

Katowice, 27/11/2023

Modified on 20/12/2023

REQUEST FOR QUOTATION 1/CPR/2023

implemented as part of the project entitled: „RADIOFARM 4.0: Construction of a new intelligent radiopharmaceuticals factory” for which the Contracting Authority is applying for funding as part of an application for grant related to robotization, artificial intelligence or digitization of processes, technologies, products or services, implemented as part of the investment A2.1.1 Investments supporting robotization and digitization in enterprises from the National Recovery and Resilience Plan (KPO).

I. CONTRACTING AUTHORITY

Alteris S.A.

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The person authorized to contact the Contracting Authority in formal matters is:

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The person authorized to contact the Contracting Authority in substantive matters is::

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II. CONTRACT AWARD PROCEDURE

This procurement procedure is conducted in accordance with the principle of competitiveness as defined in the Appendix No. 6 "Principle of competitiveness under investment A 2.1.1" for funding as part of an application for grant related to robotization, artificial intelligence or digitization of processes, technologies, products or services, carried out as part of the investment A2.1.1 Investments to support robotization and digitization in enterprises from the National Recovery and Resilience Plan.

The Contracting Authority is not an entity obliged to apply the provisions of the Act of 11 September 2019. Public Procurement Law (Journal of Laws of 2023r. pos. 1605 as amended).

III. DESCRIPTION OF THE SUBJECT OF THE CONTRACT

Delivery and installation of cyclotron with automatic solid state target system and synthesis modules set.

CPV code – basic:

CPV 33151400-7: Radiotherapy supplies

CPV 38540000-2: Machines and apparatus for testing and measuring

A detailed description of the subject of the order can be found in Annex 2 to the request for quotation.

IV. DEADLINE AND PLACE OF PERFORMANCE OF THE SUBJECT OF THE ORDER

Contract performance deadline: **30/09/2024**

Place of performance of Subject of the contract: Katowice, Poland

V. CONDITIONS FOR PARTICIPATION IN THE PROCEDURE

Contractors who meet the following conditions may apply for the contract:

1) knowledge and experience

The Contracting Authority will consider that the Contractor meets this condition if it submits a declaration that it has experience in delivering orders with parameters similar to those of the subject of the order.

2) technical potential

The Contracting Authority will consider that the Contractor meets this condition if it submits a declaration that it has the technical resources necessary to properly perform the order.

3) persons capable of performing the order

The Contracting Authority will consider that the Contractor meets this condition if it declares that it has staff with the qualifications necessary for the proper execution of the order.

4) economic or financial situation

The Contracting Authority will consider that the Contractor meets this condition if it submits a declaration that it is in an economic and financial situation ensuring proper execution of the order, in particular it is not in a state of bankruptcy, restructuring or liquidation.

How to evaluate conditions:

Verification will be based on the Contractor's declarations about meeting the conditions for participation in the procedure, in accordance with the "meets - does not meet" formula.

VI. GROUNDS FOR EXCLUSION FROM PARTICIPATION IN PROCEDURE

1. The Contractors in relation to whom there are capital or personal links, which shall mean mutual links between the Contracting Authority or persons authorised to enter into commitments on behalf of the Contracting Authority or persons carrying out activities related to the execution of the procedure for selecting the Contractor and the Contractor, consisting in particular of the following:

- participating in a company as a partner in a civil partnership or partnership,
- owning at least 10% of the shares or stock (unless a lower threshold is required by law)
- acting as a member of a supervisory or management body, proxy or attorney,
- being married, in a relationship of consanguinity or affinity in a direct line, consanguinity or affinity in a collateral line to the second degree, or being related by adoption, guardianship or custody, or being in common life with the contractor, his deputy or members of the management or supervisory bodies of the contractors competing for the award of the contract,
- remaining with the contractor in such a legal or factual relationship that there is reasonable doubt as to their impartiality or independence in connection with the procurement procedure.

2. Contractors who are subject to exclusion pursuant to Article 5k of Council Regulation (EU) No. 833/2014 of 31 July 2014 concerning restrictive measures in view of Russia's actions destabilising the situation in Ukraine (Official Journal of the EU No. L 229 of 31.7.2014, p. 1), hereinafter Regulation 833/2014, as amended by Council Regulation (EU) 2022/576 amending Regulation (EU) No 833/2014 concerning restrictive measures in view of Russia's action destabilizing the situation in Ukraine (Official Journal of the EU No L 111, 8.4.2022, p. 1), hereinafter Regulation 2022/576, i.e. the Contracting Authority excludes participation in the proceedings:

- a) Russian citizens or natural or legal persons, entities or bodies based in Russia,
- b) legal persons, entities or bodies in which more than 50 % of the ownership rights are directly or indirectly held by an entity referred to in point (a) of this point;
- c) natural or legal persons, entities or bodies acting on behalf of or at the direction of an entity referred to in points (a) or (b) of this point,
- d) including subcontractors or suppliers, where they account for more than 10% of the contract value.

3. Contractors who are subject to exclusion on the basis of Article 7(1) of the Act of 13 April 2022 on Special Solutions to Counteract Supporting Aggression against Ukraine and to Protect National Security (Journal of Laws of 2022, item 853) from the procurement procedure, i.e. the Contracting Authority excludes:

- a) A Contractor listed in the lists set forth in Regulation 765/2006 and Regulation 269/2014, or listed on the basis of a decision on listing resolving the application of the measure referred to in Article 1 item 3 of the Act,
- b) the Contractor's beneficial owner within the meaning of the AML/CFT Act of 1 March 2018 on the prevention of money laundering and terrorist financing (Journal of Laws of 2022, item 593 and 655) is a person listed in the lists set out in Regulation 765/2006 and Regulation 269/2014, or listed or being such a beneficial owner as from 24 February 2022, provided that he or she has been listed on the basis of a decision on listing conclusive of the measure referred to in Article 1 item 3 of the Act,
- c) the parent entity of the Contractor, within the meaning of Article 3 paragraph 1 item 37 of the Accounting Act of 29 September 1994 (Journal of Laws of 2021, item 217, 2105 and 2106) is an entity listed in the lists set forth in Regulation 765/2006 and Regulation 269/2014 or listed or being such a parent entity as from 24 February 2022, provided that it has been listed on the basis of a listing decision resolving the measure referred to in Article 1 item 3 of the Act.

4. In order to prove that there are no grounds for exclusion from the contract award procedure as referred to above, the Contractor should submit, together with the tender, a self-declaration according to the template included in the part "Declaration of the Contractor on the absence of relations with the Contracting Authority" and "Declaration of the Contractor on sanction related to the war in Ukraine" from Appendix No. 1 to the Request for Quotation – Offer Form.

5. The offer of an excluded Contractor shall be deemed rejected.

VII. OFFER EVALUATION CRITERIA

When evaluating offers, the Contracting Authority will be guided by the following evaluation criteria:
Price – 100 %

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

$$C = \frac{\text{total net price of the cheapest offers submitted}}{\text{total net price of the examined offer}} \times 100 \text{ points}$$

An offer can receive a maximum of 100 points.

In the Offer Form, the Contractor is obliged to provide prices rounded to two decimal places while maintaining the mathematical principle of rounding numbers.

The most advantageous offer shall be the one submitted by the Contractor not subject to exclusion from participation in the procedure and obtaining the highest number of points during the evaluation.

In the situation where the Contracting Authority is unable to select the most advantageous tender on account of the fact that two or more Contractors submit the same price, the Contracting Authority shall call upon the Contractors who submitted such tenders to submit additional tenders. The Contractors submitting additional tenders may not offer prices higher than those offered in the submitted tenders.

VIII. METHOD OF PREPARING AN OFFER

1. Offer submitted by the Contractor should be prepared on the form constituting Appendix No. 1 to the Request for Quotation – Offer Form.
2. The Contracting Authority recommends the use of the forms attached to this Request for Quotation. It is acceptable to submit forms prepared by the Contractor on their own, provided that they contain all the required information and statements contained in the Contracting Authority's forms.
3. The offer should be drawn up in Polish or English. Documents prepared in other languages should be submitted together with a translation into Polish.
4. The Offer Form and the appendices to the offer have to be signed by an authorized representative(s) of the Contractor in accordance with the form of representation of the Contractor specified in the Contractor's registration document or by a proxy, in a way which makes it possible to identify the person signing the documents.
5. The completed Offer Form must be accompanied by:
 - Declaration regarding fulfilment of the conditions of participation, the content of which is included in Appendix 1 to the Request for Quotation – Offer Form;
 - Signed and completed Appendix No. 2 to the Request for Quotation - description of the subject of the contract - confirming the fulfillment of all technical requirements specified by the Contracting Authority;
 - Declaration of no grounds for exclusion from the procedure - the content of which is included in Appendix 1 to the Request for Quotation – Offer Form;
 - Declaration on the fulfilment of information obligations provided for in Article 13 or Article 14 of the GDPR, the content of which is included in Appendix 1 to the Request for Quotation – Offer Form;
 - If an offer is signed on behalf of the Contractor by a proxy (a person not authorized to do so in the company's registration documents), a relevant power of attorney must be attached to the offer.
6. The Contracting Authority informs that the tenders submitted in the procurement procedure are open and subject to access from the moment of their opening. Tenders shall be made available upon written request of the Contractor who submitted tenders in the procedure, with the exception of information which constitutes a business secret within the meaning of the provisions on counteracting unfair competition, if the Contractor, not later than on the deadline for submission of tenders, reserved that they cannot be made available and proved that the reserved information constitutes a company secret. A company secret within the meaning of the Act of 16 April 1993 on counteracting unfair competition (i.e. Journal of Laws of 2020, item 1913, as amended) shall be understood as technical, technological and organizational information of the company or other information of economic value that has not been made publicly available, with regard to which the entrepreneur has taken necessary steps to maintain its confidentiality..
7. Should a tender contain information constituting a business secret within the meaning of the provisions on counteracting unfair competition, the Contracting Authority recommends that the

information reserved as a business secret should be sent by the Contractor in a separate file or e-mail marked "business secret" separately from the other, non-confidential elements of the tender in a manner that does not raise any doubts as to which of the information contained in the tender constitute such a secret. The pages containing the information referred to in the preceding sentence shall be separately attached to each other, but numbered in accordance with the continuation of the page numbering of the tender.

8. The Contractor may not reserve information on price, (company) name, address, completion date.
9. The Contractor may submit only one offer.
10. Before the deadline for submission of tenders, the Contractor may change or withdraw his offer.
11. The Contractor shall bear all costs related to the preparation and submission of the offer.

IX. OFFER VALIDITY PERIOD

1. The Contractor shall remain bound by the tender for a period of 90 days.
2. The time limit for the submission of tenders shall run from the expiry of the deadline for the submission of offer.
3. At the request of the Contracting Authority, the Contractor may extend the offer validity period, with the proviso that the Contracting Authority may only once, at least 3 days before the expiry of the offer validity period, request the Contractor to agree to an extension of that period by a specified period.

X. PLACE AND DATE OF SUBMISSION OF TENDERS

Offers must be submitted by December 27, 2023.

The offer should be submitted electronically to the Contracting Authority's e-mail address:

oferty@alteris.pl

The date of receipt of the offer by the Contracting Authority shall decide about the observance of the deadline.

Before the deadline for submitting offers, the Contractor may change or withdraw his offer.

Offers submitted in a manner other than that described above will not be considered.

The Contracting Authority does not plan to open offers publicly.

XI. THE METHOD OF COMMUNICATING BETWEEN THE CONTRACTING AUTHORITY AND CONTRACTORS

Questions submitted by Contractors regarding the request for quotation and requests for clarification regarding the content of the request should be sent to the e-mail address rekrutacja@alteris.pl

The Contractor may ask the Contracting Authority to clarify the content of the Request for Quotation no later than December 13, 2023.

If the request for clarification of the content of the Request for Quotation is received by the Contracting Authority at a later date, the Contracting Authority may provide explanations or leave the request without consideration.

The Contractors' questions and the Contracting Authority's answers as well as explanations to the content of the request for quotation will be posted on the Contracting Authority's website.

The Contracting Authority will answer the questions and post them on its website no later than 6 days before the deadline for submitting offers.

XII. IMPORTANT TERMS OF THE CONTRACT, CONDITIONS FOR AMENDING THE CONTRACT AND CONDITIONS FOR TERMINATION OF THE CONTRACT / WITHDRAWAL

1. Deadlines for contract performance:
Completion of the contract at the moment of signing of the handover protocol - by the end of September 2024.
2. Place of performance of the contract:
Katowice, Poland
3. Nature of remuneration:
The Contractor's remuneration for the subject of the contract is a lump sum and includes all costs related to the performance and acceptance of the subject of the contract, as well as warranty and service.
4. The Contracting Authority will pay the Contractor remuneration in three installments:
 - a. First installment in the amount of 10% of remuneration on the grounds of an invoice issued by the Contractor after the conclusion of the Contract with a 30-day payment term,
 - b. Second installment in the amount of 60% of remuneration on the grounds of an invoice with a 30-day payment term, issued by the Contractor after delivery of the products,
 - c. Third installment in the amount of 30% of remuneration on the grounds of an invoice with a 30-day payment term, issued upon the proper installation and performing the required acceptance tests, confirmed by the acceptance protocol signed by the Parties

The Contracting Authority will be entitled to deduct amounts due to the Contracting Authority from the Contractor as a result of non-performance or improper performance of the contract against the Contractor's remuneration.

5. Contractual penalties:
The Contractor will be obliged to pay the Contracting Authority contractual penalties in the event of delay in the performance of the Contract, including delays in delivery and/or installation and/or performance of tests and/or staff training in the amount of [...] % of the contract value for each day of delay. In the event of a delay by the Contractor and/or the

Contracting Authority's withdrawal from the contract due to the Contractor's delay, the Contracting Authority will be entitled to claim compensation exceeding the amount of the contractual penalties charged.

6. Contractual warranty terms:

- a. The Contractor will provide the Contracting Authority with at least twelve-month contractual warranty for the subject of the contract, counted from the moment of **commencement of production activity, understood as the production of a radiopharmaceutical for sale or administration to a patient, but no later than 12 months from the moment of signing the handover protocol of the subject of the contract. The production activity does not include the following elements of acceptance testing, qualification and validation:**

- operational tests of the cyclotron,
- hot tests required for National Atomic Energy Agency inspections in order to obtain National Atomic Energy Agency permits,
- synthesizer qualifications,
- qualifications of dispensers,
- qualifications of QC devices requiring radioactive substances,
- validation of analytical methods requiring radioactive substances,
- process validation.

During the contractual warranty period, the Contractor is obliged to repair and remove any defects or faults in the products (including replacements) revealed during the warranty period at his own expense in accordance with the notification issued by the Contracting Authority. The contractor covers the costs of any transport.

- b. If the Contractor does not proceed to remove the defects or faults or does not remove them within the indicated period or removes them improperly, the Contracting Authority has the right to entrust the removal of defects to a third party at the Contractor's expense and risk, demanding reimbursement of the costs incurred from the Contractor. The contractor is released from the warranty in this respect.
- c. Guaranteed "uptime" during the warranty and service contract > 98%.

7. Conditions for amending the contract:

The Contracting Authority provides for the possibility of changing the provisions of the concluded contract in the following cases:

- a. temporary suspension of the implementation of the Project by the Contracting Authority resulting from objective and justified reasons;
- b. delays in the implementation of the service, delivery and/or construction works carried out under the Project affecting the deadlines for the performance of the contract;
- c. changes in legal provisions, norms, standards and/or technical knowledge, actions of public administration bodies or actions of third parties requiring changes to the technical specifications of the subject of the contract;
- d. introducing changes to the adopted assumptions regarding the subject of the order justified by substantive, technical, functional and visual reasons;

- e. loss of non-repayable support from the development plan as part of the investment A.2.1.1. under the name Investments supporting robotization and digitalization in enterprises of the National Recovery and Resilience Plan and the need to obtain new financing for the Project;
- f. detecting errors, discrepancies or ambiguities in the contract that cannot be removed in any other way, and the change will enable their removal and clarification of the contract in accordance with its purpose or for the purpose of unambiguous interpretation of its provisions by the Contractor and the Contracting Authority;
- g. occurrence of force majeure - if the Contracting Authority, acting with due diligence, could not foresee the changes and their value does not exceed 50% of the order,
- h. changes regarding the implementation of additional supplies, services or construction works purchased from the Contractor, not covered by the basic order, provided that they have become necessary and the following conditions have been met:
 - i. the contractor cannot be changed for economic or technical reasons, in particular regarding the interchangeability or interoperability of equipment, services or installations ordered under the basic contract,
 - ii. a change of contractor would cause significant inconvenience or significant increase in costs for the Contracting Authority,
 - iii. the value of each subsequent change does not exceed 50% of the order value originally specified in the contract;
- i. when the change does not lead to a change in the nature of the contract and the following conditions have been met:
 - i. the need to change the contract is caused by circumstances that the Contracting Authority, acting with due diligence, could not have predicted,
 - ii. the value of the change does not exceed 50% of the order value originally specified in the contract;
- j. when the Contractor is to be replaced by a new contractor:
 - i. as a result of a merger, division, transformation, bankruptcy, restructuring or acquisition of the existing contractor or its enterprise, provided that the new contractor meets the conditions for participation in the contract award procedure, there are no grounds for exclusion against such contractor and it does not result in other significant changes to the contract ,
 - ii. as a result of the Contracting Authority taking over the contractor's obligations towards its subcontractors. In the event of a change of subcontractor, the Contracting Authority may conclude an agreement with a new subcontractor without changing the terms of performance of the order, taking into account payments made for work completed to date;
- k. changing the subcontractor with the help of which the Contractor implements the subject of the contract to another one with the same qualifications and/or professional experience, after prior approval of the Contracting Authority;
- l. when the change does not lead to a change in the general nature of the contract and the total value of the contract is less than the EU thresholds and is lower than 10% of the value of the original contract in the case of contracts for services or supplies, or 15% in the case of contracts for construction works.

Changes to the contract must be made in writing under pain of nullity.

8. Subcontractors:

The Contracting Authority allows for the participation of subcontractors in the performance of the contract. The contractor is responsible for all actions and omissions of subcontractors as for his own.

9. Termination of the contract / withdrawal:

If the Contractor fails to remedy any breach of material obligations arising from the Contract, despite being requested in writing to remedy such breach within a reasonable period not exceeding 30 business days, the Contracting Authority may, at its option, withdraw from or terminate the contract. In the event of withdrawal from the contract, the Contractor will refund all amounts paid to the Contractor to the Contracting Authority.

10. Applicable law:

The contract is subject to Polish law. Any disputes arising from the contract will be resolved by the court competent for the place of installation of the subject of the contract.

XIII. ADDITIONAL INFORMATION

1. The Contracting Authority will use the average exchange rate of the National Bank of Poland (NBP), available at www.nbp.pl, published on the date of the deadline for submitting offers as the currency conversion rate.
2. Zamówienia The Contracting Authority does not allow partial or variant offers.
3. The Contracting Authority reserves the right to change the terms of this procurement announcement at any time before the deadline for submitting offers.
4. The Contracting Authority reserves the right to revoke this procurement announcement at any time without giving a reason.
5. Contractors are not entitled to any claims against the Contracting Authority if it exercises any of the above rights.

XIV. APPENDIX TO THE REQUEST FOR QUOTATION

1. Appendix No. 1 to the Request for Quotation – Offer Form
2. Appendix No. 2 to the Request for Quotation - description of the subject of the contract
3. Power of attorney – if required