

**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 to Bidder by the Contracting Authority within 2 working days from the signing of the mutual confidentiality agreement signed with an electronic signature (via the DocuSign platform). The agreement must be completed and signed by a person authorized to represent the Bidder or holding the appropriate power of attorney. The confidentiality agreement must be accompanied by a power of attorney and/or an excerpt from the relevant register confirming the authorization to represent.

**3.5.** All results of the services and intellectual property rights to them, industrial property rights, will belong to the Ordering Party. 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 Service Provider's premises. It is acceptable to subcontract parts of the tasks to external entities cooperating with the Service Provider 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: no later than 30.11.2025.
- 5.2. Planned date of contract conclusion: till end of March 2025.
- 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**
- *Possess a quality management system for the design and production of medical devices confirmed by ISO 13485 certification*

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.

6.1.2. **knowledge and experience**

- *Have documented 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,*

- *Specialize in the development of generic inhalers for use in the pharmaceutical industry for at least 3 years*
- *Have 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**

- *have the ability to design and manufacture medical devices for the administration of inhaled drugs (inhalers) in accordance with iso 13485,*
- *have a production facility for inhalation medical devices certified by iso 13485 (current certificate during the service period and planned to be maintained in the future)*

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 the ISO 13485 certificate.

#### 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 they have the human resources necessary 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 working with medical devices and knowledge of ISO 13485.

#### 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 constitutes Attachment No. 4 to the Request for Quotation. The Contracting Authority reserves the right to*

*request the Contractor to present documentation to confirm the information contained in the statement.*

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

### GROUND 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 EUR, they will be converted using the average NBP exchange rate (<https://www.nbp.pl/>) on the day of the deadline for submitting offers.
- 7.3. If the prices in the offer are expressed in a currency other than PLN or EUR, they will be converted using the average NBP exchange rate on the day of the deadline for submission of offers.
- 7.4. The price should include all costs related to the execution of the subject of the order.
- 7.5. 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,
- $C_B$  - 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.

## **IX. PLACE AND DEADLINE FOR SUBMISSION AND OPENING OF OFFERS**

- 9.1. Offers must be submitted by 10.03.2025.
- 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.funduszeuropejskie.gov.pl/info/web\\_instruction](https://archiwum-bazakonkurencyjnosci.funduszeuropejskie.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).
- 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 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.
- 10.6. If the Bidder presents information in the offer that constitutes a trade secret within the meaning of the Act of April 16, 1993, on combating unfair competition, they should clearly indicate which sections of the offer constitute a trade secret and cannot be disclosed to third parties.
- 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.funduszeuropejskie.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.funduszeuropejskie.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.funduszeuropejskie.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](mailto: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.funduszeuropejskie.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 3.2.4 point 4 of the Guidelines on the eligibility of expenses for 2021-2027.
- 13.2. 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.
- 13.3. 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](mailto: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,
- 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:

<b>Designation of the attachment</b>	<b>Name of the Attachment</b>
Attachment No. 1	Offer Form Template
Attachment No. 2	Conflict of Interest Statement Template
Attachment No. 3	Statement on the Possibility of Performing the Service Specified in the Request
Attachment No. 4	Statement on Meeting the Conditions for Participation in the Request
Attachment No. 5	Specification of Requirements
Attachment No. 6	Non-Disclosure Agreement Template

*Attachment No. 1 to Request for Quotation No. EDPI/2/PR93893/86522-217685/2025*

### OFFER FORM

**Bidder:**

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

*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 date, no later than 30.11.2025)
			PLN / EUR/ USD*	
<b>Invoice payment term</b>	..... days			

\*select the appropriate currency

**The Bidder will present a detailed service schedule with descriptions and a price list, 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 have read the Request for Quotation along with the attachments and have no objections, and we have obtained the necessary information to prepare the offer,
- b.** the price includes a lump-sum remuneration for all obligations of the future Contractor necessary to execute the subject of the Request for Quotation,
- c.** by submitting this offer, we declare that we meet the conditions for participation specified in point VI of the request for quotation,
- d.** by submitting this offer, we are bound by it for a period of 90 days from the deadline for submitting offers,
- e.** there are no circumstances in relation to us:
  - 1. 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;
  - 2. 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).

.....  
(place and date)

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

Attachment No. 2 to Request for Quotation No. EDPI/2/PR93893/86522-217685/2025

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)*



Attachment No. 3 to Request for Quotation No.  
EDPI/2/PR93893/86522-217685/2025

**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 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/2/PR93893/86522-217685/2025

## 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**  
**- Possess a quality management system for the design and production of medical devices confirmed by ISO 13485 certification**

**2. knowledge and experience**

- we have documented 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,
- we specialize in the development of generic inhalers for use in the pharmaceutical industry for at least 3 years,
- we have knowledge and experience in the design and molding of plastic components by injection molding for 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,
- we have a production facility for inhalation medical devices certified by ISO 13485 (current certificate during the service period and planned to be maintained in the future).

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

- we have the human resources necessary for the proper execution of the contract. Key resources 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 has experience working with medical devices and knowledge of ISO 13485.

#### 4. economic or financial situation

- we are in an economic and financial situation ensuring the proper execution of the contract, in particular, we are not in a state of bankruptcy, restructuring, or liquidation.

Attachments to the statement:

1. Current ISO 13485 Certificate

.....  
(place and date)

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