

Katowice, December 16, 2025

**REQUEST FOR PROPOSALS NO. FENG.01.01-IP.02 - 12/2025**

implemented as part of the project entitled "Development of production technology and prototypes of biological valve implants for percutaneous and minimally invasive treatment of valve defects" covered by grant agreement No. FENG.01.01-IP.02-1053/23 co-financed under the European Funds for Modern Economy program, Priority 1. Support for entrepreneurs, Measure 1.1 Smart Path (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 conducting scientific research and development work in the field of natural and technical sciences. The company's goal is to develop and then market solutions, technologies, and medical devices that will improve the effectiveness of preventive measures, diagnostics, and treatment of diseases, particularly those of the circulatory system.

The planned research and development work for this project aims to develop and clinically test a new generation of biological valve implants, using innovative methods of production and valve leaflet formation.

The recipients of the project results will be hospitals performing TAVI (Transcatheter Aortic Valve Implantation) procedures.

The research and development work includes the development of a repeatable method for processing biological material, the development of a forming and sewing process, the creation of the final version of the stent, and an innovative delivery system that takes into account computer analysis of a mathematical model of valve function.

The developed TAVI biological valve will be the first medical device of this type manufactured in Poland, characterized by the possibility of personalization. The launch of a new percutaneously implanted biological aortic valve will be the main result of the project.

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e-mail: [joanna.hynek@i4hv.com](mailto:joanna.hynek@i4hv.com)**II. PROCEDURE FOR AWARDING THE CONTRACT**

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

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

The contracting authority is not an entity obliged to apply the provisions of the Act of September 11, 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 contract** is the development and manufacture of a biological component of a transcatheter valve delivery system, i.e., a steerable deflectable catheter, including the improvement of existing prototype designs and the preparation of production technology. All activities must be performed in accordance with ISO 13485, MDR (EU) 2017/745, and all other applicable regulations concerning medical device manufacturers in terms of quality, safety, and performance. The work performed by the Contractor will form part of the research and development activities carried out by the Ordering Party as part of a broader research project.

**Scope of work:**

Design and development of a catheter with external deflection (Bench-Top, 2 iterations). The handle and knob are to be 3D printed.

**Assumptions:**

The contractor will be responsible for engineering activities, including planning and designing manufacturing processes and manufacturing the tools necessary for the production of controllable deflection catheter components (applies only to the scope of work specified above). All processes will be carried out in accordance with the highest industry and regulatory standards for medical devices.

The Contractor shall be responsible for preparing and providing technical documentation as part of the complete project history documentation, containing all necessary information related to design, production, and testing, enabling full reconstruction of processes and technologies (applies only to the scope of work specified above).

The Contractor shall carry out a risk management process to identify and assess potential risks associated with development and manufacturing processes and to develop appropriate strategies to mitigate or eliminate them (applies only to the scope of work specified above).

**Other comments:**

This tender procedure is a continuation of work carried out under a previous contract with an external entity concerning the design of a transcatheter biological aortic valve delivery system. After the termination of the previous contract, the Contracting Authority accepted some of the design results, which may be used in further stages of development of the system component (deflection catheter) covered by this procedure. The Ordering Party will make the documentation and technical data developed under the previously executed agreement available to interested Contractors after signing a non-disclosure agreement (NDA) or presenting a valid non-disclosure agreement previously concluded with the Ordering Party. To obtain a template of the NDA or confirmation of the validity of an existing confidentiality agreement, please contact us at: [joanna.hynek@i4hv.com](mailto:joanna.hynek@i4hv.com). The documentation will be made available in electronic form only after verification that the above conditions have been met. The documentation is provided for informational and support purposes only.

2. The deadline for completion of the order is set at 2 months from the date of conclusion of the contract.
3. The Ordering Party does not allow partial bids.
4. The Ordering Party does not allow for the submission of variant bids. The Ordering Party does not allow for joint bids, i.e., it is not permissible for several Contractors to submit a single bid.

**IV. GROUNDS FOR EXCLUSION FROM PARTICIPATION IN THE PROCEDURE**

1. Contractors shall be excluded from participation in the tender procedure if:
  - 1.1. they have 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 activities related to the Contractor selection procedure on behalf of the Ordering Party and the Contractor, consisting in particular of:
    - a) participation in a company as a partner in a civil law partnership or a partnership,
    - b) holding 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 a supervisory or management body, proxy, representative,

d) being in a legal or factual relationship that may raise reasonable doubts as to the impartiality in the selection of the contractor, in particular being married, related by blood or affinity in a direct line, related by blood or affinity in a collateral line up to the second degree, or in a relationship of adoption, guardianship or custody.

1.2. who are subject to exclusion pursuant to Article 5k of Council Regulation (EU) No. 833/2014 of July 31, 2014 concerning restrictive measures in view of Russia's actions destabilizing the situation in Ukraine (OJ EU No. L 229 of July 31, 2014, p. 1), hereinafter referred to as Regulation 833/2014, as amended by Council Regulation (EU) 2022/576 amending Regulation (EU) No 833/2014 concerning restrictive measures in response to

Russia's actions destabilizing the situation in Ukraine (OJ EU No. L 111 of 8.4.2022, p. 1), hereinafter referred to as Regulation 2022/576, i.e. The Contracting Authority excludes from participation in the proceedings:

- a) Russian citizens or natural or legal persons, entities or bodies established in Russia,
- b) legal persons, entities or bodies in which more than 50% of the ownership rights are directly or indirectly held by an entity referred to in point (a) of this paragraph,
- c) natural or legal persons, entities or bodies acting on behalf of or under the direction of an entity referred to in point (a) or (b) of this section, including subcontractors or suppliers, where they account for more than 10% of the contract value.

1.3 who are subject to exclusion pursuant to Article 7(1) of the Act of April 13, 2022

on specific measures to counteract support for aggression against Ukraine and to protect national security (Journal of Laws of 2022, item 853)

from the procurement procedure, i.e. the Contracting Authority excludes:

- a) Contractor listed in the lists specified in Regulation 765/2006 and Regulation 269/2014 or entered in the list on the basis of a decision on entry in the list deciding on the application of the measure referred to in Article 1(3) of the Act,
- b) Contractor whose beneficial owner within the meaning of the Act of March 1, 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 in the list or being such a beneficial owner since February 24, 2022, provided that it has been entered in the list on the basis of a decision on entry in the list determining the application of the measure referred to in Article 1(3) of the Act,
- c) A contractor whose parent entity within the meaning of Article 3(1)(37) of the Accounting Act of September 29, 1994 (Journal of Laws of 2021, items 217, 2105, and 2106) is an entity listed in the registers specified in Regulation 765/ 2006 and Regulation 269/2014, or entered in the list or being such a parent entity as of February 24, 2022, provided that it has been entered in the list on the basis of a decision on entry in the list determining the application of the measure referred to in Article 1(3) of the Act.

1.4 In order to demonstrate that there are no grounds for exclusion from participation in the procurement procedure referred to in point 1 above, the Contractor should submit, together with the tender, a statement contained in the section "Statement on the absence of grounds for exclusion from the procedure" of Appendix 1 to the Request for Tenders - Tender Form.

1.5 The bid of an excluded Contractor shall be considered rejected.

## **V. CONDITIONS FOR PARTICIPATION IN THE PROCEDURE AND DESCRIPTION OF THE METHOD OF EVALUATING THEIR FULFILLMENT**

1. Bids in the tender procedure may be submitted by Contractors with the appropriate knowledge, experience, technical facilities, and personnel necessary for the proper performance of the contract. The Contractor must meet the following requirements:

- Have a team of specialists (minimum 3 people) involved in the performance of the contract, including engineers with experience in the design of implantable, minimally invasive medical devices used in interventional cardiology, cardiac surgery, or related fields.
- Each key team member must have documented experience in at least 3 projects in a similar subject area, completed with the implementation of a medical device on the market, confirmed by references, project documentation, portfolio, or other documents.
- The contractor has experience in the development, design, and prototyping of minimally invasive Class III or implantable medical devices, confirmed by participation in projects, publications, references, product portfolios, or other documents (list of at least 3 services and/or projects completed in the last 10 years).

- The Contractor's team works in accordance with ISO 13485 and the requirements of MDR (EU) 2017/745. This requirement is confirmed by a statement submitted with the offer.
- The Contractor has the technical facilities necessary to carry out prototype and engineering work, including the ability to 3D print components and process and join materials used in minimally invasive medical devices, including implant delivery system components.
- The Contractor has the technical and organizational infrastructure to carry out R&D work in the design, manufacture, and testing of delivery system components for medical devices, with access to the appropriate equipment and working environment (including an ISO 7 Clean Room).
- The Contractor is in an economic and financial situation ensuring the proper performance of the contract.
- The Contractor undertakes to perform the services using its own equipment, technical facilities, and personnel.

2. In order to confirm compliance with the above requirements, the Contractor shall submit the following documents together with the bid:

- A statement confirming compliance with the conditions for participation in the procedure – in accordance with Appendix 2;
- A list of at least 3 services and/or projects completed in the last 10 years in the field of designing implantable, minimally invasive medical devices – verified on the basis of a statement and, at the request of the Ordering Party, supplemented with references or other documents confirming completion;
- CVs of persons designated to perform the contract, confirming their qualifications and experience in the implementation of at least 3 projects completed with the implementation of a medical device on the market;
- Statement confirming the team's work in accordance with ISO 13485 and the requirements of MDR (EU) 2017/745 – verified on the basis of the statement.
- A statement confirming possession of the technical and equipment resources necessary to perform the contract, including in particular: facilities for prototyping and engineering work (including the ability to perform 3D printing, processing, and joining of materials used in minimally invasive medical devices) and technical and organizational infrastructure enabling R&D work in the field of design, manufacture, and testing of delivery system components for medical devices, with access to appropriate equipment and working environment (including ISO 7 Clean Room). Requirement verified on the basis of the Contractor's statement;
- Statement confirming good economic and financial standing, ensuring proper performance of the contract – verified on the basis of a statement. - In accordance with Appendix 2 to this request.

3. The Contracting Authority shall assess compliance with the conditions for participation in the procedure by applying the criterion of compliance or non-compliance, i.e. in accordance with the principle of whether the documents/statements attached to the tender meet the requirements specified in the request for quotation.

4. The Contracting Authority reserves the right to request additional information/documents/clarifications from Contractors regarding the submitted bid 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 of the deadline for submission of bids.

6. The bid of a Contractor who does not meet the conditions for participation in the procedure specified in sections 1 or 2 above will be rejected.

## **VI. HOW TO PREPARE AN OFFER**

1. The offer submitted by the Contractor should be prepared on the form constituting Appendix No. 1 to the Request for Proposal Offer Form.
2. The Ordering Party recommends the use of 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 statements. Oferty należy sporządzić w języku polskim lub angielskim.
3. Documents drawn up in a language other than Polish or English should be submitted together with a translation into Polish. The completed Offer Form should be accompanied by: A statement of no grounds for exclusion – in accordance with the Offer Form. A statement by the Contractor on meeting the conditions for participation in the procedure – Appendix No. 2. CVs of team members confirming the required qualifications and experience in the implementation of at least 3 projects completed with the launch of a medical device on the market. A list of at least 3 services and/or projects in the field of designing implantable, minimally invasive medical devices or related products – in accordance with Appendix 2; supplemented with references upon request. References confirming the implementation of at least 3 projects involving the implementation of numerical research results for medical implants (or equivalent). A

statement confirming the possession of the technical facilities and infrastructure necessary to perform the contract, including 3D printing, machining, material joining, and R&D infrastructure with access to appropriate equipment and an ISO 7 Clean Room. A statement confirming that the team works in accordance with ISO 13485 and the requirements of MDR (EU) 2017/745. A statement confirming the Contractor's good economic and financial standing. The bid and attachments must be signed by the Contractor's authorized representative(s) in accordance with the Contractor's form of representation specified in the Contractor's registration (record) document or by a proxy. The signature should be made in a manner that allows it to be identified.

4. The Contracting Authority hereby informs that bids submitted in the procurement procedure are public. Bids are made available upon written request of Contractors who submitted bids in the procedure, with the exception of information constituting a trade secret within the meaning of the provisions on combating unfair competition, if the Contractor has stipulated, no later than on the date of submission of bids, that they may not be made available and has demonstrated that the restricted information constitutes a trade secret. A trade secret within the meaning of the Act of April 16, 1993, on combating unfair competition (i.e. Journal of Laws of 2020, item 1913) means technical, technological, organizational information of the enterprise or other information of economic value that has not been disclosed to the public, in respect of which the entrepreneur has taken the necessary measures to preserve its confidentiality.
5. If the offer contains information constituting a trade secret within the meaning of the provisions on combating unfair competition, the Ordering Party recommends that the information classified as a trade secret be sent by the Contractor in a separate file or e-mail marked "trade secret" separately from the other, public elements of the offer in a manner that leaves no doubt 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 bound separately, but numbered in continuation of the numbering of the pages of the offer.
6. The contractor may not withhold information concerning the name (company name) and address, price, order completion date, and payment terms contained in the offer.
7. The contracting authority recommends that each page of the bid (including attachments) be numbered consecutively.
8. The Contractor may submit only one bid.
9. Before the deadline for submitting bids, the Contractor may change or withdraw its bid.
10. The Contractor shall bear all costs related to the preparation and submission of the bid.

## **VII. OFFER VALIDITY PERIOD**

1. The Contractor shall remain bound by the offer for a period of 60 days.
2. The period of validity of the offer shall commence upon expiry of the deadline for submission of offers.
3. The Contractor may, on its own initiative or at the request of the Ordering Party, 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, request the Contractors to agree to extend this period by a specified period.

## **VIII. HOW TO SUBMIT BIDS**

1. Offers in response to the Request for Proposal should be submitted via the Competitiveness Database system (hereinafter: Competitiveness Database) <https://bazakonkurencyjnosci.funduszeuropejskie.gov.pl/> via the "OFFERS" tab available in the Request for Proposal (announcement) tab. Detailed instructions on how to register as a Contractor in the Competitiveness Database and how to add an offer are available at: [https://archiwum-bazakonkurencyjnosci.funduszeuropejskie.gov.pl/info/web\\_instruction](https://archiwum-bazakonkurencyjnosci.funduszeuropejskie.gov.pl/info/web_instruction), section "Attachments", file named "BK2021 Help PDF ver. 12.04.2023".
2. The deadline for submitting offers has been specified in the announcement published on the Competitiveness Database.
3. The offer, together with the required attachments, must be sent in the form of a scan of the offer prepared in writing or in the form of an offer prepared in electronic form signed with a qualified electronic signature.
4. The deadline for submitting bids shall be understood as the date and time of sending the bid via the Competitiveness Database system in accordance with section 1 above.
5. Bids submitted after the deadline will not be considered.



6. The contracting authority reserves the right to extend the deadline for submitting bids. In each case, it will publish relevant information in the Competitiveness Database at: <https://bazakonkurencyjnosci.funduszeuropejskie.gov.pl/> in the content of the announcement.

## IX. CRITERIA FOR EVALUATING BIDS AND THE EVALUATION PROCESS

1. Bids prepared in accordance with the requirements specified in Section VI of the Request for Bids, submitted by Contractors who are not subject to exclusion in accordance with Section IV of the Request for Bids and who meet the conditions for participation in the procedure specified in Section V of the Request for Bids, will be evaluated on the basis of the following bid evaluation criteria:

CRITERIA FOR EVALUATING BIDS	POINT WEIGHT	DESCRIPTION OF THE METHOD OF AWARDING POINTS FOR MEETING A GIVEN CRITERION FOR EVALUATING BIDS
Gross price [Kc]	100	<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, constituting Appendix 1 to this Request for Quotation.</p> <p>In the Offer Form, the Contractor is required to provide the net price, the applicable VAT rate, and the gross value, rounded to two decimal places in accordance with the mathematical principle of rounding numbers. The Contractor is responsible for correctly determining the VAT.</p> <p>Foreign Contractors who, on the basis of separate regulations, are not obliged to pay tax in Poland, shall only provide the net price. For the purposes of comparing bids, the Ordering Party shall add to the net bid price submitted by foreign Contractors the amount of the applicable tax on goods and services (charged to the Ordering Party for the performance of the contract) and any customs duties that it would be required to settle in accordance with the applicable regulations.</p> <p>The gross price is the final price including all costs and price-determining factors related to the performance of the contract, e.g., transport, packaging, and insurance costs, other fees if the Contractor anticipates them, 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, complete, and timely performance of the subject of the contract, resulting from the conditions and obligations specified in the Request for Proposal, as well as their own knowledge and experience.</p> <p>There can only be one price for the offered subject of the contract; price variants are not allowed.</p> <p>The gross price in PLN will be taken into account when comparing offers.</p> <p>If the Contractor specifies a price in a currency other than PLN, the Ordering Party will use the average exchange rate of the National Bank of Poland (NBP) available at <a href="http://www.nbp.pl">www.nbp.pl</a> published on the date of publication of this Request for Quotation in the Competitiveness Database as the currency conversion rate.</p> <p>The point value for this criterion will be calculated as follows:</p> $K_{cena} = (\text{gross price of the cheapest of the submitted offers} / \text{gross price of the evaluated offer}) \times 100$ <p>The offer may receive a maximum of 100 points for the "Gross price" criterion.</p>

2. The final number of points awarded to a given bid will correspond to the number of points obtained in the criterion presented above (i.e.,  $K_c$ ). The score will be rounded to two decimal places in accordance with the mathematical rule of rounding numbers. A bid may receive a maximum of 100 points within the scope of the contract.
3. The most economically and qualitatively advantageous bid within the scope of the contract will be the bid 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 in the course of the evaluation.

4. In a situation where the Ordering Party is unable to select the most advantageous bid due to the fact that two or more bids within the scope of the contract offer the same price, the Ordering Party shall request the Contractors who submitted these bids to submit additional bids. Contractors submitting additional bids may not offer prices higher than those offered in the bids already submitted.
5. In the case of Contractors who have submitted bids within the specified time limit, but whose bids do not contain the required documents and statements, or whose submitted documents and statements are incomplete, contain errors, or raise doubts indicated by the Ordering Party, the Ordering Party shall request the submission of missing documents or statements, to supplement or correct them, or to provide explanations within a time limit specified by the Ordering Party, unless, despite their submission, supplementation or correction, or the provision of explanations, the Contractor's bid is subject to rejection or it would be necessary to invalidate the procedure. Failure by the Contractor to meet the deadline specified by the Ordering Party will result in the rejection of the offer. Only formal deficiencies or errors are subject to supplementation, correction, or clarification. It is not possible to change the terms of the submitted offer.
6. In the case of a Contractor whose bid may contain a grossly low price in relation to the subject of the contract, the Ordering Party reserves the right to request, in accordance with the procedure described in point 5 above, that the Contractor provide relevant explanations and present the method of calculating the gross price. A price may be considered abnormally low if it is at least 30% lower than the estimated value of the contract or the arithmetic mean of the prices of all non-rejected bids. When assessing the explanations provided by the Contractor, the Ordering Party shall take into account objective factors. The Contracting Authority shall reject the bid of a Contractor who has not provided explanations, has not provided them within the specified time limit, or if the assessment of the explanations together with the evidence provided confirms that the bid contains a grossly low price in relation to the subject of the contract. The obligation to demonstrate that the bid does not contain a grossly low price rests with the Contractor.
7. The Contracting Authority shall publish information on the outcome of the procedure in the Competitiveness Database <https://bazakonkurencyjnosci.funduszeuropejskie.gov.pl/> in the BIDS (announcements) tab.
8. The Contracting Authority reserves the right to cancel or invalidate the procedure at any stage if no bids have been submitted or no bids that are not subject to rejection have been submitted; the price of the most advantageous bid or the bid with the lowest price exceeds the amount that the Contracting Authority intends to allocate to finance the contract, unless the Ordering Party can increase this amount to the price of the most advantageous bid; the procedure is burdened with an irremediable defect preventing the award of the contract in accordance with the principles of fair competition and equal treatment of contractors or applicable law; there has been a significant change in circumstances resulting in the conduct of the procedure or the performance of the contract not being in the interest of the Ordering Party, which could not have been foreseen at the time of publication of the Request for Quotation. Contractors shall not be entitled to any claims against the Ordering Party if the latter exercises any of the rights indicated in the previous sentence.

#### **XI. EXPLANATIONS OF THE CONTENT OF THE REQUEST FOR PROPOSALS AND THE METHOD OF COMMUNICATION BETWEEN THE PURCHASER AND THE CONTRACTORS**

1. The Contractor may request clarification of the content of the Request for Proposal from the Ordering Party via the Competitiveness Database system using the "QUESTIONS" tab available in the Request for Proposal (announcement) tab. Detailed instructions on how to submit questions via the Competitiveness Database are available at [https://archiwum-bazakonkurencyjnosci.funduszeuropejskie.gov.pl/info/web\\_instruction](https://archiwum-bazakonkurencyjnosci.funduszeuropejskie.gov.pl/info/web_instruction), in the "Attachments" section, in a file named "BK2021 PDF Help ver. 12.04.2023".
2. The Contracting Authority shall provide explanations no later than 2 days before the deadline for submission of tenders, provided that the request for clarification of the content of the Request for Proposal is received by the Contracting Authority no later than by the end of the day on which half of the deadline for submission of tenders expires. If the request for clarification of the content of the Request for Proposal is received by the Ordering Party at a later date or concerns clarifications already provided, the Ordering Party may provide clarifications or leave the request unexamined.
3. The Contracting Authority shall publish the explanations and answers in the Competitiveness Database in the "QUESTIONS" tab available in the Request for Proposal (announcement) tab. The explanations and answers shall form an integral part of Request for Proposal No. FENG.01.01-IP.02 – 12/2025.
4. The Contracting Authority reserves the right to amend or supplement the content of the Request for Proposals at any time before the deadline for submission of proposals. In the event of such an amendment 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 necessitates the modification of bids, the Ordering Party shall, in accordance with the procedure described in point 4 above, extend the deadline for submitting bids.
6. The extension of the deadline for submitting bids shall not affect the deadline for submitting the application referred to in point 2 above.

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

1. The Ordering Party shall request the Contractor whose offer has been selected to conclude a mutually agreed contract in writing or by e-mail, specifying the place and date of its conclusion.
2. The selected Contractor shall be obliged to contact the Ordering Party within the time limit specified in the request in order to agree on all matters related to the contract to be concluded.
3. If the Contractor whose bid has been evaluated as the most advantageous refuses to conclude the contract, the Ordering Party may examine whether the Contractor who submitted the highest-rated bid among the remaining bids meets the conditions for participation in the procedure and select such a bid as the most advantageous bid.

## **XIII. TERMS AND CONDITIONS FOR AMENDING THE AGREEMENT CONCLUDED AS A RESULT OF THE PROCUREMENT PROCEDURE**

The Ordering Party reserves the right to amend the contract concluded with the Contractor selected in the course of the proceedings in the event 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 the performance of the contract may be changed in the following situations:

- a) in the event of force majeure, i.e., an extraordinary and external event over which the Ordering Party or the Contractor has no control and which they were unable to prevent despite exercising due diligence. In such a case, the deadline for the performance of the Contract shall be extended by the duration of the force majeure event and the removal of its effects;
- b) in the event of circumstances beyond the control of the Contractor or the Ordering Party, provided that the change results from circumstances which the Contractor or the Ordering Party could not have foreseen at the time of publication of the Request for Quotation or submitting the offer, despite exercising due diligence, and for which they are not at 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 Ordering Party's control, periodically preventing the continuation of the performance of the Subject of the Agreement, for the duration of the suspension. The Ordering Party shall notify the Contractor of the suspension by e-mail, indicating the reason for the suspension;
- d) due to changes in legal regulations relevant to the performance of the Subject of the Order, affecting the scope or deadline for its performance, to the extent necessary to comply with 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 timeliness of the performance of the subject of the order - by a maximum of the period of downtime and delays.

2. Other changes:

- a) changes in legal regulations in force on the date of submission of the Contractor's bid, which will introduce new requirements regarding the manner of performance of any element of the Subject Matter of the Agreement;
- b) when the need to introduce changes is a consequence of changes introduced in agreements between the Ordering Party and a party other than the Contractor, in particular the Intermediate Body, which is a party to the co-financing agreement under which this order is financed, and
- c) also other institutions which, on the basis of legal provisions, may influence the performance of the order.

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

1. The contracting authority reserves the right to award supplementary contracts to the contractor selected in this tender procedure, up to a value not exceeding 50% of the contract value specified in the contract concluded with the contractor, provided that these contracts are consistent with the subject matter of the main contract.



2. The contracting authority provides for the possibility of awarding the contractor selected in this tender procedure additional contracts not covered by the basic contract and not exceeding 50% of the value of the public contract being performed, necessary for its proper performance, the performance of which has become necessary as a result of a situation that could not have been foreseen earlier, if, for technical or economic reasons, separating the additional contract from the main contract would require disproportionately high costs or the performance of the main contract would depend on the performance of the additional contract. The above changes may only be made if both parties agree that the above circumstances have occurred and that the changes are necessary for the proper performance of the contract.

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

1. In accordance with Article 13(1) and (2) of Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 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 of 04.05.2016, p. 1), hereinafter referred to as "GDPR", I hereby inform you that:
2. The controller 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@i4hv.com
3. Personal data will be processed on the basis of Article 6(1)(c) of the GDPR for the purpose of the procurement procedure covered by Request for Quotation No. FENG.01.01-IP.02 – 12/2025 and further in connection with the contract being performed.
4. The recipients of personal data will be persons or entities to whom the documentation from the proceedings will be made available on the basis of the provisions of applicable law, including in particular the provisions of the Act of September 6, 2001, on access to public information (i.e., Journal of Laws 2018.1330, as amended).
5. Personal data will be stored for the time necessary to perform and settle the contract for co-financing of the Ordering Party, under which the order is co-financed, and necessary for the limitation period of any claims.
6. The Contractor's obligation to provide personal data results from participation in the procurement procedure covered by Request for Quotation No. FENG.01.01-IP.02 – 12/2025.
7. The provision of personal data is voluntary for the purpose of concluding and performing the contract between the Ordering Party and the Contractor within the framework of this procedure conducted in the form of a Request for Quotation, although refusal to provide such data will prevent cooperation between the above-mentioned parties.
8. With regard to the personal data received, decisions will not be made in an automated manner, pursuant to Article 22 of the GDPR.
9. The Contractor has:
  - a) the right to access personal data concerning him/her pursuant to Article 15 of the GDPR;
  - b) the right to rectify his/her personal data pursuant to Article 16 of the GDPR;
  - c) the right to erase personal data concerning them, in the situations specified in Article 17(1) of the GDPR, subject to Article 17(3) of the GDPR;
  - d) pursuant to 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/her violates the provisions of the GDPR.
10. The Contractor shall not be entitled to:
  - a) the right to erasure of personal data in connection with Article 17(3)(b), (d) or (e) of the GDPR;
  - b) the right to data portability referred to in Article 20 of the GDPR;
  - c) pursuant to 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(1)(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 a bid in response to Request for Quotation No. FENG. 01.01-IP.02 - 1/2025 and the performance of the contract, which the Contractor confirms by means of an appropriate statement on the fulfillment of its information obligations provided for in Article 13 or Article 14 of the GDPR, contained in the Bid Form, constituting Appendix No. 1 to the Request for Proposal.



Fundusze Europejskie  
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 **PARP**  
Grupa PFR

## **XVI. ATTACHMENTS TO THE REQUEST FOR PROPOSALS**

**Appendix No. 1 Bid form**

**Appendix No. 2 Contractor's statement on meeting the conditions for participation in the procedure**