REQUEST FOR QUOTATION No. EDPI/2/PR93893/86522-217685/2025

I. NAME AND ADDRESS OF THE CONTRACTING AUTHORITY

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

II. MODE OF AWARDING THE CONTRACT AND TYPE OF CONTRACT

The procedure is conducted in connection with the implementation of the project titled "Development and advancement of inhaled complex generic drugs for the treatment of respiratory diseases COPD and asthma" under the National Recovery and Resilience Plan, Component D "Efficiency, accessibility, and quality of the healthcare system", Investment D3.1.1 "Comprehensive development of research in medical and health sciences", competitive mode (hereinafter referred to as the project).

The procedure is conducted in accordance with the principle of competitiveness specified in the document titled "Catalog of eligible expenses" attached as Attachment No. 12 to the Regulations for the selection of projects to be supported under the National Recovery and Resilience Plan, Component D "Efficiency, accessibility, and quality of the healthcare system", Investment D3.1.1 "Comprehensive development of research in medical and health sciences", competitive mode.

The procedure is conducted in accordance with the principle of competitiveness specified in subsection 3.2 of the Guidelines on the eligibility of expenses for 2021-2027 dated November 18, 2022.

The provisions of the Public Procurement Law of September 11, 2019, do not apply to this procedure.

III. DESCRIPTION OF THE SUBJECT OF THE CONTRACT

3.1. Category: External Services

3.2. Subcategory: Research and Development Services

3.3. The subject of the contract is a service related to the development and production of an inhaler prototype.

3.4. A detailed description of the subject of the contract is protected as a trade secret under the provisions of the Act of April 16, 1993, on combating unfair competition (Journal of Laws of 2022, item 1233, as amended) and its disclosure requires the conclusion of a relevant confidentiality agreement (Non-Disclosure Agreement, NDA), which constitutes Attachment No. 6 to this request for quotation.

Attachment No. 5 will be made available by the Contracting Authority to the Bidder within 2 business days from the date of receipt of the confidentiality agreement signed by the Bidder with an electronic signature or with a traditional signature. The agreement must be completed and signed by a person authorized to represent the Bidder or holding an appropriate power of attorney. The agreement must be accompanied by a power of attorney and/or a current extract from the relevant register confirming the authorization to act on behalf of the Bidder.

In the event of concluding the agreement in a traditional form, the Bidder is obliged to send two identical copies of the signed agreement to the Beneficiary's address: Zakłady Farmaceutyczne Polpharma SA Oddział Medana in Sieradz, ul. Wojska Polskiego 73, 98-200 Sieradz.

Attachment No. 5 will be made available to the e-mail address indicated by the Bidder within 2 business days from the receipt of the signed original documents. Then the Contracting Authority

undertakes to sign and send two copies (one for each Party) of the agreement to the Bidder within 2 business days (the deadline for signing and sending the agreement by the Contracting Authority will not be longer than 2 business days).

The signed confidentiality agreement should be sent to the e-mail address: pawel.brzezinski@polpharma.com or traditionally no later than 4 business days before the deadline for submitting offers.

A power of attorney and/or a current extract from the relevant register confirming the authorization to represent should be attached to the agreement.

3.5. All results of the services and intellectual property rights to them, industrial property rights, will belong to the Contracting Authority. In the event that for objective reasons the transfer of all intellectual property rights is not possible, it is possible to obtain/use license granted for a period of at least until 2031, in a situation where granting a wider scope of rights is not possible based on objective premises.

3.6. The documentation produced as part of the service must be delivered to the Contracting Authority at the Bidder's expense.

3.7. Category of the subject of the contract according to the Common Procurement Vocabulary (CPV):

CPV Code:
73100000-3 Research and experimental development services
33670000-7 Medicinal products for the respiratory system
33157000-5 Gas and respiratory therapy devices

IV. PLACE OF PERFORMANCE OF THE CONTRACT

4.1. The service that is the subject of the contract is to be performed at the Bidder's premises. It is acceptable to subcontract parts of the tasks to external entities cooperating with the Bidder that offer the specialized service required for the performance of the Service. Subcontracting tasks must be approved by the Contracting Authority each time.

V. DEADLINE FOR THE PERFORMANCE OF THE CONTRACT

5.1. Deadline for the performance of the contract: within a maximum of 6 months from the conclusion of the contract.

5.2. Estimated date of conclusion of the contract: April/May 2025. The Contracting Authority reserves that this date may be postponed due to the deadline for completing the purchasing procedure.

5.3. The subject of the contract will be delivered to the address:
Zakłady Farmaceutyczne Polpharma S.A.
Medana Branch in Sieradz
Poland
98-200 Sieradz
ul. Wojska Polskiego 73,

VI. CONDITIONS FOR PARTICIPATION IN THE PROCEDURE AND GROUNDS FOR EXCLUSION

CONDITIONS FOR PARTICIPATION IN THE PROCEDURE

6.1. Bidders who meet the following conditions may apply for the contract:

6.1.1. **authorization to perform specific activities or actions**

- *The Bidder has an implemented and valid quality management system for the design and production of medical devices, confirmed by an ISO 13485 certificate or equivalent in terms of ensuring compliance with the requirements for a quality management system for medical devices, including risk management, supervision of production processes, quality control, compliance with legal regulations and the ability to trace production batches*

The Contracting Authority will consider that the Bidder meets this condition if they submit a statement that they have the necessary authorizations for the proper execution of the contract and will include a copy of the certificate with the offer.

6.1.2. **knowledge and experience**

- *The Bidder has experience in the design and development of medical devices for inhalation used in the treatment of respiratory diseases COPD and asthma for at least 3 years,*
- *The Bidder specialize's in the development of generic inhalers for use in the pharmaceutical industry for at least 3 years*
- *The Bidder has knowledge and experience in the design and molding of plastic components by injection molding for at least 3 years*

The Contracting Authority will consider that the Bidder meets this condition if they submit a statement that they have the knowledge and experience necessary for the proper execution of the contract.

6.1.3. **technical potential**

- *The Bidder has the ability to design and manufacture medical devices for administering inhaled drugs (inhalers) in accordance with ISO 13485 or equivalent in terms of ensuring compliance with the requirements for a quality management system for medical devices, including risk management, supervision of production processes, quality control, compliance with legal regulations and the ability to trace production batches,*

The Contracting Authority will consider that the Bidder meets this condition if they submit a statement that they have the technical facilities necessary for the proper execution of the contract and present's a copy of the ISO 13485 certificate or equivalent.

6.1.4. **personnel capable of performing the contract**

The Contracting Authority will consider that the Bidder meets this condition if they submit a statement that at the beginning of the work, they have the necessary human resources for the proper execution of the contract. Key resources should include:

- Documentation Specialist (requirements: higher education, documented experience in preparing project documents, including technical product documentation, design, etc.)
- Designer (requirements: technical education, knowledge of AutoCad, Inventor, or similar programs, practical and theoretical knowledge of technical drawing and dimensioning, experience in implementation projects of medical devices)

- Product Engineer (requirements: higher technical education, knowledge of AutoCad, Inventor, or similar programs, documented experience in manufacturing plastic components by injection molding)
- Person responsible for the production of inhaler components - injection molding machine operator
- Person responsible for assembling the inhaler
- Person responsible for quality control
- Person responsible for quality supervision

Each of the above-mentioned persons should have experience in working with medical devices and have knowledge of the ISO 13485 standard or equivalent in terms of ensuring compliance with the requirements for a quality management system for medical devices, including risk management, supervision of production processes, quality control, compliance with legal regulations and the ability to trace production batches.

6.1.5. **economic or financial situation**

The Contracting Authority will consider that the Bidder meets this condition if they submit a statement that they are in an economic and financial situation ensuring the proper execution of the contract, in particular, they are not in a state of bankruptcy, restructuring, or liquidation.

The statement regarding the fulfillment of the conditions described in point 6.1.1-6.1.5 constitutes Attachment No. 4 to the Request for Quotation.

The Contracting Authority reserves the right to request the Bidder to present documentation to confirm the information contained in the statement.

6.2 **Signed confidentiality agreement (Attachment No. 6)** in order to share a detailed description of the subject of the order (Attachement No. 5).

GROUNDS FOR EXCLUSION FROM PARTICIPATION IN THE PROCEDURE

6.3. Grounds for exclusion

6.3.1. Entities that are personally or financially related to the Contracting Authority are excluded from participation in the procedure.

Personal or financial relationships are understood as mutual relationships between the Contracting Authority or persons authorized to incur obligations on behalf of the Contracting Authority, or persons performing activities related to the preparation and conduct of the contractor selection procedure on behalf of the Contracting Authority and the Bidder, involving in particular:

a) participating in a company as a partner in a civil or personal partnership,

b) holding at least 10% of shares or stocks, unless a lower threshold results from legal provisions,

c) serving as a member of a supervisory or management body, proxy, or representative,

d) being in a marital relationship, kinship, or affinity in a direct line, kinship or affinity in a collateral line up to the second degree, or being related by adoption, guardianship, or custody,

e) being in a cohabitation relationship with the Bidder, their legal representative, or members of the management or supervisory bodies of the Bidders applying for the contract,

f) being in such a legal or factual relationship with the Bidder that there is a justified doubt about impartiality or independence in connection with the contract award procedure.

Verification method for grounds/lack of grounds for exclusion:

Verification will be based on the Bidder's statement and the statements of the Contracting Authority and persons performing activities related to the preparation and conduct of the contractor selection procedure on behalf of the Contracting Authority in accordance with Attachment No. 2.

The Contracting Authority reserves the right to request the Contractor to present documentation to confirm the information contained in the statement.

6.3.2. Entities are also excluded from participation in the procedure if the following circumstances apply:

a) described in Article 7(1) of the Act of April 13, 2022, on special solutions for counteracting the support of aggression against Ukraine and serving the protection of national security;

b) described in 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 L 229, 31.07.2014, p. 1), as amended by Council Regulation (EU) No. 2022/576 amending Regulation (EU) No. 833/2014 concerning restrictive measures in view of Russia's actions destabilizing the situation in Ukraine (OJ L 111, 08.04.2022, p. 1, as amended).

Verification method for grounds/lack of grounds for exclusion:
Verification will be based on the Bidder's statement in accordance with Attachment No. 1.

6.4. Offers submitted by entities that do not meet the conditions for participation in the procedure or for which there are grounds for exclusion from participation in the procedure will be rejected and will not be evaluated.

VII. DESCRIPTION OF THE METHOD OF CALCULATING THE PRICE

7.1. The price should be calculated in net and gross value and entered into the offer form.
7.2. If the prices in the offer are expressed in a currency other than PLN, they will be converted using the average NBP exchange rate (Archive of average exchange rates - table A | National Bank of Poland - Internet Information Service) on the day of the deadline for submitting offers.
7.3. The price should include all costs related to the execution of the subject of the order.
7.4. If the offered price or cost appears to be significantly low in relation to the subject of the contract, i.e., it differs by more than 30% from the arithmetic mean of all valid offers not subject to rejection or raises doubts of the Contracting Authority regarding the possibility of performing the subject of the contract in accordance with the requirements specified in the request for quotation or resulting from separate regulations, the Contracting Authority will require the Bidder to submit

explanations within a specified period, including providing evidence regarding the calculation of the price or cost. The Contracting Authority will evaluate these explanations in consultation with the Bidder and may reject the offer if the submitted explanations along with the evidence do not justify the price or cost provided in the offer.

VIII. DESCRIPTION OF THE CRITERIA THAT THE CONTRACTING AUTHORITY WILL USE WHEN SELECTING THE OFFER

8.1. When evaluating offers, the Contracting Authority will use the following criteria:
- Price – 100%

8.2. The number of points (PC) in the "Price" criterion will be calculated according to the formula:

$$P_C = \frac{C_N}{C_B} * 100$$

where:

P_C - number of points in the "Price" criterion

C_N - the lowest net price among the non-rejected offers covering the execution of the subject of the contract,

CB - the net price of the examined offer covering the execution of the subject of the contract

8.3. The offer that obtains the highest number of points will be considered the most advantageous. An offer can receive a maximum of 100 points. Calculations will be made to two decimal places.

8.4. If more than one offer receives the highest number of points, the Ordering Party will call on the Bidders who submitted these offers to submit additional offers or to negotiate a new price. The price specified in the additional offer or during negotiations cannot be higher than the price originally offered.

IX. PLACE AND DEADLINE FOR SUBMISSION AND OPENING OF OFFERS

9.1. Offers must be submitted by 25.04.2025 until 23:59.

9.2. The offer must be submitted electronically via the Baza Konkurencyjności service, in accordance with the requirements of the "Bidder's Instructions in BK2021" [https://archiwum-bazakonkurencyjnosci. funduszeeuropejskie.gov.pl/info/web_ instruction] in the form of documents signed by the Bidder or their scans, in accordance with the requirements described in point 10.3.

9.3. The date and time of submission of the offer in the Baza Konkurencyjności service will determine the compliance with the deadline.

9.4. Offers submitted in any other way than described above will not be considered. 9.5. The Contracting Authority does not foresee a public opening of offers.

X. DESCRIPTION OF THE METHOD OF PREPARING THE OFFER

10.1. The Bidder may submit only one offer. Submitting two or more offers will result in the rejection of all offers submitted by the Bidder.

10.2. The offer and other required documents must be prepared in Polish or English language, documents prepared in different foreign language must be submitted with a translation into Polish or English language (a sworn translation is not required). In case an offer is submitted in both language versions (Polish and English), the Polish version shall be considered binding.

10.3. The offer and its attachments must be signed by persons authorized to represent the Bidder in accordance with the representation resulting from the relevant register or based on a power of attorney.

10.4. If the person(s) signing the offer (representing the Bidder) acts based on a power of attorney, this power of attorney must be attached to the offer.

10.5. The offer must include:

a) the offer form (in accordance with Attachment No. 1 to the request for quotation),

b) statements and documents resulting from Chapter III and VI of the request for quotation,

c) power of attorney to act on behalf of the Bidder (if applicable),

d) a statement (Appendix No. 3) on the possibility of providing the service based on the specification of the subject of the request for quotation,

e) declaration of fulfilment of the conditions specified in the request for quotation (Attachment No. 4)

f) service implementation schedule (expressed in months) along with descriptions and price lists

10.6. If the Bidder intends to reserve the information contained in the offer as a business secret within the meaning of the Act of 16 April 1993 on Combating Unfair Competition (Journal of Laws of 2022, item 1233, as amended), they are obliged to clearly and distinctly mark this information in the content of the offer.

In particular, the Bidder should indicate specific fragments, sections or attachments of the offer that contain reserved information, together with the justification that they constitute a business secret and cannot be disclosed to third parties. Failure to provide such an indication means that the entire offer may be disclosed.

At the same time, the reservation cannot include information that, in accordance with applicable law or competition principles, should be public, including, among others, elements influencing the evaluation of the offer, such as price, payment terms, deadline or other criteria for evaluating offers.

10.7. Before the deadline for submitting offers, the Bidder may make changes to the submitted offer or withdraw it. Changes to the offer or its withdrawal are made under the same conditions as its submission.

10.8. Bidders are obliged to thoroughly familiarize themselves with the information contained in the request for quotation and any changes to the content of the request, explanations, and answers published by the Contracting Authority during the procedure and prepare the offer in accordance with the requirements specified by the Contracting Authority.

XI. METHOD OF COMMUNICATION BETWEEN THE CONTRACTING AUTHORITY AND BIDDERS

11.1. No information, explanations, or responses to inquiries directed to the Contracting Authority will be provided by telephone or email, except for the transmission of sensitive information in accordance with point 3.4 of the request for quotation, which will be communicated by email.

11.2. Questions regarding the request for quotation and requests for clarification of the content of the request should be sent exclusively via the Baza Konkurencyjności service through the "Pytania" tab on the request for quotation page [https://bazakonkurencyjnosci.funduszeeuropejskie.gov.pl/], no later than 2 working days before the deadline for submitting offers.

11.3. Responses to Bidders' questions and clarifications regarding the content of the request for quotation will be provided to Bidders exclusively by the Contracting Authority publishing the content of the questions/requests for clarification along with the provided answers/clarifications on the request for quotation page in the Baza Konkurencyjności service [https://bazakonkurencyjnosci.funduszeeuropejskie.gov.pl/].

11.4. Unless it violates competitiveness, during the examination of offers, the Contracting Authority has the right to request Bidders to clarify the content of the submitted offers and to supplement the documentation.

11.5. The Contracting Authority has the right to ask the Bidder for consent to correct obvious mistakes and accounting errors.

11.6. The contracting authority reserves the right to negotiate with all bidders who have submitted an offer meeting the access conditions (i.e., conditions for participation in the procedure) specified in the request for quotation. This is especially the case if the offer exceeds the budget allocated by the contracting authority for the execution of the order. Following the negotiations, the Bidder will submit an updated offer in accordance with the outcome of the negotiations.

11.7. In the procedure, statements, requests, notifications, and information are communicated by the Contracting Authority and Bidders in Polish. Documents submitted in a foreign language must be submitted with a translation into Polish (a sworn translation is not required).

11.8. All notifications, statements, requests, and information provided electronically require immediate confirmation of receipt upon request by either party.

11.9. In the absence of confirmation of receipt of correspondence by the Bidder, the Contracting Authority assumes that correspondence sent to the email address provided by the Bidder in the offer form and via the Baza Konkurencyjności service through the "Pytania" tab [https://bazakonkurencyjnosci.funduszeeuropejskie.gov.pl/] has been delivered in a manner that allows the content to be read.

11.10. Correspondence related to these proceedings for Non-disclosure agreement should be directed to the email address: pawel.brzezinski@polpharma.com.

11.11. In correspondence related to this procedure, Bidders should use the procedure number: Request for Quotation No. **EDPI/2/PR93893/86522-217685/2025**.

XII. PROCEDURE FOR EVALUATING OFFERS AND ANNOUNCING RESULTS

12.1. The Contracting Authority reserves the right to further verify the credibility of the documents, statements, lists, data, and information provided by Bidders during the evaluation of the offer.

12.2. Information about the outcome of the procedure will be published on the request for quotation page in the Baza Konkurencyjności service in the "Oferty" tab [https://bazakonkurencyjnosci.funduszeeuropejskie.gov.pl/].

12.3. The selected Bidder will be informed by phone or email about the date and place of signing the contract.

12.4. In the event that the Bidder whose offer has been selected does not proceed to sign the contract, the Contracting Authority has the right to sign the contract with the Bidder whose offer received the next highest number of points, without conducting a new offer procedure. The provisions of point 8.4 apply accordingly.

XIII. AMENDMENT OF THE CONTRACT TERMS

13.1. The Contracting Authority reserves the right to make significant changes to the provisions of the concluded contract in relation to the content of the offer on the basis of which the Contractor was selected, in the following scope and situations:

13.1.1. changes in European Union or national law affecting the implementation of the Contract (in particular changes in VAT rates);

13.1.2. improvement of the technical parameters of the subject of the contract, without affecting the net lump sum price;

13.1.3. extension of the contract execution period due to the need to perform additional work necessary for the proper execution of the contract, which the Contracting Authority, acting with due diligence, could not have foreseen earlier;

13.1.4. extension of the contract execution period due to force majeure, along with all consequences arising from the extension of this period;

13.1.5. extension of the contract execution period for other reasons beyond the Contractor's control;

13.1.6. changes in the parameters of the subject of the contract, changes in the scope of the contract, and changes in the method of execution of the contract, not leading to a change in the nature of the contract – technological changes, in particular: the necessity to execute the contract using different technical/technological or material solutions than those indicated in the request for quotation, in situations where the use of the envisaged solutions would threaten the non-performance or defective performance of the contract;

13.1.7. changes listed in section 7.3, point 22 of the document "Catalogue of eligible expenses".

13.2. The Contracting Authority envisages the possibility of clarifying and/or detailing the above provisions if such a need arises, among others, from the specificity of the subject of the order and/or has a positive impact on the proper understanding of the content of the provision and/or systematizes the principles of performing the Agreement.

13.3. The Contracting Authority also foresees the possibility of making insignificant changes to the provisions of the concluded contract in relation to the content of the offer on the basis of which the Contractor was selected.

13.4. Contract changes will be introduced in the form of an annex signed by both parties, and the possibility of their introduction depends on the acceptance by the Contracting Authority.

XIV. OTHER INFORMATION

14.1. The Contracting Authority reserves the right to change or supplement the content of the request for quotation before the deadline for submitting offers. Information on the introduction of changes or supplements to the content of the request for quotation will be published in the places where the request was published.

14.2. If the introduced changes or supplements to the content of the request for quotation require changes to the content of the offers, the Contracting Authority will extend the deadline for submitting offers by the time needed to make changes to the offer.

14.3. In the event of discrepancies between the content of this document and the content of the announcement appearing in the Baza Konkurencyjności form, the content of this document shall prevail. In the event of discrepancies between the content of this document and the content of other documents included in the offer procedure documentation, the content of this document shall be binding.

14.4. The Bidder bears all costs associated with the preparation and submission of the offer.

14.5. The Contracting Authority does not allow partial or variant offers.

14.6. The Bidder submitting the offer remains bound by it for a period of 90 days from the deadline for submitting the offer.

14.7. The selection of the most advantageous offer does not constitute an obligation for the Contracting Authority to conclude a contract with the Contractor.

14.8. DATA PROTECTION

With regard to personal data contained in the offers, the Contracting Authority, upon submission of the offer, will become the controller of this data within the meaning of 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 Contracting Authority will process this data for the purpose of evaluating offers, concluding a contract with the selected Contractor, and for the purposes of performing the concluded contract, i.e., based on Article 6(1)(b) and (f) of the GDPR.

The Contracting Authority has appointed a Data Protection Officer, who can be contacted on all matters related to the protection of personal data by writing to the Contracting Authority's address or by email at iod@polpharma.com.

The Contracting Authority will transfer personal data contained in the submitted offers, based on applicable legal provisions, to authorized bodies and institutions entitled to control projects co-financed from the European Union budget. This data will be transferred to the Investment Support Unit – the Medical Research Agency, and its controller will be the Director of the Medical Research Agency (in accordance with Attachment No. 15 to the competition regulations), the Minister of Funds and Regional Policy (in accordance with Attachment No. 16 to the competition regulations), and the Minister of Health (in accordance with Attachment No. 17 to the competition regulations).

The Contracting Authority will process personal data for the period in which it is obliged by applicable legal provisions to store all documentation related to the project co-financed from the EU budget. The Contractor undertakes to fulfill the information obligation on behalf of the Contracting Authority by providing each member of the Contractor's personnel, whose data has been provided to the Contracting Authority in connection with the conclusion and performance of this contract, with information on how the Contracting Authority processes their data.

Each person whose data is contained in the submitted offers has the right to access their personal data, request its rectification, request its deletion, request the restriction of or object to its processing, request the transfer of personal data, and lodge a complaint about unlawful processing of personal data to the President of the Personal Data Protection Office.

14.9. The Contracting Authority reserves the right to:

- not select any of the submitted offers,
- cancel the offer procedure at any time without giving a reason or prior notice to the Bidders,
- change or supplement the documents included in the request for quotation, which will become an integral part of it,
- extend the deadline for submitting offers,
- invalidate the procurement procedure if no bids have been submitted or if all submitted bids have been rejected, or if there has been a significant change in circumstances resulting in the fact that conducting the procedure or executing the order is not in the interest of the Ordering Party, or if the cost of the most advantageous bid or the bid with the lowest price exceeds the amount that the Ordering Party intends to allocate to finance the order, with the Ordering Party reserving that it may consider increasing the amount that it intends to allocate to finance the order, but the Bidders shall not have any claim to increase this amount,

and the Bidder has no claims against the Contracting Authority for the above reasons.

XV. LIST OF ATTACHMENTS

The following documents are attachments to this request for quotation:

Designation of the attachment	**Name of the Attachment**
Attachment No. 1	Offer Form Template
Attachment No. 2	Conflict of Interest Statement Template
Attachment No. 3	Template of the statement on the possibility of providing the service specified in the request for quotation
Attachment No. 4	Template of the declaration of compliance with the conditions set out in the request for quotation
Attachment No. 5	Detailed description of the subject of the contract constituting a business secret
Attachment No. 6	Non-Disclosure Agreement Template

Attachment No. 1 to Request for Quotation No. EDPI/3/PR93893/2025-86522-224118

OFFER FORM

Bidder:

Full name (company) or first and last name	
Registered office/place of residence/address of the main place of business	
Email address for correspondence related to the request	
NIP (Tax Identification Number)	
REGON (National Business Registry Number)	
Phone number	
Contact person for the Contracting Authority	

We offer to perform the subject of the contract in the scope of the ***service related to the development and production of an inhaler prototype,*** *in accordance with the requirements of the request:*

Scope of service	**Net price**	**Gross price**	**Currency**	**Completion time please enter the number of months)**
			PLN / EUR/ USD*	
Invoice payment term	**…….. days**			

*select the appropriate currency

The bidder will present a detailed service schedule (expressed in months) along with descriptions and price lists, which will be attached to the offer.

The Bidder has the status of - SME (Micro, small, and medium-sized enterprise) / Large Enterprise * (delete as appropriate)

We also declare that:

a. we've read the tender documentation and accepts the terms and conditions of the tender.,

b. we've obtained the information necessary to properly prepare the bid,

c. the subject of the offer is fully consistent with the description of the subject of the order and other conditions of the Request for Quotation ,

d. the offer price includes remuneration for all obligations of the future Contractor necessary to complete the order, including delivery of the subject of the order to the address indicated by the Ordering Party,

e. we have read the Request for Proposal together with the attachments and we have no reservations and we have obtained the necessary information to prepare the offer,

f. by submitting this offer, we declare that we meet the conditions of participation specified in point VI of the request for proposals,

g. by submitting this offer we are bound by it for a period of 90 days from the date of the end of the offer submission period,

h. here are no circumstances in relation to the bidder and the subcontractor(s) with whom he/she will cooperate in the performance of the subject of the contract (if any):

- described in Article 7(1) of the Act of April 13, 2022, on special solutions for counteracting the support of aggression against Ukraine and serving the protection of national security;
- described in 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 L 229, 31.07.2014, p. 1), as amended by Council Regulation (EU) No. 2022/576 amending Regulation (EU) No. 833/2014 concerning restrictive measures in view of Russia's actions destabilizing the situation in Ukraine (OJ L 111, 08.04.2022, p. 1, as amended).

i. The Bidder consents to the processing of his/her personal data for the purposes necessary to carry out the offer selection process, in accordance with the Act of 10 May 2018 on the Protection of Personal Data (Journal of Laws of 2018, item 1000) and in accordance with 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,

j. the persons signing the Bid Form are authorized to submit the bid on behalf of the Bidder.

Furthermore, I/we declare under penalty of criminal liability that the documents attached to the offer accurately describe the factual circumstances as of the date of its submission (Article 233 of the Penal Code).

…… ……

(place and date)

(signature of the person(s) authorized to make declarations of will on behalf of the Bidder)

Place, date

……
(Name of the entity submitting the offer)

Statement on the absence of conflict of interest

I, the undersigned *(first and last name)*

……

representing the company/entity *(full name of the company/entity, address)*

……

……

declare, in connection with the submitted offer, that the mentioned company/entity and/or persons authorized to represent it:

are not personally or financially related to the announcer of the procedure. Personal or financial relationships are understood as mutual relationships between the announcer or persons authorized to incur obligations on behalf of the announcer or persons performing activities related to the conduct of the contractor selection procedure on behalf of the announcer and the contractor, involving in particular:

a) participating in a company as a partner in a civil or personal partnership,

b) holding at least 10% of shares or stocks, unless a lower threshold results from legal provisions or has been specified in other documents related to the project,

c) serving as a member of a supervisory or management body, proxy, or representative,

d) being in a marital relationship, kinship, or affinity in a direct line, kinship or affinity in a collateral line up to the second degree, or being related by adoption, guardianship, or custody, or being in a cohabitation relationship with the contractor, their legal representative, or members of the management or supervisory bodies of contractors applying for the contract,

e) being in such a legal or factual relationship with the Bidder that there is a justified doubt about impartiality or independence in connection with the contract award procedure.

I also declare that I will immediately inform the Contracting Authority of any circumstances constituting a conflict of interest or that may cause its occurrence.

……..

(signature of the person authorized to submit the Offer on behalf of the Bidder)

STATEMENT ON THE POSSIBILITY OF PERFORMING THE SERVICE SPECIFIED IN THE REQUEST FOR QUOTATION

…….. *(name of the Bidder)* declares that it meets the conditions set out in the request for quotation and therefore has the ability to complete the subject of the order in the following scope:

- development and production of an inhaler prototype in accordance with the detailed description of the subject of the contract.

……	……
(place and date)	(signature of the person(s) authorized to make declarations of will on behalf of the Bidder)

Attachment No. 4 to Request for Quotation No. EDPI/3/PR93893/2025-86522-224118

STATEMENT ON MEETING THE CONDITIONS SET OUT IN THE REQUEST FOR QUOTATION

……

(name of the Bidder)

we declare that we meet the conditions set out in the request for quotation in the following scope:

1. **Authorization to perform specific activities or actions**
   We have a quality management system for the design and production of medical devices confirmed by an ISO 13485 certificate or equivalent in terms of ensuring compliance with the requirements for a quality management system for medical devices, including risk management, supervision of production processes, quality control, compliance with legal regulations and the ability to trace production batches.
2. **knowledge and experience**

   We have at least 3 years of experience in the design and development of medical devices for inhalation, which are used in the treatment of respiratory diseases COPD and asthma.

   We specialize in the development of generic inhalers for applications in the pharmaceutical industry, at least 3 years.

   We have knowledge and experience in the design and molding of plastic parts by injection molding, at least 3 years..
3. **technical potential**

   We have the ability to design and manufacture medical devices for the administration of inhaled drugs (inhalers) in accordance with ISO 13485 or equivalent in terms of ensuring compliance with the requirements for a quality management system for medical devices, including risk management, supervision of production processes, quality control, compliance with legal regulations and the ability to trace production batches.
4. **personnel capable of performing the contract**
   We have the human resources necessary to properly complete the order at the time of commencement of work. Key resources include:
   - Documentation specialist (requirements to be met: higher education, documented experience in the preparation of design documents, including technical documentation of the product, design, etc.),
   - Designer (requirements to be met: technical education, knowledge of AutoCad, Inventor or related programs, practical and theoretical knowledge of technical drawing and dimensioning, experience in implementation projects of medical devices),
   - Product engineer (requirements to be met: higher technical education, knowledge of AutoCad, Inventor or related programs, documented experience in the production of plastic components by injection molding),
   - Person responsible for the production of inhaler components - injection molding machine operator,
   - Person responsible for the assembly of the inhaler,

- Person responsible for quality control,
- Person responsible for quality supervision.

Each of the above-mentioned persons has experience in working with medical devices and knowledge of the ISO 13485 standard or equivalent in the scope of ensuring compliance with the requirements for a quality management system for medical devices, including risk management, supervision of production processes, quality control, compliance with legal regulations and the possibility of tracing production batches

5. **economic or financial situation**

We are in an economic and financial situation that ensures the proper execution of the order, in particular we are not in a state of bankruptcy, restructuring or liquidation.

Attachments to the statement:

1. Current ISO 13485 Certificate or equivalent

……	……
(place and date)	(signature of the person(s) authorized to make declarations of will on behalf of the Bidder)