer authorized for submitting a tender in the e-JN information system, submits a tender by clicking on »Oddaj« (»Submit«). The information system records the user's identity and time of tender submission. By submitting the tender, the user indicates and states the will on behalf of the tenderer to submit a binding offer (Article 18 of Code of Obligations<sup>2</sup>). The submission of tender makes is binding for the period of time indicated in the tender, unless withdrawn or changed by the tenderer's user prior to the tender submission deadline.

A tender is deemed to be submitted on time, if the contracting authority receives it via the e-JN system at <https://ejn.gov.si/eJN2> by **27.12.2019 until 12.00 AM at the latest**. A bid is deemed submitted if marked "SUBMITTED" ("ODDANO") in the e-JN system.

Bidders may withdraw or amend their bids before the closing date or deadline for the submission of tenders. If a tenderer withdraws their tender from the e-JN system, it is deemed that no tender has been submitted and the contracting authority will not see it in the e-JN system. If a tenderer amends their tender in the e-JN system, the Contracting Authority sees the last tender submitted.

It is not possible to submit any tender after the expiry of the tender submission deadline.

The page for submitting an e-tender in this e-procurement procedure can be accessed here: [https://ejn.gov.si/ponudba/pages/aktualno/aktualno\\_javno\\_narocilo\\_podrobno.xhtml?zadevald=14266](https://ejn.gov.si/ponudba/pages/aktualno/aktualno_javno_narocilo_podrobno.xhtml?zadevald=14266).

## 2.5 Time and place of tender opening

Tender opening will take place automatically in the e-JN information system on **27.12.2019** and will start at **13.00** at the following website: <https://ejn.gov.si/eJN2>.

The e-JN information system automatically displays at a certain hour set for public tender opening the data on the tenderer, variations if they were requested or permitted, and enables access to the PDF document, which is uploaded by the tenderer to the e-JN system under the heading »Predračun (Quotation)«. The tenderers who have submitted their tenders can access these data in the e-JN information system under the heading »Zapisnik o odpiranju ponudb (Reports on tender opening)«.

### 2.6. Correction of errors

Corrected errors must be marked with the initials of the person or persons signing the tender.

### 2.7. Permissible variations and supplementations of the tender

If the information or documentation which must be submitted by the economic operators, incomplete or false, or if individual documents are missing, the contracting authority will act in accordance with the provision of Paragraph 5, 6 and 6 of Article 89 of Law on Public Procurement (ZNJ-3).

### 2.8. Indication of misleading information

If the contracting authority has reasonable suspicion that an individual economic operator in the



public procurement procedure has submitted a false statement or a counterfeit or a forged document, the contracting authority will submit to the National Commission for the review of awards of public procurement procedures a proposal for introducing infringement procedure from Subparagraph 5 of the 1 Paragraph or Subparagraph 1 of Paragraph 2 of Article 112 of Law on Public Procurement (ZNJ-3).

## **2.9. Costs of preparing the tender**

Tenderers bear the costs related to the preparation and submission of tender, including the costs of brochures, catalogues, if requested by the contracting authority, and samples if the contracting authority wishes to test them.

If the contracting authority requests from the tenderer to submit brochures, catalogues or samples, these need to be delivered with 7 days at the latest. If the tenderer does not deliver the requested brochures, catalogues or samples or delivers them past deadline, the contracting authority will exclude such tenderer from further public procurement procedure.

## **2.10. Establishing suitability of economic operators**

The contracting party will establish the suitability of economic operators as follows:

### **2.10.1. Exclusion grounds**

The contracting authority will exclude the tenderer from the public procurement procedure:

1. if carrying out a revision pursuant to Articles 77, 79 and 80 of Law on Public Procurement the contracting authority establishes or is else takes notes that the economic operator or person, which is a member of administrative, management or supervisory authority of this economic subject or has been authorized for their representation or decision making or supervision, has been the subject of a conviction by final judgment which contains elements of the following criminal offences laid down in the Criminal Code (Official Journal of the Republic of Slovenia, No. 50/12 - official consolidated text and 54/12; hereinafter referred to as: KZ-1):

- terrorism
- terrorist financing, (Article 109 of KZ-1),
- provocations and public glorification of terrorist acts (Article 110 of KZ-1),
- recruitment and training for terrorism (Article 111 of KZ-1),
- bringing another person into slavery (Article 112 of KZ-1),
- human trafficking (Article 113 of KZ-1),
- bribery during elections (Article 157 of KZ-1),
- breach of a workers' fundamental rights (Article 196 of KZ-1),
- fraud (Article 211 of KZ-1),
- unlawful restriction of competition (Article 225 of KZ-1),
- causing bankruptcy by fraud or negligent business operations (Article 226 of KZ-1),
- impoverishment of claimants, (Article 227 of KZ-1),
- business scams (Article 228 of KZ-1),
- fraud against the European Union (Article 229 of KZ-1),
- circumvention at acquisition and use of loan or benefits (Article 230 of KZ-1),
- circumvention at investment banking (Article 231 of KZ-1),
- circumvention of buyers (Article 232 of KZ-1),
- unauthorized use of foreign marking or model (Article 233 of KZ-1),
- the use without due cause of foreign invention or topography (Article 234 of KZ-1),
- falsification or destruction of business records (Article 235 of KZ-1),
- disclosure and unlawful acquisition of trade secrets (Article 236 of KZ-1),
- abuse of information system (Article 237 of KZ-1),
- abuse of internal information (Article 238 of KZ-1),
- abuse of markets in financial instruments (Article 239 of KZ-1),
- breach of position or trust in economic activities (Article 240 of KZ-1),
- unauthorized acceptance of gifts (Article 241 of KZ-1),
- unauthorized giving gifts (Article 242 of KZ-1),
- currency counterfeiting (Article 243 of KZ-1),
- forgery and use of false securities (Article 244 of KZ-1),

- money laundering (Article 245 of KZ-1),
- abuse of non-cash means of payment (Article 246 of KZ-1),
- use of falsified non-cash means of payment (Article 247 of KZ-1),
- production, acquisition and disposal of accessories for counterfeiting (Article 248 of KZ-1),
- tax evasion (Article 249 of KZ-1),
- smuggling (Article 250 of KZ-1),
- abuse of official position or official rights (Article 257 of KZ-1),
- harm to public funds (Article 257.a of KZ-1),
- disclosure of classified information (Article 260 of KZ-1),
- receiving bribery (Article 261 of KZ-1),
- giving bribery (Article 262 of KZ-1),
- accepting benefits for illicit brokering (Article 263 of KZ-1),
- giving gifts for illicit brokering (Article 264 of KZ-1),
- conspiracy (Article 294 of KZ-1).

**Supporting evidence:** ESPD form for all economic operators in the tender.

2. if carrying out a revision pursuant to Articles 77, 79 and 80 of ZJN-3 the contracting authority establishes that the economic operator does not comply with the compulsory duties and other non-tax monetary liabilities pursuant to the law regulating the Financial Administration and collected by a tax authority in compliance with the legal provisions of the country in which it is established or the regulations of the contracting authority's country if the value of these outstanding liabilities amount to 50 euros or more on the day of tender submission. It is also considered that the economic operator does not comply with the obligations from the previous paragraph if on the day of tender submission he did not submit all payments of withholding tax for employment incomes for the period of the last five years until the day of tender submission.

**Supporting evidence:** ESPD form for all economic operators in the tender.

3. if the tenderer is excluded on the day the period for the submission of tenders shall expires from the public procurement procedures on account of being listed as an economic operator with negative references.

**Supporting evidence:** ESPD form for all economic operators in the tender.

4. if during the last three years before the expiry of the deadline for the submission of tenders, the competent public authority of the Republic of Slovenia or another Member State or a third country has identified at least 2 (two) infringements related to work remuneration, working hours, rest and rest periods, work based on civil-law contracts although the elements of employment relationship exist, or in relation to undeclared work for which they were issued a final decision or several final decisions to impose a fine for the offense.

**Supporting evidence:** ESPD form for all economic operators in the tender.

## **2.10.2. Conditions for participation**

### **2.10.2.1 Suitability to pursue the professional activity:**

1. registered with the competent court or other authority

**Supporting evidence:** ESPD form for all economic operators in the tender.

2. included in the business registry of operators performing wholesale distribution of medicinal products at the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (valid for tenderers established with a registered office in the Republic of Slovenia)

*or in case of a foreign tenderer*

included in the business registry of operators performing wholesale distribution of medicinal

products in compliance with the legislation of the country in which the operation is established.

**Supporting evidence:** ESPD form for all economic operators in the tender.

### 2.11 Technical specifications

The contracting authority will also reject the tender not meeting all the technical requirements for the offered types of goods from the relevant tender. Technical requirements are defined in this section, in the Specification of requirements of the contracting authority and in the Annex to the contracting party specifications.

The tenderer must provide the tendered types and amounts of goods for which the tender is submitted.

All tendered types of goods must have the CE marking which the tenderer will prove upon the contracting authority's request by submitting relevant documents.

### 2.12 Bidding value

The prices must be in euros (EUR).

The price without VAT must include all costs (transport costs, forwarding costs, customs expenses, and other possible costs), discounts and rebates). Specifically, value added tax rate needs to be invoiced.

It is necessary to indicate the final value of the tender, which it is obtained by multiplying the prices with the amounts and sum the. The tendered value must include all costs.

Price per item must remain fixed during the entire duration of the framework agreement.

### 2.13 Criteria

- **the lowest final value of individual type of goods without VAT.**

#### **Note:**

In case more tenderers offer the same price without VAT for an **individual type of goods**, the contracting authority will draw. Only those tenderers who have offered the same price can be present at drawing. The contracting authority will notify the tenderers in writing regarding the date, time and place of drawing. The contracting authority will carry out the drawing. The contract will be awarded to the tendered who will be drawn first.

### 2.14 Selection of tenderer

A successful tenderer will be the one who:

- submits an admissible tender and
- offers the lowest final price of individual type of good without VAT.

The chosen tenderer is required to submit **within 8 days** from the receipt of invitation from the contracting authority data on:

- **his founders, members, shareholders, or other owners and data on equities of listed persons;**
- **economic operators which are considered as involved companies based on the provision of law regulating companies..**

### 2.15 Tender validity

The tender must be valid until 27.06.2020.

Only after exceptional circumstances can the contracting authority request that the tenderers extend the tender validity for a certain additional period. The request and the replies of tenderers

must be provided in a written form. The tenderer may decline the request. Apart from the extension of the tender validity, the tenderer agreeing with the request will not be required or allowed to change the tender in any other manner.

## **2.16 Variants**

Variants are not allowed.

## **III FINANCIAL COLLATERAL**

The chosen tenderer is required to submit to the contracting authority the following:

1. bill of exchange statement and signed bill of exchange with authorization for its completion in the amount of 5% from the value of the framework agreement or purchase agreement in case the value exceeds 50.000,00 EUR, VAT excluded and is lower than 134.000,00 EUR, VAT excluded. The tenderer is required to ensure that the bill of exchange is negotiable for the duration of the framework agreement; or
2. guarantee (by the bank/insurance company) for proper execution of contractual obligations in the amount of 5% from the value of the framework agreement or purchase contract in case the value is the same or higher than 134.000,00 EUR, VAT excluded.

The validity of the bill of exchange or guarantee for proper execution of contractual obligations must remain valid at least 10 days after the validity of the framework agreement.

In case of realization of the bill of exchange or guarantee for proper execution of contractual obligations, the tenderer will have to appropriately substitute the realized bill of exchange or guarantee with a new one.

## **IV AWARD OF THE FRAMEWORK AGREEMENT**

### **4.1 Award of the framework agreement**

The contracting authority will conclude a framework agreement with the tenderer offering best value and chosen based on the criteria set out in Section 2.13 of these instructions according to the framework agreement draft defined in Subparagraph 2 of Section 2.3 of these instructions.

As the financial assets for the relevant public procurement for the years 2018 and 2019 are yet provided, the contracting authority will conclude framework agreement under a condition precedent. The framework agreement will enter into force when and if the funding will be provided. The framework agreement is concluded for the period from 22 February 2020 to 21 February 2021.

The tenderer is required to sign the framework agreement within 10 days after the receipt of the contracting authority's invitation to sign the framework agreement or the contracting authority will consider that the tenderer does not enter into transactions.

## **V FINAL PROVISIONS**

Along the provisions in these instructions, the provision from the framework agreement and the entire public procurement documentation are valid. In case of doubt, individual provisions are assessed pursuant to the articles of ZNJ-3 and Criminal Code (Official Journal of the Republic of Slovenia, No. 97/07).

## **VI LEGAL PROTECTION**

Legal protection of tenderers during the award procedure is ensured in accordance with the provisions of the Legal Protection in Public Procurement Procedures Act (Official Gazette of Republic Slovenia, No. 43/11, 60/11 - ZTP-D, 63/13, 90/14 - ZDU-11 and 60/17) and according to the procedure and the manner provided by law.

A legal protection request during award procedures can be filed in against any conduct of a contracting authority, unless otherwise provided by the law governing public procurements or the Legal Protection in Public Procurement Procedures Act. A legal protection request can be filed by a person with locus standi as specified in the Article 14 of the Legal Protection in Public Procurement Procedures Act.

The application for a review must include:

1. Name and address of the applicant (hereinafter referred to as applicant) and a contact person,
2. Name of the contracting authority,
3. Public procurement label or decision to award a public procurement or qualitative selection,
4. Subject of public procurement,
5. Powers of representation during the pre-audit and audit process, if the applicant is represented by a delegate,
6. Certificate of payment of fee.

Alleged violations as well as facts and evidence, which prove the violations, must be contained in the application for a review.

The applicant must pay a tax in the amount of EUR 4,000 to the following sub-account 01100-1000358802 (Bank of Slovenia) – budget implementation of the RS, stating pre-audit and review procedure as the purpose and indicating the following reference No.: 11 16110-7111290-00803019.

The application for review shall be submitted in writing directly with the contracting authority by registered mail with returned receipt to the following address:

**UNIVERZITETNI KLINIČNI CENTER MARIBOR**  
**Služba za nabavo medicinskega materiala in storitev**  
**Ljubljanska ulica 5**  
**2000 Maribor.**

The application for review relating to the content of a contract notice, an invitation to tender or a tender dossier must be filed within ten working days of the date of publication of the contract award notice or receipt of the invitation to tender. In the event that the contracting authority amends or supplements the entries in the publication, the invitation to tender or the tender dossier, the application for review relating to the amended, completed or explained content of publication, invitation or tender dossier or an entry directly associated with the original publication, invitation to tender or tender dossier can be filed within ten working days of the date of publication of additional information, information concerning pending procedures or corrections, if this publication amends or supplements the requirements or selection or award criteria.

Where the contracting authority establishes that the conditions laid down in the first, third, fourth or fifth indent of the first paragraph of Article 26 of ZPVPJN-B had not been fulfilled, the application of review shall be rejected by a decision not later than three working days from the receipt.

# TENDER

**Manner of tender submission:**

 Joint tender: (indicate: yes/no).<sup>1</sup>

<b>1. Description of the subject matter of the procurement:</b>	
<b>PERCUTANEOUS AORTIC VALVES</b>	
Public procurement was published on the public procurement portal, date of publication 18.11.2019, number of publication JN008030/2019-B01 in the EU Official Journal, date of publication 19.11.2019, number of publication 2019/S 223-546545.	
<b>2. Quoted value in EUR, VAT excluded:</b>	
<b>3. Information on the tenderer:</b>	
3.1 Company or name:	
3.2 Address:	
3.3 Legal representative:	
3.4 Identification number for VAT:	
3.5 Registration number:	
3.6 Account number:	
3.7 telephone number:	
3.8 Fax number:	
3.9 E-mail:	
3.10 Contact person:	
3.11 Person responsible for signing the framework agreement:	

Date:

Stamp and signature of the tenderer:

.....

<sup>1</sup> In the event of a joint tender, each partner of the joint tender is required to complete this form.

# DRAFT FRAMEWORK AGREEMENT

Entered into by:

UNIVERZITETNI KLINIČNI CENTER MARIBOR, Ljubljanska ulica 5, 2000 Maribor (hereinafter: UKC Maribor), represented by professor Dr. Vojko FLIS, MD, (hereinafter: Contracting authority), VAT identification no.: SI56644817, matriculation no. of Contracting authority: 5054150

And business entity:

, represented by director (hereinafter: party to the Agreement), VAT identification no.: , matriculation no. of Party to the Agreement: .

## I INTRODUCTORY PROVISIONS

### Article 1

Contracting authority and party to the Agreement find that the contracting authority became acquainted with the procedure of award of contract for procurement of goods »PERCUTANEOUS AORTIC VALVES«, by open procedure under article 40 of the Public Procurement Act (Official Journal of RS, no. 91/15 and 14/18, hereinafter: ZJN-3), with the purpose of entering into framework agreement under article 48 of ZJN-3, as published on site of public procurement, publication date 18.11.2019, publication no.: JN008030/2019-B01 and in EU Official Journal, publication date 19.11.2019, publication no. 2019/S 223-546545.

### Article 2

By this framework agreement (hereinafter: Agreement) Contracting authority and Party to the Agreement agree on general and special terms and conditions of the Framework Agreement implementation.

## II SUBJECT OF AGREEMENT

### Article 3

Parties to the Agreement agree to enter into the Agreement per individual type of goods, as laid down in the List of goods (hereinafter: List).

Offer no.: ....., dated ....., List referred to in article hereto, documentation in conjunction with award of public procurement shall be component part of Agreement hereto.

Parties to the Agreement expressly agree that the contracting authority shall, during the effectuation of Agreement hereto, purchase from Party to the Agreement only those types and quantities of goods, which it shall be needful during the period hereto.

quantities of goods are indicative in nature. Contracting authority shall not be bound to award certain quantities of goods.

The indicative quantities are tendered assuming the contracting party will receive an approval by the Health Insurance Institute of Slovenia for extending the programme. Otherwise, the contracting party shall purchase smaller amounts of percutaneous aortic valves.

### **III PRICES**

#### **Article 4**

Should Contracting authority find Party to Agreement had per goods subject of Agreement hereto, during effectuation of Agreement hereto, decreased prices or should other offerors decrease them, ones also offering same type goods at comparable terms and conditions, it retains right to endeavour to agree with Party to Agreement on appropriate decrease of price under Agreement.

Prices per individual types of goods from offer are fixed during the entire Agreement hereto effectuation.

In the price of individual goods items, all expenses (customs, forwarding and other expenses, if any), all deductions and rebates, as well as the value added tax, are covered. Prices are in force contracting authority ddp storage, disassembled.

Should a change in law governing value added tax, by which tax rate be altered per types of goods subject of offer during Agreement hereto effectuation, prices referred to in offer may be corrected exclusively in amount of tax change having come about.

### **IV AWARING GOODS AND DELIVERY TIME**

#### **Article 5**

Contracting authority shall, per individual type of goods needed during the Agreement hereto effectuation, purchase from Party to the Agreement under purchase orders in writing issued. Contracting authority shall lay down types and quantities of goods items in purchase orders.

Party to the Agreement binds itself that it shall supply the goods not later than within 48 hours i.e. in urgent cases within 24 hours upon receipt of purchase order at issue and that it shall with respect to each individual purchase order supply the entire quantity of goods ordered.

Goods need to be supplied ddp Univerzitetni klinični center Maribor – disassembled into storage premises of Contracting authority.

Party to the Agreement binds itself to provide, bearing entire expenses incurred, scavangery of packaging, subject of goods supplied.

In case of technological progress for items offered during the execution of the agreement, the older version of the item may be replaced with a new version. Such replacement should be documented in written form and confirmed by both parties of the agreement and the price of an individual item cannot increase due to this replacement.



## **V TAKE-OVER OF GOODS**

### **Article 6**

Contracting authority binds itself to take over goods ordered in entirety, as under purchase order. Purchase order needs to be written in Slovene language and mandatorily needs to contain purchase order number.

Goods supplied under purchase order need always to bear same title as ordered, equal measurements and equal catalogue number. Supplied goods also need to be designated by bar code, containing particulars of item, including serial number and lot. Catalogue numbers need always to be the equal (dots, commas, spaces, ....) on all documents (purchase order, invoice) and goods sticker on box.

Quantitative take over of goods shall be rendered at take over, whereas qualitative take over shall be implemented under time limits in customary practice.

## **VI QUALITY OF GOODS**

### **Article 7**

Quality of goods shall comply to standards existing and quality declared in goods packaging.

## **VII TERMS OF PAYMENT**

### **Article 8**

Contracting authority shall pay entire amount of goods received to Party at Agreement to transaction account no. \_\_\_\_\_, not later than within 60 days as of date of having been served correctly submitted invoice upon goods having been taken over.

Invoice needs mandatorily to contain entire purchase order number.

Total amount of individual types of goods shall be computed by goods being multiplied by number of items supplied.

Total value of goods supplied shall be calculated by adding all values of each all goods supplied, computed in and referred to in previous paragraph of article hereto.

Party to the Agreement needs to serve all invoices to Contracting authority exclusively in electronic form (e-invoice), in conformity with Provision of payment services for budget users act (Official Journal of RS, no. 77/16 and 47/19).

Should there be lateness as to payment, Contracting authority shall pay statutory lateness interest.

## **VIII AGREEMENT ADMINISTRATOR**

### **Article 9**

Agreement Administrator for Contracting authority shall be: .....

Agreement Administrator for Party to the Agreement shall be: .....

## IX COLLATERALISING OBLIGATIONS

### Article 10

Party to the Agreement shall present the Contracting authority at signing the Agreement hereto, as instruments of collateral:

- Bill of exchange statement and own signed bill of exchange with authorisation in amount of 5% of the Agreement value, should value exceed 50.000,00 EUR DDV excluded and lower than 134.000,00 EUR, VAT excluded. Party to the Agreement need to assure that the bill of exchange be cashable the entire time of the Agreement; i.e.
- guarantee (by bank or insurer) for good performance of contractual obligations in amount of 5% of Agreement value, should the value be equal or exceed 134.000,00 EUR, VAT excluded.

Validity of financial collateralisation instruments referred to in previous indents needs to be not less than 10 days upon the Agreement validity.

Should cashing bills of exchange i.e. warrantees for good performance come about, Party to Agreement shall be needful to replace the cashed bill of exchange i.e. warrantee by a new one.

Should Party to the Agreement with respect to cashing the bills of exchange not dispose of sufficient funds on account, Contracting party shall sever Agreement with it.

Contracting authority shall cash the bill of exchange i.e. warrantee, should goods ordered at individual supply:

- not correspond to standards and quality;
- not receive them within time limit and in quantities laid down in purchase order,
- in other cases of violation of Agreement hereto.

## X ENTERING AGREEMENT, AGREEMENT EFFECTUATION AND AGREEMENT WITHDRAWAL

### Article 11

Agreement hereto is entered From 22 February 2020 to 21 February 2021; the Agreement is entered into on date of signing by Contracting authority and Party to the Agreement and when Party to the Agreement serves collateral instruments referred to in article 10 of Agreement hereto.

As financial funds for the public procurement at issue for 2020 have not been provided for yet, the Contracting part shall enter into Agreement hereto with suspensive condition. Agreement shall commence to effectuate only when funds shall have been provided for.

Agreement hereto shall cease to effectuate, should Contracting authority become acquainted of violation of obligation under article 3 ZJN-3, para. 2, which has been conclusively established by court, as perpetrated by the Party to the Agreement, or its sub-contractor, further, should the Contracting authority become acquainted of competent state authority having established the Party to the Agreement or its sub-contractor, during the effectuation of Agreement hereto, not less than two violations have been perpetrated relating to payment for work, working time, repose, conducting work by civil law contracts, in spite of labour law elements existing, or relating to illegal work,

where a fine for misdemeanour was pronounced to it by a conclusive decision or by multiple conclusive decisions.

The resolutive condition referred to in previous paragraph shall be rendered provided that the time period since being acquainted with the violation and the expiry of validity shall be not less than six months, in case of sub-contractor appearing further that violations established with sub-contractor Party to the Agreement has not appropriately replaced or replaced the sub-contractor within time limit of 30 days as of becoming acquainted with violation.

Should resolutive condition be met, it shall be considered Agreement hereto to be dissolved on the date of entering into new framework agreement on implementation of public procurement i.e. on thirtieth day as of acquaintance with violation, should Contracting authority not commence with awarding public procurement without delay i.e. not later than within 30 days as of acquaintance with violation.

## **Article 12**

Contracting authority shall communicate in writing all complaints relating to the Agreement implementation to parties to the Agreement. Should Party to the Agreement not take into consideration legitimate complaints by the Contracting authority, Contracting authority may exclude Party to the Agreement from Agreement hereto. Contracting authority shall inform Party to the Agreement in writing.

Contracting authority may withdraw from Agreement hereto should Party to the Agreement:

- reject a purchase order without foundation,
- be late with purchase order implementation,
- implement a purchase order in a manner lacking quality.

## **XI ANTI-CORRUPTION CLAUSE**

### **Article 13**

Agreement hereto shall be null and void, should it be established that, at the implementation of the public procurement, under which Agreement hereto was entered into, or at the implementation of Agreement hereto, anyone on his own behalf or on behalf of the Agreement counterparty had promised, offered or had given any inadmissible benefit for the attainment of the transaction or entering into transaction hereto under more favourable conditions or for failure of due supervision of contractual obligations implementation or for other conduct or failure to conduct, under which damage was afflicted to organ or organisation from public sector or for the attainment of inadmissible benefit has been enabled to organ representative, organ or organisation from the public sector, intermediary to a representative of the Contracting authority and intermediary of the Contracting authority or another organ or organisation from the public sector, the contractual counterparty or its representative, agent, intermediary.

## **XII FINAL PROVISIONS**

### **Article 14**

Terms and conditions laid down in Agreement hereto shall be in force for the entire period of Agreement effectuation.

Agreement hereto may be altered or amended by annex in writing, adopted and signed by all Parties to the Agreement. Should any of the Agreement provisions be or become invalid, this shall have no effect upon other Agreement provisions. The invalid provision shall be replaced by a valid one, to the most appropriate to the intent, pursued by the invalid provision.

#### **Article 15**

Disputes under Agreement hereto, if any, which Parties were not able to resolve by agreement, shall be resolved by competent court in Maribor.

#### **Article 16**

Agreement hereto has been drafted in two equal copies, of which each Party to the Agreement shall retain one.

No. ....

In            on

In Maribor, on.....

Party to the Agreement:

Contracting Authority:

UKC Maribor:

Director:

UKC Director:

prof. dr. Vojko Flis, MD

## CONSENT FOR OBTAINING PERSONAL DATA

### 1 TENDERER'S DATA:

Tenderer's name: .....  
 Address: .....  
 City and postal code: .....  
 VAT no. .... ID number: .....  
 Court registry number (application no.) .....

### 2 Legal representative data<sup>1</sup>:

2.1 Legal representative: .....

Address: .....

Address of permanent residence

City and postal code: .....

ID number: .....

2.2 Legal representative: .....

Address: .....

Address of permanent residence

City and postal code: .....

ID number: .....

2.3 Legal representative: .....

Address: .....

Address of permanent residence

City and postal code: .....

ID number: .....

2.4 Legal representative: .....

Address: .....

Address of permanent residence

City and postal code: .....

ID number: .....

University Medical Center Maribor, Ljubljanska ulica 5, 2000 Maribor (as the contracting authority), is given the consent in accordance with Article 77 of the Public Procurement Act (Official Gazette of the Republic of Slovenia, no. 91/15 and 14/18, hereinafter referred to as ZJN-3), to deliver the following supplies within the public procurement: PERCUTANEOUS AORTIC VALVES, published at the Public Procurement Portal,

In the event that the tenderer operates with more legal representatives than provided in this form, it is necessary to use a form with all representatives listed.

date of publication 18.11.2019, No. of publication JN008030/2019-B01 and in the Official Journal of EU, date of publication 19.11.2019, No. of publication 2019/S 223-546545 obtains information from the relevant Ministry of Justice, that there are no exclusion grounds listed in Article 75 of ZJN-3.

1. ....  
(Legal Representative's Signature)

Stamp:

2. ....  
(Legal Representative's Signature)

Place and date: .....

3. ....  
(Legal Representative's Signature)

4. ....  
(Legal Representative's Signature)

This consent is an integral part of the tender for public procurement: PERCUTANEOUS AORTIC VALVES.

TENDERER:

CONTRACTI **UNIVERZITETNI KLINIČNI CENTER MARIBOR**  
Ljubljanska ulica 5, 2000 Maribor

***Specification of the contracting authority requirements***

**SUBJECT MATTER OF THE PUBLIC PROCUREMENT: PERCUTANEOUS AORTIC VALVES**

Title	Code	EM	Indicative Quantities	Pack.	Manufacturer	Protected name	Catalogue No.
Expandable biological percutaneous aortic valve made of bovine pericardium (see technical specifications)	920300	PCS	25				
Self-expandable biological percutaneous aortic valve made of porcine or bovine pericardium (see technical specifications)	920400	PCS	25				

STAMP AND SIGNATURE:

Date:





## **ANNEX TO THE CONTRACTING PARTY SPECIFICATIONS**

### **TECHNICAL SPECIFICATIONS FOR PERCUTANEOUS AORTIC VALVES**

**IDENT 920300:** Self-expanding biological percutaneous aortic valve made of bovine pericardium. The valve has to be suitable for at least transfemoral, transaortic and transapical implantation. The valve has to be suitable for implantation in patients with aortic ring diameter measuring at least 18-29mm and calcified aortic leaflets. The valve kit has to include all the additional material required for valve placement. External catheter diameter for transfemoral valve implantation should not exceed 16F, which enables a transition through the peripheral arteries with an internal diameter of 6.0mm and more.

**IDENT 920400:** Self-expanding biological percutaneous aortic valve made of porcine or bovine pericardium. The valve has to be suitable for at least transfemoral, transaortic and transapical percutaneous implantation. The valve has to be suitable for implantation in patients with aortic ring diameter measuring at least 19-27 mm and calcified aortic leaflets. The valve kit has to include all the additional material required for valve placement. External catheter diameter for transfemoral valve implantation should not exceed 19F, which enables a transition through the peripheral arteries with an internal diameter of 6.5 mm and more.

## **PUBLIC PROCUREMENT REQUIREMENTS**

1. The tenderer should provide A DECLARATION OF CONFORMITY upon the request of the contracting authority.
2. For all products offered, the tenderer is required to provide the contracting authority with catalogues containing a full visual description (text and images) of the product.
3. All products to be delivered must be labeled with a product name, catalogue number and lot number.
4. The tenderer reserves the right during the review to call on the tenderer to provide free samples of the products offered. The tenderers are required to submit these samples within 7 days of the receipt of the contracting authority request.
5. The tenderer is required to submit the results of a one-year follow-up of patients after valve implantation. The results of a one-year follow-up of patients after valve implantation should be published in a journal with an impact factor (IF).
6. The tenderer is required to provide the latest valve type available in the EU market.
7. In case of technological progress for items offered during the execution of the agreement, the older version of the item may be replaced with a new version. Such replacement should be documented in written form and confirmed by both parties of the agreement and the price of an individual item cannot increase due to this replacement.
8. The tendered is required to provide training for healthcare professionals participating in the implantation procedure.
9. In the event of changes in new product implantation techniques (percutaneous valves) the tenderer is required to ensure proper additional staff training where appropriate.
10. The tenderer is required to provide continuous professional support during the period of introducing the percutaneous valve implantation method. In the initial phase of introducing the new valve type also the support of an expert in valve implantation (proctor) as well as appropriate additional technical support (product specialist), and after the implantation of 10 valves also a permanent product specialist support (at the request of the center also in a larger number of implantations).

TENDERER:

CONTRACTING **UNIVERZITETNI KLINIČNI CENTER MARIBOR**  
Ljubljanska ulica 5, 2000 Maribor

***SPECIFICATION WITH PRICES***

**SUBJECT MATTER OF THE PUBLIC PROCUREMENT: PERCUTANEOUS AORTIC VALVES**

Title	Code	EM	Indicative Qua	Price, VAT excl.	VAT	Value, VAT excl.
Expandable biological percutaneous aortic valve made of bovine pericardium (see technical specifications)	920300	PCS	25			
Self-expandable biological percutaneous aortic valve made of porcine or bovine pericardium (see technical specifications)	920400	PCS	25			

STAMP AND SIGNATURE

Date: