…………………………………….

place, date

ORDERING PARTY:

Innovations for Heart and Vessels Sp. z o.o.

ul. Ligocka 103, 40-568 Katowice

NIP: 9542733146,

KRS: 0000399063

BIDDER

|  |  |
| --- | --- |
| Contractor: |  |
| Address of the Contractor's registered office and correspondence address: |  |
| NIP: |  |
| REGON: |  |
| KRS (jeżeli dotyczy): |  |
| Name and surname of the contact person: |  |
| Phone number: |  |
| Email address: |  |

By participating in the tender procedure, the subject of which is the development and manufacture of 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, for the implementation of which the Ordering Party has obtained co-financing under the European Funds for Modern Economy program, Priority 1. Support for entrepreneurs, Measure

1.1 Smart Path (hereinafter: Project) on the basis of request for quotation No. FENG.01.01-IP.02 - 12/2025

I/we declare that:

I/we meet the conditions for participation in the procedure specified in the request for quotation, namely:

1. Knowledge and experience

□ We have experience in the development, design, and prototyping of minimally invasive Class III or implantable medical devices, as evidenced by our participation in projects, references, product portfolio, publications, or other documents.

□ Over the last 10 years, we have completed at least 3 services and/or projects in the field of designing implantable, minimally invasive medical devices.

List of key projects/services (in accordance with the Request for Proposal)):

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We have a proven track record in scientific research, with publications in scientific journals such as.:

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1. Human resources potential

□ We have a team of at least three specialists involved in the implementation of the order, 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 has documented experience in at least 3 projects in a similar field, completed with the implementation of a medical device on the market.

We have documented participation in projects or services such as:

|  |  |  |  |
| --- | --- | --- | --- |
| N.O. | Specialist's first and last name | Project/service name | project/service description, scope of work/ Number of projects completed |
| 1. |  |  |  |
| 2. |  |  |  |
| 3. |  |  |  |

1. Technical facilities and R&D infrastructure

□ We have the technical facilities necessary to carry out prototyping and engineering work, including in particular:

• the ability to 3D print components,

• processing and joining materials used in minimally invasive medical devices,

• work on components for implant delivery systems..

□ We have the technical and organizational infrastructure to conduct research and development work in the field of design, manufacture, and testing of delivery system components for medical devices, including:

• access to appropriate research equipment,

• an ISO 7 Clean Room working environment.

1. Compliance with standards and regulations

□ The work carried out by the Contractor's team is conducted in accordance with the requirements of ISO 13485 and MDR (EU) 2017/745..

1. Economic and financial situation

☐ We are in an economic and financial situation that ensures the proper and timely execution of the order.

1. Method of order fulfillment

☐ We undertake to perform the order using our own personnel, equipment, and technical facilities..

Place …………………,date …………… ..…..….....................................................................................

(signatures of persons indicated in the document authorizing them to act in legal transactions or holding power of attorney)