Warsaw, 23.09.2024

PRICE INQUIRY NO. NUSI/77/PR65652/2024

In connection with the implementation of the project titled *"Development of a universal fast-response platform, based on RNA technology, ensuring the national drug and epidemiological safety* co-financed from the state budget by the Medical Research Agency, Zakłady Farmaceutyczne Polpharma S.A. requests the submission of bids **for the purchase and supply of sterilization system (Autoclave) dedicated to sterilization of filling line components and tooling in a pharmaceutical GMP controlled environment.**

I. NAME AND ADDRESS OF THE BUYER

Zakłady Farmaceutyczne Polpharma S.A.
ul. Pelplińska 19
83-200 Starogard Gdański

II. PRICE INQUIRY PROCEDURE

1. This Price Inquiry is not subject to the provisions of the Public Procurement Law of 11 September 2019 (consolidated text: Journal of Laws of 2019, item 2019).

2. The procedure is being conducted as an intentional and cost-efficient market assessment study while respecting the following rules:
   1) achieving the best possible outcomes using the available measures;
   2) choosing the best possible means and methods to meet the pre-defined objectives;
   3) ensuring transparency, fair competition and equal treatment of contractors.

III. DESCRIPTION OF THE SUBJECT OF THE PRICE INQUIRY

3.1. The subject matter of this Price Inquiry is the delivery of an autoclave for sterilization of aseptic filling line parts being used in highly controlled GMP class A isolator environment.

3.2. The sterilizer will be used to sterilize change parts that have contact with product of an isolator-enclosed unit, performing filling and capping (of vials, ampoules and cartridges) in an isolated Class A environment in a Class C environment as a background. Also additional tools and clothing will be subject to sterilization.

3.3. **The functionalities described in section 5.2 are regarded as critical.** If the Contractor fails to meet one of these requirements, the bid will be rejected by the Buyer.

3.4. The Contractor will be responsible for performing the tests described in detail in the User Requirements Specification and for providing reports on these tests.

3.5. The documentation listed in the User Requirements Specification should be considered part of the delivery.

3.6. Training of Buyer's personnel is included in the scope of delivery.

3.7. The autoclave will be covered by a mechanical warranty for 24 months counted from the Final Acceptance date, but no longer than 30 months from the physical delivery date, if delay in Final Acceptance occurred through the Buyer's fault.

3.8. Partial bids or variants will not be accepted by the Buyer.

3.9. A detailed description of the subject of contract (***Attachments 4A-4D*** containing the User Requirements Specification with attachments to be completed by the Contractor) will be provided to the Contractors after signing the Confidential Disclosure Agreement

(***Attachment 3***). The Contractor should send the completed Confidential Disclosure Agreement in editable version to email barbara.wendolowska@polpharma.com. After the receipt of the Confidential Disclosure Agreement, signatures by authorised person(s), in accordance with the rules of representation of the respective Contractor, will be collected via the DocuSign platform. The Buyer shall make ***Attachments 4A-4D*** hereto available via digital channels no later than within two business days of signing the Confidential Disclosure Agreement.

IV. PRICE INQUIRY DELIVERY SITE AND DATE

4.1. Time limit for the subject of contract:

4.1.1. The Factory Acceptance Test (FAT) of the Autoclave will be performed **no later than within 9 months** from the date of conclusion of the agreement. **Bids with a longer deadline will be rejected.**

4.2. **Planned contract signing date : October/November 2024**

4.3. The Autoclave that is the subject of the Price Inquiry will be delivered and installed at the research and production site located in Starogard Gdański at 19 Pelplińska Street on the premises of Zakłady Farmaceutyczne Polpharma SA. - Parenteral Dosage Forms Production Facility.

4.3. The Contractor shall transport the subject of contract described in section III to the address indicated in section 4.3 and supervise unloading and location of the line at the installation site.

V. REQUIREMENTS FOR CONTRACTORS

5.1. The procedure is open to any Contractors who meet all of the following requirements:

5.1.1. have experience in the implementation of similar projects, i.e. they can confirm, in the form of a declaration, the manufacture, delivery and installation of at least four sterilizing systems with similar characteristics over the last 5 years,

5.1.2. sign a Confidential Disclosure Agreement prior to the commencement of works *(**Attachment 3***),

5.1.3. declare compliance with Sanction clause requirements *(**Attachment 5***),

5.1.4. confirm compliance with the Buyer's requirements by returning completed documents attached as ***Attachments 1, 2, 4A-4D*** to the Price Inquiry.

5.1.5. **Attachment 4B** should also be sent in excel version.

Assessment procedure:

*The Buyer will consider the Contractor as meeting the above conditions if the Contractor submits a declaration of compliance with the conditions for participation in the procedure (**Attachment 2**) with completed and signed forms (**Attachments 1, 4A-4D**).*

The Buyer reserves the right to verify the fulfilment of the conditions at the Contractor's premises or to call for relevant documentation to be submitted.

5.2. Bids submitted by Contractors who demonstrate that they meet the specified requirements will be taken forward to the bid examination and assessment stage. The compliance with the above requirements will be assessed based on a 'meet – does not meet' basis. Bids submitted by Contractors who fail to meet any of the above requirements will be rejected. THE AUTOCLAVE CRITICAL FUNCTIONALITIES ARE DETAILED DESRIBED AND INDICATED IN ***ATTACHMENTS 4B-1 - -4B-6***:

5.2.1 Attachment 4B-1: section I pos. 1, 2

5.2.2 Attachment 4B-2: section I pos. 1, 3,7,8,9; section II pos. 12, 13; section V pos. 1-8

5.2.3 Attachment 4B-3: section I pos.1,4

5.2.4 Attachment 4B-6: section I pos. 1, 2, 4, 5.

5.3. Entities for which the following circumstances occur are also excluded from the tender:

a) as described in Article 7(1) of the Act of 13 April 2022 on Special Measures to Counteract Support for the Aggression against Ukraine and to Protect National Security;

b) as described in Article 5k of the Council Regulation (EU) No 833/2014 of 31 July 2014 concerning restrictive measures in view of Russia's actions destabilising the situation in Ukraine.

Method of verification of grounds/lack of grounds for exclusion:

*The verification shall take place on the basis of the Contractor's declaration (**Attachment 1**).*

VI. METHOD OF PRICE CALCULATION

6.1. Bid price calculation: the price should be calculated as a net and a gross amount.

6.2. For evaluation bids with the price given in a currency other than PLN will be converted to PLN at the average exchange rate of the National Bank of Poland (https://www.nbp.pl/) as at the final date for the submission of bids.

6.3. The price should include all the costs related to the preparation and performance of the subject of the Price Inquiry.

6.4. All payments required until the date of physical delivery of the autoclave to the address specified in section 4.3 will be secured by an Advance Repayment Guarantee (the guarantee will remain valid until the delivery date + 1 month).

6.5. Payment of not less than 10% of the total contract value will only be made after the Final Acceptance.

6.6. The requirement is a Bank Performance Guarantee (issued after the Final Acceptance and valid throughout the guarantee period) of 5% of the total contract value.

6.7. The price included in the Tender Procedure report and entered in the agreement between the Buyer and the Contractor cannot change during the performance of such an agreement.

VII. CONTRACT AWARD CRITERIA

7.1. The bids will be evaluated based on the following criteria:

- Technical - 50%
- Price - 50%.

7.2. The scoring of the bid will be calculated according to the following formula:

$$\boldsymbol{O_P = P_C + P_W}$$

where:

O_P	-	the bid score
P_C	-	score for technical criteria
P_w	-	score for price criteria

7.3. Score (P_C) for technical criteria will be calculated according to the formula:

$$P_C = \frac{C_B}{C_N} * 50 \text{ points}$$

where:

P_C - score for technical criteria
C_N - among non-rejected bids, the bid with the highest total number of points awarded for the technical criteria
C_B - total number of points awarded for the technical criteria of the bid under evaluation

As part of the technical criterion, the bids will be verified in terms of compliance with the provisions contained in the URS. This verification will take place through an expert evaluation performed by the Buyer's representatives. The outcome of this evaluation will be an expert evaluation report.

7.4. The score (P_w) for price criteria will be calculated according to the formula**:**

$$P_w = \frac{W_N}{W_B} * 50 \text{ points}$$

where:

P_W - score for trade criteria
W_N - among non-rejected bids, the offer with the lowest total net price
W_B - total net price of the bid under evaluation

Bids with the price given in a currency other than PLN will be converted to PLN at the average exchange rate of the National Bank of Poland as at the final date for the submission of bids.

7.5. The bid with the highest score out of all the non-rejected bids will be considered the best bid. The maximum score to be awarded to the Contractor is 100 points. Calculations will be made to two decimal places.

VIII. PLACE AND DATES FOR SUBMITTING AND OPENING BIDS

8.1. The **final deadline** for submitting bids is **09.10.2024.**
- bids can be sent in electronic format as signed electronically or scanned documents to the following address: barbara.wendolowska@polpharma.com.

8.2. The date and the time when the bid is received by the Buyer determines whether the submission deadline has been complied with.

8.3. No bids submitted past the submission deadline will be taken into consideration.

8.4. The Buyer is not planning to hold a public opening of the bids.

8.5. Bids may be modified or withdrawn prior to the end of the time limit for the submission of bids.

IX. PREPARATION OF BIDS

9.1. The Contractor must draw up a single price bid using the form attached as ***Attachment 1***. Submitting more than one bid for a particular part will result in all bids submitted by the Contractor being rejected.

9.2. The bid must be prepared in Polish or English language version.

9.3. The bid with attachments must be signed by persons authorised to represent the Contractor in accordance with the representation resulting from the relevant register or pursuant to a power of attorney granted. If the person(s) signing the bid (representing the Contractor) is(are) acting under a power of attorney, the power of attorney must be attached to the bid.

9.4. Contractors are required to carefully read the information contained in the Price Inquiry and in the User Requirements Specification (***Attachments 4A-4D***), confirming compliance with the requirements YES or NO (if NO is entered, Contractor's comment is required). **Entering NO in the items identified as critical will result in rejection of the bid.**

9.5. Any costs and expenses incurred in connection with the preparation and submission of bids are to be paid by the respective Contractors.

9.6. Until the end of the time limit for the submission of bids, the Buyer reserves the right to amend or add new information to this Price Inquiry.

9.7. The Contractor submitting the bid remains bound by it for 90 calendar days from the end date of the time limit for the submission of bids.

9.8. If the supplier's income earned in association with project execution is subject to withholding tax in Poland, Zakłady Farmaceutyczne Polpharma S.A. is obliged by law to deduct the withholding tax from the supplier's remuneration and remit it to the Polish tax authorities **(remuneration includes withholding tax).**

X. COMMUNICATION BETWEEN THE BUYER AND THE CONTRACTORS, PERSONS AUTHORISED FOR CONTACT

10.1. During the procedure, the Buyer and the Contractor shall submit all declarations, requests, notices and information in English.

10.2. The receipt of any notices, statements, requests and information submitted electronically must be immediately confirmed at the request of either Party.

10.3. If the Contractor has not confirmed the receipt of the correspondence, the Buyer will assume that the correspondence sent by the Buyer to the email address provided by the Contractor has been delivered in a way that enables the Contractor to read it.

10.4. Any correspondence about this Price Inquiry should be sent to: barbara.wendolowska@polpharma.com.

10.5. In any correspondence related to this Price Inquiry, the Contractor shall refer to the procedure number: Price Inquiry No. **NUSI/77/PR65652/2024.**

10.6. Barbara Wendołowska is the person authorised to communicate with the Contractor.

10.7. No information, clarifications or answers will be provided orally or by phone to inquiries addressed to the Buyer.

10.8. Any questions about this Price Inquiry should be sent by e-mail to the address provided above, not later than 3 days before the end of the time limit for the submission of bids.

10.9. Replies to the questions and more detailed information on the Price Inquiry following from questions asked by prospective Contractors will be sent to the entity requesting that information.

XI. BID EVALUATION PROCEDURE AND PUBLICATION OF RESULTS

11.1. During the examination and evaluation of the submitted bids, the Buyer may request the Contractor to provide additional information (if it does not infringe competitiveness) and clarifications related to the submitted bids. The Buyer may also ask the Seller to correct evident mistakes and calculation errors.

11.2. The Buyer reserves the right to verify, during the procedure, the documents, declarations, lists, data and information provided by the Contractor.

11.3. **The Procuring Entity reserves the right to negotiate bids** with all bidders who submit valid bids, especially if the price offered by the Bidders exceeds the budget allocated by the Procuring Entity for the execution of the contract.

XII. AMENDMENTS TO THE CONTRACT

12.1 **The Buyer reserves the right to make material changes to the provision of the contract**, as compared to the bid based on which the Buyer was awarded the contract, to the following extent and in the following situations:

12.1.1 To reflect changes in law that affect the delivery of the services covered by the Contract (in particular changes in VAT rates);

12.1.2 To improve technical parameters of the Contract in line with new solutions brought about by technological advancements, without any effects on the gross flat rate;

12.1.3 To extend the deadline for the delivery of the services covered by the Contract due to additional works which need to be carried out to ensure proper delivery of the services covered by the Contract and which the Customer, while exercising due diligence, could not have foreseen beforehand, subject to section 12.1.6 below;

12.1.4 To extend the deadline for the delivery of the services covered by the Contract due to force majeure event(s), with any consequences of such an extension;

12.1.5 To change the parameters of the services covered by the Contract without altering the nature of the Contract – technology-related changes, in particular: the need to deliver the services covered by the Contract using other solutions – in terms of technology or materials – than those specified in the Request for Quotation in the event that the use of the original solutions could lead to non-delivery or improper delivery of the services covered by the Contract, subject to section 12.1.7. below;

12.1.6 To make changes with respect to additional deliveries or services to be provided by Contractor, which are not covered by the Contract, as long as they are necessary and when all of the following requirements are met:

- Contractor cannot be replaced due to economic or technical reasons, in particular relating to the interchangeability or interoperability of equipment, services or systems contracted under the original Contract,
- Contractor replacement could cause significant inconvenience or a material increase in costs for the Buyer,
- each subsequent change does not exceed 50% net of the original Contract net amount;

12.1.7 To make changes without altering the nature of the Contract, when all of the following requirements are met:

- the Contract needs to be changed due to circumstances which could not have been foreseen by the Buyer while exercising due diligence,
- the change does not exceed 50% of the original Contract net amount;

12.1.8 To replace the Contractor with a new contractor:

- as a result of merger, division, transformation, bankruptcy, restructuring or purchase of Contractor or its enterprise as long as the new contractor meets the conditions for participation in the procedure, there are no grounds for its exclusion and the change does not result in other material amendments to the Contract,
- as a result of the Buyer taking over Contractor's obligations towards its subcontractors;

12.2 **The Buyer can also make non-material amendments to the Contract** as compared to the bid based on which Contractor was awarded the Contract.

12.3 Any amendments to the Contract will be made in the form of an annex signed by both parties and will require approval from the Buyer.

XIII. ADDITIONAL INFORMATION

13.1. The Contractor submitting the bid remains bound by it for 90 calendar days from the end date of the time limit for the submission of the bid. Following the procedure, the Buyer may conclude the Contract for the performance of the subject of contract with the Contractor whose bid is considered to be the best. The selection of the best bid does not mean that the Buyer is obliged to conclude a Contract with the Contractor.

13.2. With respect to the Tender Procedure, the Buyer makes the reservation that it has:

- the right not to choose any of the submitted Bids;
- the right to cancel the Tender Procedure at any time, without giving a reason or without prior notification of the Contractors;
- the right to change or supplement the documents making up the Price Inquiry, in which case such documents will become an integral part of the Inquiry;
- the right to extend the time limit for the submission of bids;

and the Contractors have no claims against the Buyer with respect to the above rights.

13.3. The Buyer makes the reservation that it has:

- option to terminate the agreement in the event of negative results of the Factory Acceptance Test (FAT), which shall be tantamount to the reimbursement by the Contractor of previously paid amounts,
- option to terminate the agreement in the event of negative results of the Site Acceptance Test (SAT), which shall be tantamount to the reimbursement by the Contractor of previously paid amounts,

13.4. PERSONAL DATA PROTECTION.

As far as personal data contained in bids are concerned, the Buyer – as soon as the bid is submitted – will become the Data Controller as defined under Article 4(7) 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 ("GDPR"). The Buyer will process the data for the purposes of bid evaluation, concluding an agreement with the awarded contractor and implementing the concluded agreement, i.e. under Article 6(1)(b) of the GDPR.

The Buyer will transfer the personal data contained in the submitted bids, under relevant regulations, to authorised bodies and institutions entitled to audit projects co-financed from the funds of the Medical Research Agency. For more information on the processing of personal data by competent institutions, visit: https://abm.gov.pl/pl/wolnytekst/198,Polityka-dotyczaca-cookies.html

The Buyer will process the personal data throughout the period during which it is required, under relevant regulations, to store the whole documentation related to projects co-financed from the funds of the Medical Research Agency.

XIV. LIST OF ATTACHMENTS

The following attachments are attached to this Price Inquiry:

Attachment number	Attachment title
Attachment 1	Bid Form
Attachment 2	Contractor's Declaration
Attachment 3	Confidential Disclosure Agreement

Attachment 4	User Requirements Specification ATTACHMENT NR 4A_DSCURS004_3_URS_Autoclave ATTACHMENT NR 4B_DSCURS004_3_URS_Autoclave Att1 - Attachment 4B-1 Materials - Attachment 4B-2 Technical Requirements - Attachment 4B-3 Control System - Attachment 4B-4 Qualification Requirements - Attachment 4B-5 Documentation - Attachment 4B-6 Delivery of Device and System ATTACHMENT NR 4C_DSCURS004_3_URS_Autoclave_rysunek ATTACHMENT NR 4D-1_DSCURS004_3_URS_Autoclave_STERICAP_PARTS ATTACHMENT NR 4D-2_DSCURS004_3_URS_Autoclave_SYRINGE_PARTS ATTACHMENT NR 4D-3_DSCURS004_3_URS_Autoclave_VIAL_PARTS
Attachment 5	Sanction Clouse

Attachment 1 *to the Price Inquiry No.* ***NUSI/77/PR65652/2024***

BID FORM

Bidder:

Name / Company	
Registered office/home address/address of the principal place of business	
E-mail address for the Buyer to send information related to the Price Inquiry	
NIP [Taxpayer ID Number]	
REGON [Statistical ID Number]	
Phone number	
Contact person for the Buyer	

We offer the delivery of the subject of contract **for the supply of sterilization system (Autoclave) dedicated to sterilization of filling line components and tooling** along with the performance of the necessary activities at the Buyer's premises and delivery of the required documentation**,** in accordance with the requirements of the Price Inquiry and the attached completed attachments, for the **total price of:**

net amount: …… PLN/EUR/USD*

IN ALL DOCUMENTS SENT BY THE BIDDER, THE TOTAL NET AMOUNT SHOULD BE THE SAME.

applicable VAT (if applicable): ……% …… PLN/EUR/USD*

gross amount: …… PLN/EUR/USD*

(say: ……...……..)

***delete as appropriate, select the appropriate currency**

The Factory Acceptance Test (FAT) of the Autoclave will be performed no later than within …….. months from the date of conclusion of the agreement (maximum 9 months).

The autoclave will be covered by **a mechanical warranty for 24 months** counted from the Final Acceptance date, but no longer than 30 months from the physical delivery date, if delay in Final Acceptance occurred through the Buyer's fault.

We also declare that:

a. We have read the Price Inquiry and attachments thereto and we have obtained the information necessary to prepare our bid,

b. Our bid price includes a lump sum remuneration that covers all the obligations of the Contractor as necessary to deliver the subject of the Price Inquiry,

c. Our bid will remain valid and binding for 90 calendar days from the end date of the time limit for the submission of bids,

d. The following circumstances do not occur with respect to us:

a) as described in Article 7(1) of the Act of 13 April 2022 on Special Measures to Counteract Support for the Aggression against Ukraine and to Protect National Security;

b) as described in Article 5k of the Council Regulation (EU) No 833/2014 of 31 July 2014 concerning restrictive measures in view of Russia's actions destabilising the situation in Ukraine.

……	……
(place and date)	(signature(s) of person(s) authorised to submit statements of will on behalf of the Contractor)

CONTRACTOR'S DECLARATION

When entering the bid for the purchase of **for the supply of sterilization system (Autoclave) dedicated to sterilization of filling line components and tooling** along with the performance of the necessary activities at the Buyer's premises and delivery of the required documentation**,** we hereby declare that:

1) We have experience in the implementation of similar projects, i.e. over the last 5 years, we have manufactured, delivered and installed at least four autoclaves with similar characteristics,
2) we undertake to comply with the principles set forth in the Ethics and Corporate Social Responsibility Clause and the Anti-Corruption Clause available at the following link: https://polpharma.pl/klauzule/compliance/
3) we make the declarations contained in the Sanction Clause as set forth in **Attachment 5** and undertake to comply with the principles contained therein.

…… (place and date)

…… (signature(s) of person(s) authorised to submit statements of will on behalf of the Contractor)