



Request for quotation

in competitive bidding

for the production of a medical device for in vitro diagnostics, including: transfer of the technological process, production and verification of the test series of the device, production and delivery of 3 batches of the final product, quality control tests, preparation of production documentation

I. Contracting Authority (Purchaser)

I.1. Contracting Authority:

Urteste S.A.

Starodworska 1

80-137 Gdańsk

I.2. E-mail address for enquiries related to this request for quotation:

grzegorz.zielinski@urteste.eu

I.3. The contact person for matters related to the quotation is Grzegorz Zieliński,

Phone no. + 48 690 319 260

II. Subject and deadline for the order

II.1. The subject of the contract is the production of a medical device for in vitro diagnostics, consisting of 3 substrates, 2 buffers, and positive control, in accordance with the description of the subject of the contract, constituting Appendix No. 3 to the request for quotation.

II.2. The Bidder and/or its subcontractor(s) will be obliged to provide the equipment and infrastructure necessary to perform the subject of the contract (i.a. peptide synthesizer, preparative chromatograph (HPLC), microplate reader, equipment necessary to control the quality of raw materials and semi-finished products, freeze-dryer).

II.3. Due to the need to protect business confidential information, the details will be shared to the potential Bidder after the signed NDA confidentiality agreement is provided to the Contracting Authority (Appendix No. 4 to the announcement). A potential Bidder who

undertakes to maintain confidentiality will be provided with the documents necessary to estimate the remuneration.

II.4. The order will be processed in 5 stages.

Stage I – order completed (delivery of 270 sets) by 31.09.2025.

Stage II – V – order completed (delivery of 14 sets in each stage) at intervals of approx. 3 months, where the delivery of the order in stage II will take place 3 months after the delivery of the order in stage I.

* the above-mentioned deadline for the implementation of Stage I may be changed, due to the nature of the R+D works being carried out, however, it cannot be changed to a date earlier than 31.07.2025. The Contracting Authority will inform the Contracting Authority about the change of the above-mentioned deadline no later than 2 calendar months from the date of completion of Stage I.

II.5. The order will be carried out from the moment of signing the contract (planned for December 2024) until 30.09.2026 r.

II.6. Place of contract performance: activities related to the production of a medical device for in vitro diagnostics, in accordance with the description of the subject of the order, will be carried out at the place indicated by the selected Bidder.

II.7. Deliveries of the Stage I kits will be carried out to the Urteste laboratory and one location in the United States of America. The exact address of deliveries in the United States of America will be provided no later than 1 calendar month before the date of delivery of products from Stage I. Delivery of the final product by the Bidder should take place under temperature-controlled transport conditions. Transport costs will be covered by the Bidder.

II.8. Deliveries of the systems under stages II – V will be carried out to one location in the United States of America. The delivery of the final product by the Bidder should take place under temperature-controlled transport conditions. Transport costs will be covered by the Bidder.

II.9. Name and code describing the subject of the contract specified in the Common Procurement Vocabulary

(CPV): 73000000-2– Research and experimentation and development services and related



consulting services;

- II.10. The Bidder is obliged to perform all services resulting from the request for quotation and its attachments.
- II.11. The contract will be concluded immediately after the selection of the most advantageous offer, within the time limit set by the Contracting Authority.

III. Basis of the quotation and the possibility of change

- III.1. The request for quotation is carried out in accordance with the principle of competitiveness in accordance with the Guidelines on the eligibility of expenditure for 2021-2027.
- III.2. The provisions of the Public Procurement Law do not apply to the quotation.
- III.3. The request for quotation has been published in the Competitiveness Database:
<https://bazakonkurencyjnosci.funduszeuropejskie.gov.pl/>.
- III.4. In case of doubt, the Bidder may ask the Contracting Authority a question in order to clarify the content of the request for quotation by sending it via the quotation page in the Competitiveness Database. The Contracting Authority will answer all questions no later than 5 working days before the deadline for submitting offers. The Contracting Authority stipulates that questions sent less than 5 working days before the deadline for submitting offers may remain unanswered.
- III.5. The contracting authority may modify the content of the request for quotation, in particular due to the need to remove defects in the quotation, adapt the quotation to the requirements of generally applicable law or other regulations binding on the Contracting Authority, and if it turns out to be necessary for the proper implementation of the project or the subject of the quotation (in particular due to the proper quality of the subject of the quotation and its compliance with the objectives of the project).
- III.6. In the event of modification of the content of the quotation, the deadline for submitting offers will be extended, if it is necessary due to the scope or date of the changes introduced.
- III.7. Information about the content of the questions and explanations provided and about the modification of the content of the quotation will be published in the same way as the quotation itself.

IV. Requirements for the Bidder and demonstration of their fulfillment

- IV.1. The contracting authority requires that the Bidder has an ISO 13485 certificate and is registered with the FDA (has a registration number). In a situation where the Bidder plans to outsource part of the production process of the subject of the contract to a subcontractor or subcontractors, the necessary condition is that the subcontractor or subcontractors have an ISO 13485 certificate.
- IV.2. In order to demonstrate compliance with the requirement for the Bidder specified in point IV.1, the information relating to the requirement should be completed in the Offer Form constituting Appendix No. 1 to the request for quotation **and the ISO 13485 certificate and the document confirming registration with the FDA should be submitted together with the offer.** In a situation where the Bidder will use **a subcontractor or subcontractors, the information** relating to the requirement should be completed in the Offer Form constituting Appendix No. 1 to the request for quotation **and the required ISO 13485 certificate should be submitted.**
- IV.3. Bidders who are personally or financially related to the contracting authority in the manner specified in Appendix 2 to the request for quotation may not participate in the request for quotation.
- IV.4. In order to demonstrate compliance with the requirement for the Bidder specified in point IV.3. A statement of no relations with the Contracting Authority should be submitted together with the offer in accordance with Appendix No. 2 to the request for quotation.
- IV.5. The Contracting Authority requires that the Bidder, within the last six years prior to the offer submission deadline (or, if the period of business activity is shorter, during that time), has completed at least 3 contracts in the production of medical devices, including at least 1 that covered the scope of IVD medical device production, including peptide synthesis and freeze-drying.
- IV.6. In order to demonstrate the fulfilment of the requirement for the Bidder specified in point IV.5. the information relating to the requirement should be completed in the Offer Form constituting Appendix No. 1 to the request for quotation and a confirmation of the fulfilment

of the above condition should be submitted together with the offer, i.e. a delivery and acceptance protocol, references, contract, an Internet link to information on the conclusion of the contract, containing the date and entity with which the contract was concluded or another document enabling verification of the fulfilment of the criterion.

- IV.7. The contracting authority requires the Bidder to demonstrate that in last 3 years before the deadline of the offers submission, and if the period of conducting business activity is shorter – during this period, it has been inspected by the FDA.
- IV.8. In order to demonstrate compliance with the requirement for the bidder specified in section IV.7, the information relating to the requirement in the Offer Form constituting Appendix No. 1 to the request for proposal must be completed and a statement or other document confirming that the FDA inspection has been completed, as well as the schedule of the inspections, must be submitted with the offer.

V. Offer evaluation criteria

- V.1. The Contracting Authority will evaluate the unrejected offers on the basis of the following bid evaluation criteria:

Criterion	Scales	Description of the criterion and method of awarding points
Net price	100%	Evaluation of the criterion according to the formula: The lowest net price offered among the non-rejectable offers / the net price offered in the examined offer x 100 points

- V.2. The price without VAT (net price) will be evaluated.
- V.3. The Contracting Authority allows offers to be submitted in foreign currencies. In the case of offers presented in a foreign currency, the net price converted into PLN using the average



exchange rate of the National Bank of Poland as of the date of publication of this quotation will be taken into account.

- V.4. If the currency is not indicated in the offer form, the Contracting Authority will consider that the price has been expressed in PLN.
- V.5. If the information necessary to evaluate the offer in a given criterion is not indicated, the contracting authority will assume that the Bidder does not declare more favourable conditions of implementation than specified in the quotation, and the Bidder will obtain 0 points in a given criterion.

VI. Requirements for the offer

- VI.1. The offer must be submitted in electronic form – as a scan of a signed document or a document with a qualified electronic signature, a trusted signature or another electronic signature enabling the identification of the person signing and thus a declaration of intent – via the Competitiveness Database (<https://bazakonkurencyjnosci.funduszeuropejskie.gov.pl/>). The offer must be submitted in accordance with the requirements described in the quotation using the offer form constituting Appendix No. 1.
- VI.2. The deadline for submitting offers expires at the end of the day indicated in the announcement in the Competitiveness Database. The time of submitting an offer in the Competitiveness Database is important.
- VI.3. The offer should be signed by a person authorized to make declarations of intent on behalf of the Bidder, however, the Contracting Authority does not require documents confirming the authorization of the person signing the offer to be attached to the offer.
- VI.4. The Bidder is bound by the submitted offer for 90 calendar days from the deadline for submission of offers. By this date, the contract for the performance of the contract should be signed.
- VI.5. The offer must be complete, and the submitted documents and statements must contain confirmation of meeting the requirements specified in the quotation.
- VI.6. The offer should be prepared in Polish or in English.
- VI.7. A Bidder may submit only one offer.



- VI.8. The tenderer may stipulate that information covered by trade secrets within the meaning of the provisions on combating unfair competition may not be made available to other Bidders. This information should be appropriately marked with the inscription: "Information constituting trade secrets" and at the same time demonstrate that the restricted information is a trade secret. The tenderer may not reserve information constituting a criterion for the evaluation of offers.

VII. Examination of offers and selection of the most advantageous offer

- VII.1. An offer that does not meet the requirements of this request for quotation, in particular an incomplete offer or an offer that not falls under the provisions of civil law or otherwise inconsistent with the provisions of law, will be rejected, subject to a clearly defined possibility of correcting formal errors and completing deficiencies.
- VII.2. The contracting authority will require the Bidder to provide explanations within the specified period, including the submission of evidence regarding the calculation of the price or cost if the offered price or cost seems to be abnormally low in relation to the subject of the contract, i.e. it differs by more than 30% from the arithmetic average of the prices of all valid offers not subjected to rejection, or raises doubts of the contracting authority as to 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 assess the explanations in consultation with the contractor. The contracting authority will reject the offer if the explanations provided together with evidence do not justify the price or cost specified in the offer.
- VII.3. The contracting authority allows for the correction of formal errors and supplementation of deficiencies in the submitted offer (this does not apply to the offer evaluation criteria or the wrong form of the offer or the lack of a signature on the offer). The Contracting Authority will notify the Bidder of such a necessity by contacting the Bidder via competitiveness database, and if it is not possible for technical reasons, by e-mail in accordance with the contact details provided in the offer. The Bidder should correct errors or supplement deficiencies within 5 working days. Failure to do so will result in the rejection of the offer by the Contracting Authority.

- VII.4. The Contracting Authority reserves the right to withdraw from calling for the correction of formal errors and to supplement deficiencies in the submitted offer, if even their correction or supplementation does not result in the offer receiving the highest score among the evaluated offers.
- VII.5. An offer supplemented or corrected at the request of the Contracting Authority should meet all the requirements of the request for quotation.
- VII.6. The Contracting Authority reserves the right to verify in detail the compliance of the submitted documents and statements with the factual situation, including by calling on the Bidder to clarify the content of the documents or statements. This right includes checking and explaining the compliance of the subject of the offer with the requirements of the request for quotation. The Bidder must be able to demonstrate compliance under penalty of rejection of the offer.
- VII.7. The Contracting Authority will correct obvious errors in the bid, i.e. those for which there is no doubt, what content of the bid should be corrected.
- VII.8. The Contracting Authority will examine the offers in accordance with the requirements of the request for quotation. Offers that meet these requirements will be evaluated in accordance with the bid evaluation criteria specified in the quotation.
- VII.9. The offer that obtains the highest number of points within the bid evaluation criteria will be considered the most advantageous.
- VII.10. The Contracting Authority reserves the right to cancel the request for quotation at any stage of the procedure in justified cases, in particular when the price of the most advantageous offer exceeds the price it is able to pay for the performance of the contract or in the event that the settlement of the procedure would involve the risk of reducing the value of the co-financing due to a defect in the procurement process.
- VII.11. Information on the selection of the most advantageous offer or cancellation of the procedure will be published in the same way as the quotation itself.

VIII. Signing the contract

- VIII.1. After the selection of the most advantageous offer, a contract will be signed with the Bidder



whose offer has been considered the most advantageous.

- VIII.2. The Contracting Authority provides for the possibility of making significant changes to the provisions of the contract in relation to the content of the Bidders's offer on the basis of which the selection was made, including the date of contract completion, in the event of:
- a) force majeure having a direct impact on the performance of the subject of the contract. Force majeure is understood as extraordinary, unforeseeable events and circumstances, independent of the goodwill and intentions of any of the parties to the contract.
 - b) changes in generally applicable laws that affect the performance of the subject matter of the contract;
 - c) other external events or situations which the Contracting Authority or the contractor could not have foreseen or prevented, and which prevent the performance of the subject of the contract in accordance with the contract;
 - d) receipt of a decision of the granting entity, containing changes in the scope of tasks, implementation dates or establishing additional provisions to which the Contracting Authority will be obliged.
 - e) the occurrence of circumstances resulting from substantive reasons, e.g. changes in the deadlines for the implementation of project stages, justifying the introduction of such changes.
 - f) the need to provide additional services not covered by the basic contract, if they have become necessary to perform the subject of the basic contract.
- VIII.3. Any changes and additions to the contract concluded with the selected contractor must be made in the form of annexes to the contract signed by the parties, otherwise they will be null and void.
- VIII.4. The contracting authority does not require the Bidder to provide a performance bond.
- VIII.5. For the avoidance of doubt, except for the cases indicated below, the possibility of unilateral termination or termination of the contract for the performance of the subject of the contract is excluded. Subject to point VIII 6 below, termination of the agreement during its term is possible only for important reasons indicated below or important reasons within the



meaning of Article 746 § 3 of the Act of 23 April 1964. Civil Code, but in such a case, it is necessary to maintain a 3-month notice period, with effect at the end of the calendar month. At the same time, it is agreed that the important reason referred to above will be understood as, i.a. occurrence of circumstances leading to lack of justification (including economic or substantive) for the further implementation of the production process with the use of elements included in the subject of the contract or the cessation or suspension of the implementation by the Contracting Authority of the project under which the order is being performed.

VIII.6. The Contracting Authority may terminate the Agreement without notice if:

- 1) The contracting authority finds that the contractor (Bidder) performs the subject of the contract in a way that does not conform to the contract or the arrangements of the parties (in particular, does not meet the deadlines agreed by the parties),
- 2) the contractor (Bidder) acts to the detriment of the contracting authority,
- 3) the contractor (Bidder) does not perform its duties and has not provided a justification of such and has not undertaken to perform them despite the request from the Contracting Authority,
- 4) the contractor (Bidder) violates the confidentiality provisions,
- 5) a petition for bankruptcy of the contractor (Bidder) is filed;
- 6) restructuring proceedings will be opened against the contractor (Bidder).

VIII.7. The remuneration for the performance of the subject of the contract will be paid in parts, on the basis of a VAT invoice, covering a specific scope of work, agreed in writing by the parties before the performance of a given part of the contract. The contractor (Bidder) shall issue an invoice only after the receipt of a given part of the order is accepted by the Contracting Authority, documented in writing and signed by both parties, in the form of a partial delivery and acceptance report and a report on the release of the product.

VIII.8. The Contracting Authority reserves the right to include contractual penalties in the contract with the contractor, in the amount of 25% of the total gross remuneration, which will be imposed on the contractor, in the event of termination of the contract by the Contracting Authority for the reasons specified below:



- 7) The Contracting Authority finds that the contractor (Bidder) performs the Subject of the Contract contrary to the contract or the arrangements of the parties (in particular, does not meet the deadlines agreed by the parties),
- 8) the contractor (Bidder) acts to the detriment of the Contracting Authority,
- 9) the contractor (Bidder) does not perform its duties without justification and has not undertaken to perform them despite the request from the Contracting Authority,
- 10) the contractor (Bidder) violates the confidentiality provisions,
- 11) a petition for bankruptcy of the contractor (Bidder) is filed,
- 12) Restructuring proceedings will be opened against the contractor (Bidder).

- VIII.9. The Contracting Authority reserves the right to include contractual penalties in the contract with the contractor (Bidder), which will be imposed on the contractor (Bidder) in the event of delay in the performance of the subject of the contract or its part or delay in removal of defects found upon acceptance within the time limit specified by the Contracting Authority, in the amount of 0.5% of the total gross remuneration for each day of delay (but not more than 30% in total gross remuneration), calculated from the end date of completion of a given part of the subject of the order or from the end date set for the removal of defects found upon receipt.
- VIII.10. Regardless of the contractual penalties referred to above, the Contracting Authority reserves the right to seek damages in excess of the amount of contractual penalties on general terms.

IX. GDPR Information

- IX.1. Personal data provided to the Contracting Authority in the course of the procedure will be processed in accordance with the provisions of European Parliament and Council Regulation (EU) 2016/679 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 (General Data Protection Regulation) (Journal of Laws of the Republic of Poland). EU L 119 of 04.05.2016, p. 1).
- IX.2. Pursuant to Article 13(1) and (2) 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 (General Data Protection Regulation) (Official Journal 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 (General Data Protection Regulation) (Official Journal of the European Parliament and of the Council of 27 April 2016). UE L 119 of 04.05.2016, p. 1), hereinafter referred to as "GDPR", the contracting authority informs that:

- Urteste S.A. is the administrator of personal data, with its registered office in Gdańsk 80-137, 1 Starodworska Street.
 - personal data will be processed on the basis of Article 6(1)(c) of the GDPR for the purpose related to this quotation.
- IX.3. The recipients of personal data will be the Contracting Authority as well as persons or entities to whom the tender documentation will be made available based on the project financing agreement and the Guidelines on the eligibility of expenditures for the years 2021- 2027.
- IX.4. Personal data will be stored in accordance with the grant agreement under the European Funds for Modern Economy 2021-2027 Programme for 10 years from the date of granting the last aid under the aid programme (i.e. for a period of 5 years from 31 December of the year in which the institution made the last payment to the Contracting Authority)
- IX.5. The obligation for a natural person to provide personal data directly concerning him or her is a requirement set out in the provisions of the guidelines, related to participation in the procurement procedure; The consequences of not providing certain data result from the guidelines.
- IX.6. With regard to personal data, decisions will not be made by automated means, in accordance with Article 22 of the GDPR.
- IX.7. A natural person has:
- pursuant to Article 15 of the GDPR, the right of access to personal data concerning him/her;
 - pursuant to Article 16 of the GDPR, the right to rectification of your personal data (the right to restrict processing does not apply to the storage of data solely for the



- purpose of legal protection or to protect the rights of another natural or legal person, or for important public interest reasons of the European Union or a Member State);
- pursuant to Article 18 of the GDPR, the right to request the controller to restrict the processing of personal data, subject to the cases referred to in Article 18(2) of the GDPR (The right to restrict processing does not apply to data storage for the purpose of ensuring the use of legal remedies or protecting the rights of another natural or legal person, or for reasons of important public interest of the European Union or a Member State);
 - the right to lodge a complaint with the President of the Office for Personal Data Protection if a natural person considers that the processing of personal data concerning him or her violates the provisions of the GDPR.

IX.8. A natural person is not entitled to:

- in connection with Article 17(3)(b), (d) or (e) of the GDPR, the right to erasure of personal data;
- the right to transfer personal data referred to in Article 20 of the GDPR;
- pursuant to Article 21 of the GDPR, the right to object to the processing of personal data, as the legal basis for the processing of personal data is Article 6(1)(c) of the GDPR.

X. Attachments

- 1) Offer form
- 2) Declaration of non-affiliation with the contracting authority
- 3) Description of the subject of the contract
- 4) Non-disclosure agreement