

Katowice, 19/05/2025

**REQUEST FOR PROPOSAL NO. FENG.02.09-IP.01 - 1/2025**

implemented as part of the project entitled " Polymer transcatheter aortic valve implants with a dedicated delivery system " under the funding agreement no . FENG.02.09-IP.01-0008/23-00, co-financed under the European Funds for Modern Economy program, Priority 2. Innovation-friendly environment , Measure 2.09 Seal of Excellence (hereinafter: Project)

**I. ORDERING PARTY**

Innovations for Heart and Vessels Sp. z o. o  
ul. Ligocka 103, 40-568 Katowice  
NIP: 9542733146, KRS: 0000399063

The company's business is to conduct scientific research and development work in the field of natural sciences and technology. The company's goal is to develop and then introduce to the market solutions, technologies and medical products that will increase the effectiveness of preventive measures, diagnostics and treatment of diseases, in particular of the circulatory system.

The project in question aims to develop a prototype of a polymer heart valve and its manufacturing process. The direct recipients of the project will be patients with valve defects.

The planned research and development work includes: • development of a polymer material, along with the development of a production technology, quality control processes, production of material and product for testing purposes, • development of a technology for the production of prefabricated elements: electrospinning of polymer fibers for the production of stents using biocompatible polymer composites with an optimal microstructure and composition of polymers, selected from the group of polycarbonate -urethanes and silicone elastomers based on polycarbonates,

• determination of the optimal parameters of the electrolytic refining process, guaranteeing the receipt of a material with stable physicochemical and strength properties. As a result of the project, it is assumed that stable batches of material with optimal properties will be obtained, which will enable the performance of fatigue tests of valves. Polymer- stent bond tests will be carried out in parallel with work on obtaining material for mechanical tests. It is planned to obtain the first batch of sleeves and manufacture valves for toxicity tests and first fatigue tests.

After the completion of the project, further work is planned on the implementation of the valve (TAVI, transcatheter aortic valve implantation ), confirmation of the required parameters and clinical studies. Additionally, it is expected that at least three patent applications will be filed regarding the valve and components.

**Contact person for orders:**

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**II. PROCEDURE FOR AWARDING THE ORDER**

This procurement procedure is conducted in accordance with the principle of competitiveness specified in the Guidelines of the Minister of Finance, Funds and Regional Policy of 18 November 2022

on the award of contracts under the European Regional Development Fund, European Funds for a Modern Economy 2021-2027

The Ordering Party is not an entity obliged to apply the provisions of the Act of 11 September 2019 – Public Procurement Law (Journal of Laws of 2019, item 2019).

**III. DESCRIPTION OF THE SUBJECT OF THE ORDER**

## 1. Name and code of the contract according to the Common Procurement Vocabulary (CPV):

73100000-3 Research and experimental development services

**The subject of the order is the design and production of stents for initial testing as part of the implementation of a research and development project. The order includes comprehensive development of the concept, design, technology development and production of prototypes of metal heart valve frames combined with a polymer leaflet in accordance with the Applicant's proprietary design.**

### Scope of Work

- Development of the concept and detailed design of prototype valve frames intended for a polymer heart valve, with particular emphasis on commissure attachment.
  - Preparation of designs and production of valve frames and commissure attachments to be subjected to preliminary testing.
  - Development of manufacturing technology for metal heart valve frames integrated with a polymer material, as well as technology for the production of commissure attachments.
  - Consulting on the development and optimization of manufacturing technology for metal heart valve frames integrated with a polymer leaflet, tailored to the Applicant's design requirements.
  - Analysis of technical and functional requirements.
  - Execution of engineering tests and development of production technology for valve frames and commissure attachments.
  - Fabrication of prototypes (a minimum of 15 stents for preliminary tests) of valve frames and commissure attachments, in accordance with the developed design.
  - Selection and testing of suitable materials for the production of metal frames and commissure attachments, ensuring compliance with technical requirements and biocompatibility.
  - Production of prototypes and working models of valve frames and commissure attachments.
  - Execution of mechanical tests.
  - Documentation of test results in the form of reports including analysis of technical parameters.
  - Preparation of complete technical documentation, i.e., a "design history file" covering the project history from concept to final product, including all stages of development and testing of the valve frame.
2. Order fulfillment time
  3. The subject of the order will be carried out for the period of 8 months from the date of signing the agreement with the Contractor, subject to reservation.
  4. The Ordering Party does not allow the submission of partial offers.
  5. The Ordering Party does not allow the submission of variant offers.
  6. The Ordering Party does not allow combined offers, i.e. it is inadmissible for several Contractors to submit one offer.

## IV. GROUNDS FOR EXCLUSION FROM PARTICIPATION IN THE PROCEEDINGS

1. The following Contractors are excluded from participating in the tender procedure:
  - 1.1. in relation to which there are capital or personal ties. Capital or personal ties are understood as mutual ties between the Ordering Party or persons authorized to incur liabilities on behalf of the Ordering Party or persons performing on behalf of the Ordering Party activities related to conducting the procedure for selecting the Contractor and the Contractor, consisting in particular of:
    - a) participating in a company as a partner in a civil partnership or a partnership,
    - b) owning at least 10% of shares or stocks, unless a lower threshold results from legal provisions or has been specified by the Program Operator,

- c) performing the function of a member of the supervisory or management body, proxy, authorised representative,
- d) being in a legal or factual relationship that may give rise to justified doubts as to the impartiality in the selection of the contractor, in particular being in a marital relationship, in a relationship of consanguinity or affinity in the direct line, in a relationship of consanguinity or affinity in the collateral line up to the second degree or in a relationship of adoption, care or guardianship.

1.2. who are subject to exclusion under Article 5k of Council Regulation (EU) No 833/2014 of 31 July 2014 concerning restrictive measures in view of Russia's actions destabilising the situation in Ukraine (OJ EU No L 229, 31.7.2014, p. 1), hereinafter referred to as Regulation 833/2014, in the wording given by Council Regulation (EU) 2022/576 amending Regulation (EU) No 833/2014 concerning restrictive measures in view of Russia's actions destabilising the situation in Ukraine (OJ EU No L 111, 8.4.2022, p. 1), hereinafter referred to as Regulation 2022/576, i.e. the Ordering Party excludes from participation in the procedure:

- a) Russian citizens or natural or legal persons, entities or bodies based in Russia,
- b) legal persons, entities or bodies whose ownership rights directly or indirectly exceed 50% are held by the entity referred to in point a) of this point,
- c) natural or legal persons, entities or bodies acting on behalf of or under the direction of the entity referred to in point a) or b) of this point,

including subcontractors or suppliers, if they account for more than 10% of the order value.

1.3 who are subject to exclusion under Article 7 paragraph 1 of the Act of 13 April 2022 on special solutions for counteracting support for aggression against Ukraine and protecting national security (Journal of Laws of 2022, item 853 ) from the contract award procedure, i.e. the Ordering Party excludes:

- a) A contractor listed in the lists specified in Regulation 765/2006 and Regulation 269/2014 or entered on the list based on a decision on entry on the list deciding on the application of the measure referred to in Art. 1 item 3 of the Act,
- b) The Contractor, whose beneficial owner within the meaning of the Act of 1 March 2018 on Counteracting Money Laundering and Terrorist Financing (Journal of Laws of 2022, items 593 and 655) is a person listed in the lists specified in Regulation 765/2006 and Regulation 269/2014 or entered on the list or being such a beneficial owner from 24 February 2022, provided that he or she was entered on the list on the basis of a decision on entry on the list deciding on the application of the measure referred to in Art. 1 item 3 of the Act,
- c) A contractor whose parent entity within the meaning of art. 3 sec. 1 item 37 of the Act of 29 September 1994 on Accounting (Journal of Laws of 2021, items 217, 2105 and 2106) is an entity listed in the lists specified in Regulation 765/2006 and Regulation 269/2014 or entered on the list or being such a parent entity from 24 February 2022, provided that it was entered on the list on the basis of a decision on entry on the list deciding on the application of the measure referred to in art. 1 item 3 of the Act.

2. In order to demonstrate the absence of grounds for exclusion from participation in the procedure for the award of the contract in question, referred to in point 1 above, the Contractor should submit, together with the offer, a self-declaration contained in the section "Declaration on the absence of grounds for exclusion from the procedure" of Appendix No. 1 to the Request for Proposals Offer Form.
3. The offer of an excluded Contractor is deemed to be rejected.

## V. CONDITIONS OF PARTICIPATION IN THE PROCEDURE AND DESCRIPTION OF THE METHOD OF ASSESSING THEIR FULFILMENT

1. Bids in the procedure may be submitted by Contractors who demonstrate confirmed experience of at least 5 years in conducting work on medical implants used in cardiology, including the production of medical components for cardiology, in particular stents, using medical grade metals and other materials (e.g. through publications / participation in projects / orders in other projects / implementations or other documents confirming successful implementation of similar or related projects ). The Contractor must have a team dedicated to the implementation of the subject of the order, consisting of at least 2 specialists with at least 3 years of experience in the design and production of stents (baskets) for valves, made using laser cutting technology from metal tubes with the desired properties, operating in accordance with the principles of ISO 13485 or similar . Verification will be based on the CVs of people dedicated to the implementation of the subject of the order, with experience in projects or services from a similar thematic area . Technical background:

The contractor must have appropriate facilities to perform the subject of the contract, including:

- a ) IT and computing resources enabling work to be carried out using tools such as SolidWorks , CAD/ Autodesk or equivalent,
  - b) a laboratory base enabling mechanical and functional testing of prototypes,
  - c) lasers for precise cutting of stents,
  - d) devices for grinding metal surfaces ( electropolishing ),
  - e) devices for annealing and setting material properties,
  - f) high-resolution microscopes and SEM microscope,
  - g) strength testing devices.
- The Contractor is in a good economic and financial situation ensuring the proper performance of the contract.
2. In order to assess the Contractor's fulfillment of these conditions, the Contractor shall submit, together with the offer, the Contractor's Declaration on Fulfillment of the Conditions for *Participation in the Proceedings in the Content of Annex No. 2* to this inquiry; CVs of persons designated to perform the subject of the order; List of services and/or projects completed in the last 5 years in the scope of work on medical implants in cardiology, including the production of stents made of medical grade metals and other materials , publications or other documents confirming the successful implementation of similar or related projects. The documents should be consistent with the content of Annex No. 2 to this inquiry.
  3. The Ordering Party will assess whether the conditions for participation in the procedure have been met by applying the meets-does not meet criterion, i.e. in accordance with the principle of whether the documents/declarations attached to the offer meet the requirements specified in the request for proposals.
  4. The Ordering Party reserves the right to request additional information/documents/clarifications from Contractors regarding the submitted offer at any stage of the procedure.
  5. The submitted documents should confirm that the Contractor meets the conditions for participation in the procedure, no later than on the date on which the deadline for submitting offers expires.
  6. The offer of a Contractor who does not meet the conditions for participation in the procedure specified in paragraph 1 or 2 above will be rejected.

## VI. METHOD OF PREPARING THE OFFER

1. The offer submitted by the Contractor should be prepared on the form constituting Appendix No. 1 to the Request for Quotation Offer Form.
2. The Ordering Party recommends using the forms provided by the Ordering Party. It is permissible to submit offers on forms developed by the Contractor, provided that they contain all the required information and declarations.
3. Offers should be prepared in Polish or English. Documents prepared in a language other than Polish or English should be submitted together with a translation into Polish.
4. The completed *Offer Form* must be accompanied by: A declaration of no grounds for exclusion from the procedure in accordance with the template included in the Bid Form - *A declaration of no grounds for exclusion from the procedure* ; CVs of team members confirming professional experience, including positions and periods of employment, which include the required years of experience. *A declaration of the contractor on meeting the conditions for participation in the procedure* in Appendix No. 2 to the Request for Bids, including a list of services and/or projects completed in the last 5 years in the scope of work on medical implants in cardiology, including the production of stents from medical grade metals and other materials in accordance with Appendix No. 2 to this request for bidding.
5. The offer and attachments must be signed by the authorized representative( s ) of the Contractor in accordance with the form of representation of the Contractor specified in the registration document (registration) of the Contractor or by a proxy. The signature should be made in a way that allows its identification.
6. The Ordering Party informs that offers submitted in the procurement procedure are public. Offers are made available at the written request of Contractors who submitted offers in the procedure, with the exception of information constituting a business secret within the meaning of the provisions on combating unfair competition, if the Contractor, no later than the deadline for submitting offers, stipulated that it cannot be made available and demonstrated that the reserved information constitutes a business secret. A business secret within the meaning of the Act of 16 April 1993 on combating unfair competition (i.e. Journal of Laws of 2020, item 1913) is understood as technical, technological, organizational information of an enterprise or other information of economic value not disclosed to the public, in respect of which the entrepreneur has taken the necessary action to maintain its confidentiality.

7. If the offer contains information constituting a business secret within the meaning of the provisions on combating unfair competition, the Ordering Party recommends that information reserved as a business secret be sent by the Contractor in a separate file or e-mail marked "business secret" separately from other, public elements of the offer in a manner that does not raise any doubts as to which of the information contained in the offer constitutes such a secret. The pages containing the information referred to in the previous sentence should be separately connected to each other, but numbered in accordance with the continuation of the page numbering of the offer.
8. The Contractor may not reserve information regarding the name (company) and address, price, order completion date, and payment terms contained in the offer.
9. The Ordering Party recommends that each written page of the offer (including attachments to the offer) be numbered consecutively.
10. The contractor may submit only one offer.
11. Before the deadline for submitting offers, the Contractor may change or withdraw its offer.
12. The contractor bears all costs associated with preparing and submitting the offer.

## **VII. OFFER VALIDITY PERIOD**

1. The contractor remains bound by the offer for a period of 60 days.
2. The validity period of the offer begins upon expiry of the deadline for submission of offers.
3. The Contractor, independently or at the request of the Ordering Party, may extend the period of validity of the offer, provided that the Ordering Party may only once, at least 3 days before the expiry of the period of validity of the offer, ask the Contractors for their consent to extend this period by a specified period.

## **VIII . METHOD OF SUBMITTING OFFERS**

1. Offers in response to the Request for Proposals should be submitted via the Competitiveness Database system (hereinafter: Competitiveness Database) <https://bazapórcyjnosci.funduszeuropejskie.gov.pl/> via the "OFFER" tab available in the Request for Proposals (announcements) tab. Detailed instructions regarding the registration of the Contractor in the Competitiveness Database and the method of adding an offer are available at: [https://archiwum-bazapórcyjnosci.funduszeuropejskie.gov.pl/info/web\\_instruction](https://archiwum-bazapórcyjnosci.funduszeuropejskie.gov.pl/info/web_instruction), section "Attachments", file named "Pomoc BK2021 PDF wer . 12.04.2023".
2. The deadline for submitting offers was specified in the announcement published on the Competitiveness Database.
3. The offer, together with the required attachments, must be sent as a scan of the offer prepared in writing or as an offer prepared in electronic form signed with a qualified electronic signature.
4. The date of submission of the offer is understood as the date and time of sending it via the Baza Konkurencyjności system in accordance with paragraph 1 above.
5. Any offer submitted after the deadline will not be considered.
6. The Ordering Party reserves the right to extend the deadline for submitting offers. Each time, it will place appropriate information in the Competitiveness Database at: <https://bazapórcyjnosci.funduszeuropejskie.gov.pl/> in the content of the announcement.

## **IX. CRITERIA FOR EVALUATING OFFERS AND THE METHOD OF CONDUCTING THE EVALUATION**

1. Offers prepared in accordance with the requirements specified in section VI of the Request for Proposals, submitted by Contractors who are not subject to exclusion in accordance with section IV of the Request for Proposals and who meet the condition for participation in the procedure specified in section V of the Request for Proposals, will be assessed on the basis of the following offer evaluation criterion:

<b>BID EVALUATION CRITERION</b>	<b>POINT WEIGHT</b>	<b>DESCRIPTION OF THE METHOD OF AWARDED SCORING FOR FULFILLING A GIVEN OFFER EVALUATION CRITERION</b>
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<p><b>Gross price [ Kc ]</b></p>	<p><b>100</b></p>	<p>In the “Gross Price” criterion, the Ordering Party will make an assessment based on the information provided by the Contractor in the Offer Form, which constitutes Appendix No. 1 to this Request for Quotation.</p> <p>In the Bid Form, the Contractor is required to provide the net price, the applicable VAT rate and the gross value, rounded to two decimal places while maintaining the mathematical principle of rounding numbers. The correct determination of VAT is the Contractor's responsibility.</p> <p>Foreign Contractors who, based on separate regulations, are not obliged to pay tax in Poland, shall only provide a net price. For the purposes of comparing offers, the Ordering Party shall add to the presented net offer price of the foreign Contractors the amount of the due (charged to the Ordering Party by virtue of the performance of the contract) tax on goods and services and any customs duty that it would be obliged to settle in accordance with the applicable regulations.</p> <p>The gross price is the final price including all costs and price components related to the performance of the subject of the order, e.g. transport, packaging and insurance costs, other fees if the Contractor provides for such, as well as any discounts and rebates applied by the Contractor. The Contractor is obliged to include in the offer price all costs necessary for the proper, full and timely performance of the subject of the order, resulting from the conditions and obligations specified in the Request for Proposal, as well as its own knowledge and experience.</p> <p>There can be only one price for the offered item of the order; price variants are not permitted.</p> <p><b>For the purpose of comparing offers, the gross offer price in PLN will be taken into account.</b></p> <p>If the Contractor specifies the price in a currency other than PLN, the Ordering Party will adopt the average exchange rate of the National Bank of Poland (NBP) as the currency conversion rate, which is available at <a href="http://www.nbp.pl">www.nbp.pl</a> published on the date of publication of this Request for Proposals in the Competitiveness Database.</p> <p>The point value in this criterion will be calculated as follows:</p> $\text{Price} = \frac{\text{cena brutto najtańszej spośród złożonych ofert}}{\text{cena brutto badanej oferty}} \times 100$ <p>An offer can receive a maximum of 100 points for the “Gross Price” criterion.</p>
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- The final number of points that a given offer will receive will correspond to the number of points obtained in the criterion presented above (i.e. Kc ). The score will be rounded to two decimal places, while maintaining the mathematical principle of rounding numbers. The offer can receive a maximum of 100 points within a given part of the subject matter of the contract.
- The most economically and qualitatively advantageous offer within the subject of the contract will be the offer of the Contractor who is not subject to exclusion, meets all the conditions for participation in the procedure and obtains the highest number of points during the evaluation.
- In a situation where the Ordering Party is unable to select the most advantageous offer due to the fact that two or more offers within the subject of the order present the same price, the Ordering Party will call on the Contractors who submitted these offers to submit additional offers. Contractors submitting additional offers cannot offer higher prices than those offered in the submitted offers.
- In the case of Contractors who submitted offers within the specified deadline, but they do not contain the required documents and declarations or the submitted documents and declarations are incomplete, contain errors or raise doubts indicated by the Ordering Party, the Ordering Party will call for the submission of missing documents or declarations, their supplementation or correction or for providing explanations within the deadline indicated by it, unless despite their submission, supplementation or correction or provision of explanations, the Contractor's offer is subject to rejection or it would be necessary to invalidate the procedure. Failure by the Contractor to meet the deadline indicated by the Ordering Party will result in the rejection of the offer. Only deficiencies or errors of a formal nature are subject to supplementation, correction or explanation. It is not permitted to change the terms of the submitted offer.
- In the case of a Contractor whose offer may contain an abnormally low price in relation to the subject of the order, the Ordering Party reserves the right to request him, in the manner described in point 5 above, to submit appropriate explanations and present the method of calculating the gross price. The price may be considered abnormally low if it is lower by at least 30% than the estimated value of the order or the arithmetic mean of the prices of all non-rejected offers. When assessing the explanations provided by the Contractor, the Ordering Party takes into account objective factors. The Ordering Party will reject the offer of a Contractor who has not

provided explanations, does not provide them within the deadline set for this purpose or if the assessment of the explanations, together with the evidence provided, confirms that the offer contains an abnormally low price in relation to the subject of the order. The Contractor is obliged to prove that the offer does not contain an abnormally low price.

7. The Ordering Party will post information on the outcome of the procedure in the Competitiveness Database <https://bazapórcyjnosci.funduszeuropejskie.gov.pl/> in the OFFERS (announcements) tab.
8. The Ordering Party reserves the right to cancel or invalidate the procedure at any stage if no offer has been submitted or no offer has been submitted that is not subject to rejection; the price of the most advantageous offer or the offer with the lowest price exceeds the amount that the Ordering Party intends to allocate to finance the order, unless the Ordering Party can increase this amount to the price of the most advantageous offer; the procedure is burdened with an irremovable defect that makes it impossible to award the order while respecting the principle of fair competition and equal treatment of contractors or applicable law; there has been a significant change in circumstances that means that conducting the procedure or executing the order is not in the interest of the Ordering Party, which could not have been foreseen at the time of publication of the Request for Proposal. Contractors shall not be entitled to any claims against the Ordering Party in the event that it exercises any of the rights indicated in the previous sentence.

#### **XI. EXPLANATION OF THE CONTENT OF THE REQUEST FOR PROPOSALS AND THE METHOD OF COMMUNICATION BETWEEN THE ORDERING PARTY AND CONTRACTORS**

1. The Contractor may request the Ordering Party to clarify the content of the Request for Proposal via the Competitiveness Database system via the "QUESTIONS" tab available in the Request for Proposal (announcements) card. Detailed instructions on how to submit questions via the Competitiveness Database are available at [https://archiwum-bazapórcyjnosci.funduszeuropejskie.gov.pl/info/web\\_instruction](https://archiwum-bazapórcyjnosci.funduszeuropejskie.gov.pl/info/web_instruction), section "Attachments", file named "Pomoc BK2021 PDF wer . 12.04.2023".
2. The Ordering Party shall provide explanations no later than 2 days before the deadline for submitting offers, provided that the request for explanation of the content of the Request for Proposal is received no later than by the end of the day on which the half-time limit for submitting offers expires. If the request for explanation of the content of the Request for Proposal is received by the Ordering Party at a later date or concerns explanations provided, the Ordering Party may provide explanations or leave the request without consideration.
3. The Ordering Party will post the content of explanations and answers in the Competitiveness Database in the "QUESTIONS" tab available in the Request for Proposals (announcements) card. Explanations and answers will constitute an integral part of the Request for Proposals No. FENG.02.09-IP.01 - 1/2025 .
4. The Ordering Party reserves the right to amend or supplement the content of the Request for Proposals at any time before the deadline for submitting offers. In the event of such a change or supplement, information about this fact will be immediately included in the announcement published in the Competitiveness Database.
5. If the change referred to in point 4 above will require modification of the offers, the Ordering Party shall simultaneously extend the deadline for submission of offers in the manner described in point 4 above.
6. The extension of the deadline for submitting offers does not affect the deadline for submitting applications referred to in point 2 above.

#### **XII. FORMALITIES RELATED TO SIGNING THE AGREEMENT**

1. The Ordering Party shall call in writing or by e-mail on the Contractor whose offer was selected under the order to conclude an agreement of the content agreed bilaterally, specifying the place and date of its conclusion.
2. The selected Contractor is obliged to contact the Ordering Party within the time specified in the request in order to agree on all issues related to the concluded contract.
3. If the Contractor whose offer was assessed as the most advantageous refuses to conclude the contract, the Ordering Party may examine whether the Contractor who submitted the offer that was assessed as the most advantageous among the remaining offers meets the conditions for participation in the procedure and select such offer as the most advantageous offer.

#### **XIII. CONDITIONS FOR CHANGING THE AGREEMENT CONCLUDED AS A RESULT OF THE CONDUCTED PROCEDURE FOR THE AWARD OF ORDER**

The Ordering Party reserves the right to change the contract concluded with the Contractor selected during the procedure in the event of the occurrence of one of the circumstances listed below, taking into account the conditions for their introduction:

1. Except for the cases specified in point 1.1 above, the deadline for completing the subject of the order may change in the following situations:
  - a) In the event of force majeure, i.e. an extraordinary and external event, the occurrence and duration of which the Ordering Party or the Contractor have no influence on and which they were unable to prevent despite exercising due diligence. In such a case, the term of the Agreement performance will be extended by the time of the occurrence of the event of force majeure and the removal of its effects;
  - b) In the event of circumstances beyond the control of the Contractor or the Ordering Party, provided that such change results from circumstances that the Contractor or the Ordering Party could not have foreseen at the stage of publishing the Request for Quotation or submitting the offer despite exercising due diligence and it is not their fault;
  - c) The Ordering Party's decision to suspend the performance of any part of the subject of the order due to technical or organizational reasons beyond the control of the Ordering Party, periodically preventing the continuation of the performance of the Subject of the Agreement, for the duration of the suspension. The Ordering Party will notify the Contractor of the suspension by e-mail, indicating the reason for the suspension;
  - d) Due to changes in legal provisions relevant to the implementation of the Subject Matter of the Order affecting the scope or deadline for its implementation to the extent necessary to adapt to the new regulations .
  - e) When the need for change results from the course of research and development work within the project.
  - f) Due to downtime and delays caused by the Ordering Party, having a direct impact on the timely completion of the subject of the order - a maximum of the period of downtime and delays.
2. Other changes:
  - a) Changes to legal regulations in force on the date of submission of the offer by the Contractor, which will introduce new requirements as to the manner of implementation of any element of the Subject Matter of the Contract;
  - b) When the need to introduce changes is a result of changes introduced in agreements between the Ordering Party and a party other than the Contractor, in particular the Intermediary Institution, which is a party to the co-financing agreement under which this order is financed, and
  - c) Also other institutions which, under legal provisions, may influence the execution of the order.

#### **IX. SUPPLEMENTARY ORDERS AND ADDITIONAL ORDERS**

1. The Ordering Party envisages the possibility of awarding the contractor selected in this tender procedure supplementary orders in an amount not exceeding 50% of the value of the order specified in the agreement concluded with the contractor, provided that these orders are consistent with the subject of the basic order.
2. The Ordering Party envisages the possibility of awarding the contractor selected in this tender procedure with additional orders, not covered by the basic order and not exceeding 50% of the value of the public order being implemented, necessary for its proper performance, the performance of which has become necessary as a result of a situation that could not be foreseen earlier, if for technical or economic reasons, separating the additional order from the basic order would require incurring disproportionately high costs or the performance of the basic order will depend on the performance of the additional order. The changes indicated above may be introduced only if both parties recognize that the circumstances indicated above have occurred and the introduction of changes is necessary for the proper performance of the order.

#### **X. INFORMATION CLAUSE REGARDING ARTICLE 13 AND ARTICLE 14 OF REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (GDPR)**

In accordance with Article 13 paragraphs 1 and 2 of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ EU L 119, 4.5.2016, p. 1), hereinafter referred to as "GDPR", I inform you that:



1. The administrator of personal data is Innovations for Heart and Vessels Sp. z o. o. ul. Ligocka 103, 40-568 Katowice NIP: 9542733146, KRS: 0000399063, e-mail: info@innovations.com.pl.
2. Personal data will be processed pursuant to Article 6, paragraph 1, letter c of the GDPR for the purpose of the contract award procedure covered by the Request for Quotation No. FENG.02.09-IP.01 – 1/2025 and further in connection with the performed contract.
3. The recipients of personal data will be persons or entities to whom the documentation from the proceedings will be made available based on the provisions of applicable law, including in particular the provisions of the Act of 6 September 2001 on access to public information (Journal of Laws of 2018, item 1330, as amended).
4. Personal data will be stored for the time needed to execute and settle the contract for co-financing of the Ordering Party, under which the order is co-financed, and for the time necessary to expire any claims.
5. The Contractor's obligation to provide personal data results from its participation in the contract award procedure covered by the Request for Quotations No. FENG.02.09-IP.01 - 1/2025 .
6. Providing personal data is voluntary in order to conclude and perform the contract between the Ordering Party and the Contractor under this procedure conducted in the Request for Proposals mode, although refusal to provide them will prevent cooperation between the above-mentioned parties.
7. In relation to the personal data received, decisions will not be made in an automated manner, pursuant to Article 22 of the GDPR.
8. The contractor has:
  - a) under Article 15 of the GDPR, the right to access personal data concerning him;
  - b) under Article 16 of the GDPR, the right to rectify his or her personal data;
  - c) the right to delete personal data concerning them, in the situations specified in Article 17(1) of the GDPR, subject to Article 17(3) of the GDPR;
  - d) under Article 18 of the GDPR, the right to request the controller to restrict the processing of personal data, subject to the cases referred to in Article 18(2) of the GDPR;
  - e) the right to lodge a complaint with the President of the Personal Data Protection Office if the Contractor considers that the processing of personal data concerning him violates the provisions of the GDPR
9. The Contractor is not entitled to:
  - a) in connection with Article 17 paragraph 3 letters b, d or e of the GDPR, the right to have personal data deleted;
  - b) the right to transfer personal data, as referred to in Article 20 of the GDPR;
  - c) under Article 21 of the GDPR, the right to object to the processing of personal data, as the legal basis for the processing of personal data is Article 6 paragraph 1 letter c of the GDPR.

The Contractor is obliged to provide the above information to all persons whose personal data will be provided to the Ordering Party in connection with the submission of an offer in response to the Request for Quotation No. FENG.02.09-IP.01 - 5/2024 and the execution of the order, which the Contractor confirms with an appropriate declaration on the fulfillment of his information obligations provided for in Art. 13 or Art. 14 of the GDPR contained in the *Offer Form* , constituting Annex No. 1 to the Request for Quotation.

## **XVI. ANNEXES TO THE REQUEST FOR PROPOSAL**

**Annex No. 1** *Offer form*

**Annex No. 2** *Contractor's declaration on fulfillment of conditions for participation in the procedure*