Blizne Łaszczyńskiego, on 21.03.2025

OFFER INQUIRY ABM/2/2025

In connection with the implementation of the research and development project entitled. "*Development of an innovative device with a dedicated probe for intraoperative cryoanalgesia to implement a unique and effective pain management therapy for cardiothoracic surgery*" (Contract no: **2022/ABM/02/00019-00**), for which the Company has received a grant from the Medical Research Agency from the public funds of the State Budget under the *"Competition for enterprises to finance the development, performance evaluation, clinical evaluation of innovative medical devices"* and the obligation to make purchases based on the most economically advantageous offer, observing the principles of fair competition, efficiency, openness and transparency, Metrum Cryoflex Sp. z o.o. **submits an inquiry for "*Services for preparation of plan and execution of validation of ethylene oxide sterilization with preparation of report in accordance with ISO 11135 standard for cryosurgical disposable probe",* described in detail in item. III of this inquiry.**

I. CONTRACTOR:

METRUM CRYOFLEX Sp. z o.o.
Zielna 29
05-082 Blizne Łaszczyńskiego
NIP: 5272320862

II. PROCUREMENT PROCEDURE:

1. This proceeding is not subject to the provisions of the Act of January 29, 2004. Public Procurement Law (Journal of Laws of 2021, item 1129, 1598).
2. This proceeding is conducted in accordance with the market discernment
3. This proceeding shall be conducted in accordance with the principles of fair competition, efficiency, openness, transparency and equal access.
4. The contracting authority will make every effort to avoid conflicts of interest understood as a lack of impartiality and objectivity.
5. The Contracting Authority reserves the right to cancel the proceedings or amend or supplement the contents of the Request for Tender at any time, before the deadline for submission of tenders, in particular due to the necessity to remove defects in the announcement to the requirements of generally applicable law or other regulations binding on the Contracting Authority, and if it proves necessary for the proper implementation of the project or the subject of the announcement (in particular, due to the due quality of execution of the subject of the contract and its compliance with the objectives of the project). Information on the cancellation of the proceedings or on the amendment or supplementation of the content of the Request for Proposal will be published at https://bazakonkurencyjnosci.funduszeeuropejskie.gov.pl/. Information on cancellation of the proceedings or on introduction of changes or additions to the contents of the Request for Proposal, the Contracting Authority will also send directly to the entities from which the Contracting Authority has already received an offer by e-mail, in person or by mail. If the introduced changes or additions to the content of the Request for Proposals require changes to the content of the tenders, the Contracting Authority will extend the deadline for submission of tenders by the time needed to make changes to the tender.
6. The Contracting Authority reserves the right to request additional information, documents or clarifications from Bidders after the deadline for submission of bids. The Contracting Authority's contact with the Bidder will be through the e-mail indicated in the Bidder's submitted bid.
7. The contracting authority does not allow partial bids or variant bids under this procedure.
8. The Procuring Entity reserves the right to enter into negotiations with all Bidders who have submitted a bid that meets the conditions of access (i.e., conditions for participation in the proceedings) indicated in the body of the request for proposals. Negotiations will be conducted according to the following rules:

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a. After the deadline for submission of bids, the Procuring Entity will notify all Bidders who submitted non-rejectable bids of the possibility to negotiate and invite these Bidders to negotiate, arranging individual meeting dates with each Bidder,
b. Negotiation date arrangements will be conducted by e-mail,
c. Only the parameters that constitute the criteria for evaluating bids are subject to negotiation,
d. The course of negotiations shall be documented in the form of a written protocol, signed by the negotiating teams of the Procuring Entity and the Bidder,
e. Within 7 days from the date of completion of negotiations, the Bidder shall submit a modified offer, taking into account the findings of the negotiations. The modified offer shall not contain terms less favorable than the original offer,
f. in the event that the Bidder refuses to participate in the negotiations, the negotiations do not lead to binding arrangements, or the Bidder does not submit a modified bid, the Bidder's originally submitted bid will be evaluated,
g. The Contracting Authority will evaluate the bids within 30 days from the date of submission of the last modified bid and select the Contractor whose bid is the most advantageous,
h. The Contracting Authority may require Bidders to agree to extend the bidding period for up to 60 days.

III. DETAILS OF THE SUBJECT OF THE CONTRACT:

1. COMMON PROCUREMENT VOCABULARY (CPV) AND CPV CODE NAME

- **73110000-6** - Research services
- **73111000-3** - Laboratory testing services

2. DETAILED DESCRIPTION OF THE SUBJECT MATTER OF THE CONTRACT

The subject of the contract is the service of preparing a plan and performing validation of ethylene oxide sterilization with the preparation of a report in accordance with the ISO 11135 standard for a disposable cryosurgical probe. The probes are made of steel tubing (316 and 304 steel) and titanium-coated copper tubing, and this constitutes the component directly in contact with the patient. The probe also consists of a handle, power cords and plug, which are made of plastic (mainly polyamide). In addition, the scope of validation should include tests for bioburden, sterility and ethylene oxide release, among others.

The service should be carried out on the basis of norms and standards that cover the requirements of European and American legislation in this field, in particular: ISO 10993-7, ISO 11135, ISO 11138-1, ISO 11138-2, ISO 11737-1, ISO 11737-2, ISO 13485, ISO 14644-1.

DETAILED SCOPE OF THE STUDY:

On the basis of ethylene oxide sterilization cycles and tests, a sterilization validation report (hereinafter: report) should be prepared summarizing the results obtained and allowing an unambiguous assessment of compliance with the requirements of ISO 11135. The report should be supplemented with all raw data and the results of the analyses and tests conducted.

2.1. SCOPE OF PREPARATION AND EXECUTION OF THE STUDY:

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- Perform validation of the bioburden method for bioburden,
- Perform validation of sterility assessment method
- Perform a series of sterilization cycles to:
    - Confirmation of the effectiveness of the sterilization process in the context of ensuring sterility of the tested devices,
    - The suitability of the adopted method for assessing sterility after sterilization cycles,
    - compatibility of the component materials used and the design in terms of penetration and release of EO/ECH from the processed products,
    - Product functionality and packaging tests together with the Purchaser.
- In particular, the execution of sterilization cycles:
    - sublethal cycle,
    - half cycles,
    - full cycles.
- The cycles should be planned in such a way that, with the agreement of the ordering party, the ordering party can use the samples after the sterilization process for other tests, such as aging tests, functional tests or other tests to validate the ordering party's internal production processes.

2.2. SERVICE DELIVERY METHODOLOGY

The methodology for the implementation of the service should take into account all the specified information in this request, including but not limited to:

- Development of a validation protocol in accordance with ISO 11135
- Carry out a number of sterilization cycles and tests to verify the assumptions made, define and confirm the sterilization parameters, confirm the possibility of ethylene oxide sterilization of the tested product in the context of the materials used and the design of the product, its packaging, palletization and placement in the sterilization chamber,
- Summarize the results and prepare a sterilization validation report in accordance with ISO 11135.

2.3. REQUIREMENTS

- Experience in conducting sterilization and sterilization validation of medical devices, developing sterilization validation protocols and reports.
- Requirements for the team include at least 3 years of experience working in sample preparation and conducting sterilization validation, particularly for the medical device industry.
- The contractor should have its own sterilization chamber and have the necessary infrastructure to conduct such activities,
- The contractor should have a valid quality management system certificate in accordance with ISO 13458 for the performance of this contract (sterilization of medical devices).

2.4. CONSULTATION MEETINGS

The service should take place in active cooperation with the Contracting Authority. Accordingly, at least 4 status meetings of the Contractor's experts with the Employer's representatives will be necessary during the course of the services. Requirements for status meetings:

- The meetings must be attended each time by at least 2 people from the team responsible for the implementation of the service,
- Each meeting will last at least 60 minutes,
- Meetings are to be held at the Employer's premises, unless otherwise agreed by the parties,
- The Principal shall notify the Contractor of the meeting at least 2 working days before the scheduled meeting date. During the performance of the service, the Contractor may change the date of the meeting set by the Employer a maximum of two times.
- The contractor should initiate meetings whenever there is a need for urgent consultation on ongoing activities.

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IV. CONDITIONS FOR PARTICIPATION (ACCESS CRITERIA):

1. **BIDDERS WHO:**

   a) have the necessary knowledge and experience, as well as technical and personnel potential capable of performing the subject matter of the contract:

   - have completed at least 3 services related to sterilization validation for the medical industry, including at least 1 in the field of ethylene oxide sterilization validation and at least 1 in the field of sterilization validation of products that are manufactured from plastic and steel parts (by documentation confirming experience, it is understood, in particular: references of recipients, acceptance protocols, contracts, orders or other),

   b) have the authority to carry out specific activities or actions, if the laws require such authority,

   c) have / will have adequate infrastructure facilities to perform the subject matter of the contract,

   d) conduct activities in accordance with the description of the subject of the contract,

   e) are in an economic and financial position to ensure the performance of the contract,

   f) They are not in liquidation or bankruptcy,

   g) are not in arrears in the payment of taxes, fees or contributions to social or health insurance,

   h) have not been validly convicted of an offense committed in connection with procurement procedure, an offense of bribery, an offense against business transactions, or any other offense committed for financial gain; and a partner in a general partnership, a partner or a member of the management board of a partnership; a general partner of a limited partnership and a limited joint-stock partnership; a member of the governing body of a legal entity has not been validly convicted of a crime committed in connection with the procurement procedure, a crime of bribery, a crime against economic turnover or any other crime committed for the purpose of financial gain.

2. **FROM COMPETING FOR THE CONTRACT WILL BE EXCLUDED:**

   Bidders who have personal or capital ties with the Contracting Authority (mutual ties between the Contracting Authority or persons authorized to incur liabilities on behalf of the Contracting Authority or persons performing activities on behalf of the Contracting Authority related to the preparation and execution of the procedure for selecting the Bidder and the Bidder). A capital or personal relationship means a mutual relationship between the Contracting Authority or persons authorized to incur liabilities on behalf of the Contracting Authority or persons performing activities on behalf of the Contracting Authority related to the preparation and conduct of the procedure for the selection of the Bidder and the Bidder, consisting in particular of:

   - participating in a company as a partner in a civil partnership or partnership,
   - owning at least 10% of shares,
   - Serving as a member of the supervisory or management body, proxy, attorney,
   - being married, in a relationship of consanguinity or affinity in the direct line, consanguinity of the second degree or affinity of the second degree in the collateral line, or in a relationship of adoption, custody or guardianship.

Fulfillment of the conditions indicated above will be verified on the basis of the Bidder's statement. The evaluation of the fulfillment of the conditions presented above will be made according to the formula: "meets - does not meet". The Bidder who fails to meet any of the conditions will be rejected from the proceedings.

The Procuring Entity will also reject the bid if the Bidder fails to provide documents confirming the credibility of the statements at the request of the Procuring Entity. If the bid is rejected, the Bidder shall not be entitled to any claims.

V. DEADLINE AND METHOD OF SUBMITTING BIDS:

1. Bids must be submitted by **the end of the day on March 28, 2025.**
2. The bid should be prepared in Polish.

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3. The bid completed with the required attachments should be initialed and signed by persons authorized to represent the company. The contracting authority shall accept bids bearing electronic signatures.
4. Bids should be submitted:
   a. By email: rafal.pyzel@metrum.com.pl
   b. by mail or courier or in person to the address: Metrum Cryoflex Sp. z o.o., 29 Zielna St., 05-082 Blizne Łaszczyńskiego St.
   c. via the Competitiveness Database portal: https:
5. The deadline for submission of a bid is considered to be the date (including time) of delivery of the bid to the Contracting Authority (also applies to bids submitted electronically).
6. Bids received after the deadline and those that do not have the required attachments will not be evaluated.
7. Costs associated with the preparation and delivery of the bid shall be borne by the Bidder.
8. Inquiries regarding the subject matter of the contract should be submitted until 26/03/2025.
9. The person authorized to contact the Bidders is: Rafał Pyzel tel 502 327 874 from 8 am to 4 pm Monday to Friday e-mail: rafal.pyzel@metrum.com.pl
10. Submission of a bid is tantamount to unreserved acceptance of the contents of this request for proposal and its attachments.
11. **The offer should include the term of the offer (a minimum of 30 days from the date of submission).**
12. The bid should be prepared in accordance with the form attached as Appendix 1 to this request.
13. Each Bidder may submit only one bid.

VI. PLACE OF DELIVERY OF THE SUBJECT OF THE ORDER:

Metrum Cryoflex Sp. z o.o., Zielna Street 29, 05-082 Blizne Łaszczyńskiego.

VII. THE DATE OF EXECUTION OF THE SUBJECT ORDER:

No later than 30.09.2025.

The purchaser reserves the right to change the date of execution of the subject of the contract based on the status of the project or in the event of force majeure or the conditions of the grant agreement or the results achieved during the research work.

VIII. BID EVALUATION CRITERIA

1. The Contracting Authority will evaluate and compare only those bids that are not rejected by the Contracting Authority.
2. Bids will be evaluated by the Contracting Authority based on the following criteria and their importance:

Criterion	Percentage importance of the criterion	The maximum number of points an offer can receive for a given criterion
Price	100%	100 points

3. **Evaluation rules for the criterion "Price" (C) .**
   For the "Price" criterion, the bid will receive the number of points resulting from the operation rounded to two decimal places:

$$P_i(C) = {}_{C(min)}/C_{(i)} - \text{Max } (C)$$

Where:

$P_i(C)$	The number of points that bid "i" will receive for the criterion "Price";

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C_{min}	The lowest price among all valid and non-rejected bids;
C_i	bid price "i";
Max (C)	The maximum number of points an offer can receive for the "Price" criterion, i.e. 100 points.

In the event that a bid is submitted in a currency other than PLN, the Contracting Authority, for evaluation purposes, will convert the currency into PLN of the submitted bid using the average sales rate of the currency in question on the day of closing the call for bids according to the table of the National Bank of Poland.

The contractor can earn a maximum of 100 points.

The bid, not subject to rejection, that receives the highest number of points will be considered the most advantageous.

IX. MODE OF EVALUATION OF BIDS AND ANNOUNCEMENT OF RESULTS:

1. Clarification of the content of bids and correction of obvious errors.
   In the course of examining and evaluating bids, the Contracting Authority may request clarifications from Bidders regarding the content of their bids.
2. Checking the credibility of offers.
   The Contracting Authority reserves the right to check the credibility of the documents, statements, lists, data and information presented by Contractors in the course of bid evaluation.
3. Announcement of the results of the proceedings.
   Contractors who submit bids will be notified of the results of the proceeding electronically to the e-mail address indicated in the bid immediately after the evaluation of the bids. Information on the results of the proceedings will be published in the places where the announcement is published.

X. REJECTION OF THE CONTRACTOR:

The bidder will be rejected from this procedure:

1. In case of non-fulfillment of the conditions for participation in the proceedings or failure to provide the required supporting documents;
2. If the offer does not comply with this request;
3. If the Bidder presents false information;
4. If the Bidder has a personal or capital relationship with the Contracting Authority.

Bidders who are excluded from bidding will be:

1. within the last 3 years prior to the initiation of the proceedings caused damage by not performing the contract or performing it improperly, and this damage has not been voluntarily repaired by the date of initiation of the proceedings, unless the non-performance or improper performance is a consequence of circumstances for which the Bidder is not responsible. Thus, the Contracting Authority will exclude the Bidder from the proceedings if the following conditions are met together:
   a. in the last 3 years prior to the initiation of proceedings, he caused damage by not performing the contract or performing it improperly,
   b. the damage had not been voluntarily repaired by him by the date the proceedings were initiated,
   c. a contrario, the non-performance or improper performance of the contract is a consequence of circumstances for which the Bidder is responsible.
2. natural persons who have been validly convicted of a crime committed in connection with the contract award procedure, a crime against the rights of persons performing gainful employment, a crime against the environment, a crime against bribery, a crime against economic turnover or any other crime committed for

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financial gain, as well as a fiscal crime or a crime of participation in an organized group or association aimed at committing a crime or fiscal crime,

3. general partnerships, a partner of which has been legally convicted of a crime committed in connection with the contract award procedure, a crime against the rights of persons performing gainful employment, a crime against the environment, a crime against bribery, a crime against economic turnover or other crime committed to achieve financial gain, as as a fiscal crime or a crime of participation in an organized group or association aimed at committing a crime or fiscal crime,
4. partnerships whose partner or member of the management board has been legally convicted of a crime committed in connection with the contract award procedure, a crime against the rights of persons performing gainful employment, a crime against the environment, a crime against bribery, a crime against economic turnover or other crime committed to achieve financial gain, as well as a fiscal crime or a crime of participation in an organized group or association aimed at committing a crime or fiscal crime,
5. limited partnerships and limited joint-stock partnerships, the general partner of which has been legally convicted of a crime committed in connection with the procurement procedure, a crime against the rights of persons performing paid work, a crime against the environment, a crime against bribery, a crime against economic turnover or any other crime committed to achieve financial gain, as well as a fiscal crime or a crime of participation in an organized group or association aimed at committing a crime or fiscal crime,
6. legal persons whose incumbent member of the governing body has been validly convicted of a crime committed in connection with the contract award procedure, a crime against the rights of persons performing paid work, a crime against the environment, a crime against bribery, a crime against economic turnover or other crime committed to achieve financial gain, as well as a fiscal crime or a crime of participation in an organized group or association aimed at committing a crime or fiscal crime,
7. are collective entities that have been banned by the court from competing for contracts, based on the provisions of liability of collective entities for acts prohibited under penalty.

XI. TERMS OF THE CONTRACT FOR THE EXECUTION OF THE SUBJECT OF THE CONTRACT:

1. The Procuring Entity will enter into a contract with the Bidder whose bid is deemed the most advantageous (obtains the highest number of points) and who meets the requirements specified in the Request for Proposal
2. The Procuring Entity will notify the Bidder of the date of conclusion of the contract by e-mail along with information on the results of the proceedings.
3. In the event that the selected Bidder withdraws from entering into a contract with the Contracting Authority, or in the event that the contract is not signed within 30 days from the announcement of information on the selection of the most advantageous bid, the Contracting Authority shall have the right to enter into a contract with the next Bidder who obtained the next highest number of points in the procurement procedure.
4. The contracting authority reserves the right to amend the terms of the contract concluded as a result of this procurement. The changes will be able to relate to:
   a. The term of the Agreement - changes resulting from, among other things, the extension of project implementation,
   b. The existence of conditions having the characteristics of "*force* majeure.
   c. adjust for changes in the implemented Grant Agreement - if any.

XII. ADDITIONAL INFORMATION:

1. The Contracting Authority reserves the right to award additional contracts to the Contractor, in an amount not exceeding 50% of the value of the contract specified in the contract concluded with the Contractor, consistent with the subject of the basic contract. The Contracting Authority reserves the right to award the Contractor additional contracts, not included in the basic contract and not exceeding 50% of the value of the executed contract, necessary for its proper execution, the execution of which has become necessary due to a situation impossible to foresee earlier, if:

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a. for technical or economic reasons, separating the additional contract from the basic contract would require incurring disproportionately high costs,
b. performance of the basic contract is contingent on the execution of an additional contract.

2. The Contracting Authority stipulates that an increase or decrease in the scope of the contract shall not constitute grounds for claims by the Contractor. The Contractor's remuneration for the execution of supplementary or additional orders will be specified in a separate agreement concluded with the Ordering Party, which will include the scope and terms of the contract.
3. Due to the fact that the subject matter of the contract is a component of a research and development project and, as is well known, research and development projects are characterized by a rather high degree of research uncertainty, which is immanently associated with such an advanced project and its high degree of technological advancement. In the case of innovative Projects, it is important for the business success of the project to make improvements and test new research hypotheses, therefore, after the prototype is made, the Purchaser allows the possibility of making design improvements.
4. The Ordering Party allows the execution of the entire subject of the contract in stages, which will be separately received and invoiced. Details will be included in the concluded Contract.
5. The Contracting Authority allows the granting of advance payments. Details will be included in the concluded Contract.

XIII. ATTACHMENTS TO THE REQUEST FOR PROPOSAL:

1. APPENDIX NO. 1 - BID FORM
2. APPENDIX NO. 2 - STATEMENTS

XIV. LIST OF REQUIRED DOCUMENTS AND STATEMENTS FOR THE REQUEST FOR PROPOSAL:

1. APPENDIX NO. 1 - OFFER FORM.
2. APPENDIX 2 - STATEMENTS.
3. DOCUMENT(S) CONFIRMING THE CONDITIONS FOR PARTICIPATION (ACCESS CRITERIA) - THE BIDDER'S OWN DOCUMENT(S).

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