

NRPP Mission 4, Component 2, Investment 1.4 "Strengthening of research facilities and creation of "national R&D champions" on some Key Enabling Technologies"

Initiative funded by the European Union – NextGenerationEU.

National Center for Gene Therapy and Drugs based on RNA Technology

RNA Gene Therapy and Drug Development

Project code MUR: CN00000041 – CUP UNINA: E63C22000940007

UNIVERSITY OF NAPLES FEDERICO II



DEPARTMENT OF PHARMACY

OPEN PROCEDURE SPECIFICATIONS

Open procedure with the application of the criterion of the most economically advantageous offer identified on the basis of the best value for money, pursuant to art. 71 and 108 paragraph 1 of Legislative Decree no. n. 36/2023 as amended, concerning the supply of an *"Automated mRNA Production System at scale suitable for drug discovery and preclinical development with Critical Reagent Supply and Processing System – Lot 1; " Automated System for GMP mRNA production at scale for clinical stages and commercial production with Critical – Lot 2"*.

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LOT 1 - CIG: B2397BBE86

LOT 2 - CIG: B2397BCF59

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Open procedure with the application of the criterion of the most economically advantageous offer identified on the basis of the best value for money, pursuant to articles 71 and 108 paragraph 1 of Legislative Decree no. 36/2023 as amended and supplemented concerning the supply of *"Automated mRNA Production System at scale suitable for drug discovery and preclinical development with Critical Reagent Supply and Processing System – Lot 1; " Automated System for GMP mRNA production at scale for clinical stages and commercial production with Critical – Lot 2"* - PROCEDURE DIVIDED INTO TWO LOTS

1. PREAMBLE

With determination to contract no. 707 of 20/06/2024, this Administration issued a two-lot tender for the supply of an *"Automated mRNA Production System at scale suitable for drug discovery and preclinical development with Critical Reagent Supply and Processing System – Lot 1; " Automated System for GMP mRNA production at scale for clinical stages and commercial production with Critical – Lot 2"*.

The award will take place through an open procedure with the application of the criterion of the most economically advantageous offer identified on the basis of the best value for money, pursuant to art. 71 and 108, par. 1 of Legislative Decree no. 36/2023 as amended (hereinafter: Code).

The Department of Pharmacy of the University of Naples Federico II, as part of the scientific research activity of the CN00000041, National Center for Gene Therapy and Drugs based on RNA Technology, with a specific milestone dedicated to the establishment of a facility for the GMP production of clinical batches of therapeutic mRNA, intends to purchase two automated systems for the production of mRNA with critical supply of reagents and processing system. To this end, in order to create a rational development pipeline, the following are indispensable: a) Lot 1) a high-performance instrumentation capable of automatically synthesizing mRNA at scale suitable for drug discovery and preclinical development, and b) Lot 2) a second automated system for GMP production of mRNA at scale for clinical phases and commercial production. The mRNA production steps that must be performed automatically and with high repeatability are transcription from a DNA model, purification, and processing of the synthesized mRNA molecule to remove any contaminants and unwanted species. The final products must meet a high process yield and a high-quality profile.

The award in question is financed with PNRR resources Mission 4, Component 2, Investment 1.4 "Enhancement of research and reaction facilities of "national R&D champions" on some Key Enabling Technologies" Initiative funded by the European Union – NextGenerationEU – Funding granted by Directorial Decree granting funding no. 1035 of 17.06.2022 under PNRR MUR-"M4C2"-Investment1.4-Notice "CentriNazionale"-D.D.n.3138 of 16 December 2021 corrected with D. Dn. 3175 of 18 December 2021.

The place of delivery of the supplies is:

- **LOT 1:** Department of Pharmacy of the University of Naples Federico II, via Tommaso De Amicis floor -1 (NA) (NUTS code ITF33);

- **LOT 2:** Department of Pharmacy of the University of Naples Federico II, via Tommaso De Amicis floor -1 (NA) (NUTS code ITF33);

The Sole Person in Charge of the Project, pursuant to Article 15 of the Code, is Dr. Mariarosaria Persico pec: mariarosaria.persico@pec.personaleunina.it.

As represented by the Sole Project Manager: *"There are no active Framework Agreements and/or Consip Conventions pursuant to art. 26, paragraph 1, of Law no. 488 of 1999 and subsequent amendments, nor notices on the Dynamic System for the Acquisition of Goods and Services for the Public Administration (SDAPA), for the supply subject to this award procedure".*

The Project Manager also announced that: *"Due to the specific type of purchase, there are no minimum environmental criteria (CAM) applicable to the contract".*

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1.1. THE ELECTRONIC TRADING SYSTEM

The use of the System implies the tacit and unconditional acceptance of all the terms, conditions of use and warnings contained in the tender documents - including the Rules of the e-procurement system of the public administration (hereinafter Rules) - in particular, of EU Regulation no. 910/2014 (hereinafter eIDAS Regulation - electronic IDentification Authentication and Signature), of Legislative Decree no. 82/2005 on the Digital Administration Code (CAD) and of the AGID Guidelines, as well as of what is brought to the attention of users through communications on the System.

The use of the System is carried out in compliance with the principles of self-responsibility and professional diligence, in accordance with the provisions of Article 1176, paragraph 2, of the Italian Civil Code. The Contracting Authority assumes no responsibility for loss of documents and data, damage to files and documents, delays in entering data, documents and/or in submitting the application, malfunction, damages, prejudices resulting to the economic operator, from:

- malfunctions of the equipment and connection systems and programs used by the individual economic operator to connect to the System;
- use of the System by the economic operator in a manner that does not comply with the Regulations and the provisions of the Rules.

In the event of failure of the system or malfunction of the same, not due to the aforementioned circumstances, which prevent the correct submission of tenders, in order to ensure maximum participation, the contracting authority may order the suspension of the deadline for the submission of tenders for a period of time necessary

to restore the normal functioning of the System and the extension of the same for a duration proportional to the duration of the failure or non-operation proper functioning, taking into account the severity of the same. The contracting authority reserves the right to do so even when, apart from negligence on the part of the economic operator, it is not possible to ascertain the cause of the malfunction or malfunction. The activities and operations carried out within the System are recorded and attributed to the economic operator and are fully evidenced to the users of the System. These system records are confidential and will not be disclosed to third parties, unless ordered by the court or in the event of a legitimate request for access to the records, in accordance with current legislation. The activities and operations carried out within the System are considered to have been carried out at the time and day resulting from the system records. The operating system of the System is synchronised on the national time scale referred to in the decree of the Minister of Industry, Commerce and Crafts of 30 November 1993, no. 591, using NTP protocol or higher standard. The use and operation of the System take place in accordance with the provisions of the Rules that are an integral part of these regulations, even if they are not physically attached and can be consulted on the website [acquistinretepa.it](https://www.acquistinretepa.it)>about us>how it works at the following link:

https://www.acquistinretepa.it/opencms/opencms/programma_comeFunziona_RegoleSistema.html.

The purchase, installation and configuration of hardware, software, digital signature certificates, certified e-mail address or a qualified certified electronic delivery service address, as well as connections for access to the Internet, remain the sole responsibility of the economic operator. The System is normally accessible 24 hours a day, seven days a week. In any case, access to the System may be slowed down, hindered or prevented due to scheduled maintenance work on the System or technical problems, which will be reported to users with appropriate notice where possible. By registering and submitting the bid, the competitors indemnify and hold harmless the MEF, Consip S.p.A. and the System Operator, compensating for any prejudice, damage, cost and burden of any kind, including any legal fees, that may be suffered by the latter and/or third parties, due to violations of the rules contained in these Tender Regulations, of the relevant annexes, incorrect or improper use of the System or violation of current legislation. In the event of violations of the above, of legal or regulatory provisions and irregularities in the use of the System by competitors, in addition to what is provided for in the other parts of these Tender Regulations, the MEF, Consip S.p.A. and the System Operator, each to the extent of their respective competence, reserve the right to act for damages, direct and indirect, patrimonial and image damages, which may have been suffered.

1.2. TECHNICAL EQUIPMENT

In order to participate in this procedure, each economic operator must equip itself, at its own expense, and responsibility, with technical and IT equipment in accordance with that indicated in these regulations and in the document Rules of the e-Procurement system, which governs the operation and use of the Platform.

In any case, it is essential to:

- have at least one personal computer that complies with the latest market standards, with an internet connection and equipped with a common browser suitable for operating correctly on the Platform;
- have a public system for the management of the digital identity (SPID) referred to in Article 64 of Legislative Decree no. 82 of 7 March 2005 or other means of electronic identification for cross-border mutual recognition pursuant to the eIDAS Regulation;
- have a digital domicile present in the indexes referred to in Articles 6-bis and 6 ter of Legislative Decree no. 82 of 7 March 2005 or, for the cross-border economic operator, a certified electronic delivery service address qualified pursuant to the eIDAS Regulation;
- have a valid digital signature certificate from the legal representative of the economic operator (or from a person with appropriate powers of signature) issued by:
 - a body included in the public list of certifiers kept by the Agency for Digital Italy (provided for in Article 29 of Legislative Decree No. 82/05);
 - a certifier operating on the basis of a license or authorization issued by a Member State of the European Union and meeting the requirements of Regulation no. 910/14;
 - a certifier established in a non-EU country when one of the following conditions is met:
 - a) the certifier meets the requirements of Regulation No. 910/14 and is qualified in a Member State;
 - b) the qualified certificate is guaranteed by a certifier established in the European Union, in possession of the requirements set out in Regulation No. 910/14;
 - c) the qualified certificate, or certifier, is recognized by virtue of a bilateral or multilateral agreement between the European Union and third countries or international organizations.

1.3 IDENTIFICATION

In order to submit a bid, it is necessary that at least one entity, endowed with the necessary powers to commit the economic operator on whose behalf it intends to operate, accesses the System after specific Registration. Access to the System is free of charge and is allowed following online identification, which can take place:

1. through the public system for the management of the digital identity of citizens and businesses (SPID) with LoA3 guarantee level, through the electronic identity card (CIE) referred to in Article 66 of Legislative Decree no. 82 of 7 March 2005 or through eIDAS for European users.
2. for non-EU users or those without an Italian eIDAS node, through credentials issued downstream of an extra-system identification process, in compliance with the regulations on digital identity.

It should be noted that identification in the aforementioned manner is necessary for any subsequent access to the telematic phases of the procedure.

Once the identification procedure has been completed, in order to participate in the tender, the user must associate himself with the VAT number/Other identifier of the economic operator on whose behalf he is

operating, regardless of the desire to participate in the procedure in an associated form: this intention can be concretized in the phase of submission of the offer. The economic operator, by registering and, in any case, by submitting the offer, takes as valid and recognizes without any dispute what has been put in place within the System by the user attributable to the economic operator itself; any action concerning the user within the System will therefore be considered directly and incontrovertibly attributable to the economic operator for which the user is operating.

Any requests for IT assistance must be made by contacting the dedicated Call Center at the addresses indicated on the www.acquistinretepa.it website.

1.4 SYSTEM MANAGER

Without prejudice to the fact that, for this procedure, the contracting authority and the contracting authority is the Department of Pharmacy of the Federico II University of Naples, the same avails itself, through Consip, of the technical support of the System Operator (i.e. the entity indicated on the website www.acquistinretepa.it the successful bidder of the public procedure carried out for this purpose) also in charge of the technical management services of the IT applications necessary for the operation of the System, assuming all responsibility in this regard. The System Operator is responsible for checking the main operating parameters of the System itself, reporting any anomalies in the same. The System Operator is, in particular, responsible for the logical and application security of the System itself and is also responsible for the adoption of adequate and appropriate technical and organizational measures in order to ensure compliance 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, as well as the free movement of such data (hereinafter also referred to as the "EU Regulation" or "GDPR").

2. TENDER DOCUMENTATION, CLARIFICATIONS AND COMMUNICATIONS

2.1 TENDER DOCUMENTS

The tender documentation includes:

- Technical drawing;
- Economic framework;
- Special tender specifications;
- Call for Tenders;
- Competition regulations;

- ESPD;
- Annex A1): Application form;
- Annexes: A2), A3), A4), D);
- Declaration of Legislative Decree no. 231 of 2001;
- DNSH Card No. 3;
- Declaration of beneficial owner;
- Declaration of absence of conflict of interest of the beneficial owner;
- Deed of Commitment;
- Contract Scheme;
- Operating instructions for accessing the Platform and technical rules for the use of the same e-Procurement System Rules;
- Code of Conduct for Civil Servants;
- University Code of Conduct contained in the current Integrated Plan of Activities and Organisation of the University - PIAO, [appendix 2.3.D] approved by resolution of the Board of Directors on 31/01/2024 and available on the University website at <http://www.unina.it/trasparenza/piao>;
- Rules for the prevention of corruption of the University contained in the current Integrated Plan of Activities and Organization of the University - PIAO, [and in particular in Appendix 2.3.E CONTR] approved by resolution of the Board of Directors of 31/01/2024 and available on the University website at <http://www.unina.it/trasparenza/piao>.
- Memorandum of Understanding for the legality and prevention of criminal infiltration attempts in the legal economy (hereinafter: Protocol of Legality), stipulated between the Prefecture of Naples, the Metropolitan City of Naples, the Chamber of Commerce of Naples and the Municipalities of the Metropolitan Area of Naples, to which the University adhered on 10/12/2021, following resolution of the Board of Directors no. 34 of 27.10.2021.

The tender documentation is available in electronic format, digitally signed, on the University's institutional website, in the Administration, Transparency, Calls for Tenders and Contracts section. If one or more of the above-mentioned documents cannot be viewed correctly, the interested parties can send an immediate report

to the Head of the Public Relations and Transparency Office, via certified email to the address: urp@pec.unina.it.

To read the digitally signed documentation, it is necessary to have the appropriate software for the verification of the digital signature, issued by one of the certifiers registered in the List referred to in Article 29 of Legislative Decree 82/2005 and available on the www.agid.gov.it website. The electronic version of the documentation is available on these websites in PDF/Word/Excel format, which is not digitally signed. In the event of a discrepancy between the two versions in electronic format, the digitally signed version shall prevail.

2.2 CLARIFICATIONS

It is possible to obtain clarifications on this procedure by submitting written questions to be submitted within the deadline provided for in the OJEU Notice, exclusively electronically through the section of the System reserved for requests for clarification, after registering on the system itself. The answers to the questions will be provided by the Project Manager.

Requests for clarification must be made exclusively in Italian.

Pursuant to art. 88, paragraph 3 of the Code, the answers to all requests submitted in good time will be provided in electronic format, digitally signed at least six days before the expiry of the deadline set for the submission of bids, by anonymous publication on the ASP platform and on the University website.

Telephone clarifications are not permitted.

2.3. COMMUNICATIONS

Pursuant to art. 29 of the Code, the economic operator, by submitting the bid, automatically elects domicile in the appropriate "Communications Area" reserved for it for the purpose of receiving any communication relating to this procedure. The economic operator shall also elect domicile at the registered office and the certified e-mail address that it indicates at the time of submission of the OFFER. All communications and exchanges of information between the contracting authority and economic operators shall be carried out in accordance with the provisions of Legislative Decree no. 82/05, through the digital procurement platforms and, for what is not provided for by them, through the use of the digital domicile extracted from one of the indices referred to in Articles 6-bis, 6-ter, 6-quarter, of Legislative Decree no. 82/05 or, for cross-border economic operators, through a certified electronic delivery service address qualified pursuant to the eIDAS Regulation. In the event of a malfunction of the platform, the contracting authority will send any communication to the digital domicile present in the indices referred to in the aforementioned articles 6-bis, 6-ter, 6-quarter of Legislative Decree no. 82/05. In the case of temporary groupings, EEIGs, aggregations of network undertakings or ordinary consortia, even if not yet formally constituted, the communication delivered to the authorized representative/lead partner shall be deemed to have been validly given to all the economic operators grouped, aggregated or consortium members. In the case of consortia referred to in art. 65(2)(b), (c) and (d) of the Code,

the communication delivered to the consortium shall be deemed to have been validly given to all the consortium members. In the event of an endorsement, the communication delivered to the tenderer shall be deemed to have been validly given to all ancillary economic operators.

3. SUBJECT, AMOUNT AND SUBDIVISIONS INTO LOTS

The contract is divided into the following lots:

Table no. 1 – Description of the lots

Number of lots	Lot Object	CIG
1	Automated mRNA Production System at scale suitable for drug discovery and preclinical development with Critical Reagent Supply and Processing System;	B2397BBE86
2	Automated System for GMP mRNA production at scale for clinical stages and commercial production with Critical	B2397BCF59

The details of the services and the amount of each lot (net of VAT, and/or other taxes and legal contributions, as well as security charges deriving from interfering risks not subject to reduction), is as follows:

Table no. 2 – Object of the contract – Lot 1 – CIG: B2397BBE86

n.	Asset description	CPV	P (main) S (secondary)	Amount
1	Automated mRNA Production System at scale suitable for drug discovery and			



	preclinical development with Critical Reagent Supply and Processing System	38000000-5	P	809.261,00 € incl.
2	Security charges not subject to rebate			0,00 € incl.
Total starting price				809.261,00 € incl.

The basic amount of the tender is net of VAT and/or other taxes and legal contributions as well as security charges due to zero interference risks.

The basic tender amount was calculated by considering the market reference prices between the companies producing the requested good. The basic tender amount was calculated on the basis of the average of these prices.

Table no. 2 – Object of the contract – Lot 2 – CIG: B2397BCF59

n.	Asset description	CPV	P (main) S (secondary)	Amount
1	Automated System for GMP mRNA production at scale for clinical stages and commercial production with Critical	38000000-5	P	5.245.371,00 €
2	Security charges not subject to rebate			0,00 € incl.
Total starting price				5.245.371,00 €

The basic amount of the tender is net of VAT and/or other taxes and legal contributions as well as security charges due to zero interference risks.

The basic tender amount was calculated by considering the market reference prices between the companies producing the requested good. The basic tender amount was calculated on the basis of the average of these prices.

Participation in multiple lots

Each competitor may submit a bid for one or more lots (even all of them). There are no limitations on the award of a maximum number of lots.

3.1 TECHNICAL CHARACTERISTICS OF THE SUPPLY

The equipment covered by this supply contract must meet, under penalty of exclusion, the minimum technical requirements and technical specifications pursuant to Article 79 of Legislative Decree 36/2023 also reported in the Technical Supply Specifications attached to this procedure.

4. DURATION OF THE CONTRACT, OPTIONS AND RENEWALS

4.1 DURATION

Supplies shall be made as follows for each batch:

- **LOT 1: within 4 months** from the signing of the contract (or from the report of early execution, pursuant to Articles 17 paragraph 8, 9 of Legislative Decree 36/2023 as amended, and Article 8 of Law No. 120 of 11 September 2020, converting into law, with amendments, Legislative Decree No. 76 of 16 July 2020);
- **LOT 2: within 8 months** from the signing of the contract (or from the early execution report, pursuant to Articles 17 paragraph 8, 9 of Legislative Decree 36/2023 as amended, and Article 8 of Law No. 120 of 11 September 2020, converting into law, with amendments, Legislative Decree No. 76 of 16 July 2020);

4.2 OPTIONS AND RENEWALS

Pursuant to art. 14, paragraph 4 of the Code, the maximum estimated value of the contract (maximum payable including all options), is equal to € 6,410,926.96 net of VAT and/or other taxes and contributions required by law, including security charges due to risks from interference, is determined as follows:

- 1) Total amount of the contract subject to reduction: € 6,054,632.00 plus VAT (€ 809,261.00 plus VAT for lot no. 1; € 5,245,371.00 plus VAT for lot 2);
- 2) Security charges not subject to discount: € 0.00 for lot 1 and lot 2;

3) Amount for contingencies and options: € 356,294.96 plus VAT (€ 37,871.14, plus VAT for lot 1; € 318,423.82, plus VAT for lot 2).

5. INDIVIDUALS ADMITTED INDIVIDUALLY AND IN ASSOCIATION AND CONDITIONS OF PARTICIPATION

Economic operators, including those established in other Member States, may participate in this call for tenders individually or in combination, in accordance with the provisions of art. 65 of the Code, provided that they meet the requirements set out in the following articles.

The provisions of art. 67 and 68 of the Code.

Competitors are prohibited from participating in the tendering procedure in more than one temporary grouping or ordinary consortium of competitors or aggregation of undertakings participating in the network contract (hereinafter referred to as aggregation of network undertakings).

It is forbidden for the competitor who participates in the race in an ordinary grouping or consortium of competitors, to participate even individually.

It is forbidden for the competitor who participates in the tender in aggregation of network companies, to participate even individually. Network companies not participating in the tender may submit bids for the same tender, either individually or in combination.

The consortia referred to in art. 65, par. 2 of the Code, are required to indicate, at the time of the bid, for which consortium members the consortium is competing; The consortium members designated by the Consortium for the execution of the contract may not, in turn, designate another party for the execution, except in the case where the designated consortium member is, in turn, a consortium referred to in art. 65, par. 2 required by law to indicate, at the time of the bid, the consortium members for which it is competing; The latter are forbidden to participate, in any other form, in this race. In the event of a violation, both the Consortium and the consortium member are excluded from the tender; In the event of non-compliance with this prohibition, Article 353 of the Criminal Code applies.

Aggregations between companies adhering to the network contract pursuant to art. 65(2)(g) of the Code, comply with the rules laid down for temporary groupings of undertakings in so far as they are compatible. Especially:

- a) **In the event that the network is equipped with a common body with the power of representation and legal subjectivity (so-called network - subject)**, the aggregation of network companies participates through the common body, which will assume the role of the agent, if in possession of the relevant requirements. The common body may also indicate only some of the network companies for participation in the tender, but must be part of these;
- b) **In the event that the network has a common body with the power of representation but without legal subjectivity (so-called network-contract)**, the aggregation of network companies participates through the

common body, which will assume the role of the agent, if it meets the requirements for the agent and if the network contract mandates the same to apply or offer for certain types of tender procedures. The common body may also indicate only some of the network companies for participation in the tender, but must be part of these;

c) **In the event that the network has a common body without the power of representation or does not have a common body, or if the common body does not meet the qualification requirements**, the aggregation of network undertakings participates in the form of a group formed or in the process of being formed, with full application of the relevant rules (cf. ANAC Resolution no. 3 of 23 April 2013).

For all types of networks, joint participation in tenders must be identified in the network contract as one of the strategic objectives included in the joint programme, while the duration of the joint programme must be commensurate with the timing of the contract (cf. ANAC Resolution no. 3 of 23 April 2013).

The role of principal of a temporary grouping of companies may also be assumed by a consortium referred to in art. 65, par. 2, l. b), c), d) and f) or by a sub-association, in the form of an RTI or ordinary consortium or an aggregation of network companies.

To this end, if the network has a common body with the power of representation (with or without legal subjectivity), this body will assume the role of agent of the sub-association; If, on the other hand, the network has a common body without the power of representation or does not have a common body, the role of agent of the sub-association is conferred by the network companies participating in the tender, by means of a mandate pursuant to art. 68, paragraph 5 of the Code, giving evidence of the distribution of the shareholdings. Pursuant to art. 186-bis, paragraph 6 of Royal Decree no. 267 of 16 March 1942, the company in composition with creditors with business continuity may also participate in a joint venture provided that it does not have the status of agent and provided that the other companies belonging to the RTI are not subject to insolvency proceedings.

6. GENERAL REQUIREMENTS

Competitors must be in possession of the general requirements provided for by the Code as well as the additional requirements indicated in this article, **under penalty of exclusion**.

The existence of the automatic grounds for exclusion referred to in Article 94 shall entail direct exclusion, while the existence of the non-automatic grounds for exclusion referred to in Article 95 must be ascertained after an examination with the economic operator.

The contracting authority verifies that the general requirements are met by accessing the virtual file of the economic operator (hereinafter FVOE).

Economic **operators for whom there are grounds for exclusion referred to in Sections 94 and 95 of the Code are excluded from the tender.**

In any case , economic operators who have entrusted tasks in violation of art. 53, paragraph 16-ter, of Legislative Decree no. 165 of 2001.

Economic operators with their registered office, residence or domicile in the countries included in the so-called "economic operators" are not allowed to do so. **black list** referred to in the decree of the Minister of Finance of 4 May 1999 and the decree of the Minister of Economy and Finance of 21 November 2001 must, **under penalty of exclusion from the tender**, be in possession of the valid authorisation issued pursuant to the Ministerial Decree of 14 December 2010 of the Ministry of Economy and Finance (pursuant to Article 37 of Legislative Decree no. 78 of 3 May 2010 conv. in Law no. 122/2010) or of the application for authorisation submitted pursuant to art. 1 paragraph 3 of the Ministerial Decree of 14 December 2010.

Failure to accept the clauses contained in the Legality Protocol constitutes **a cause for exclusion** from the tender, pursuant to art. 1, paragraph 17 of Law No. 190 of 6 November 2012, or termination of the contract, as provided for in Article 3, paragraph 3 of Law No. 120 of 11 September 2020, converting Decree-Law No. 76 of 16 July 2020. It should be noted, in fact, that the contract is also governed by the provisions contained in the Legality Protocol, to which the University adhered on 10.12.2021.

The clauses of this Protocol, with the clarifications formulated by this Administration, must be signed by the company at the time of stipulation of the contract or subcontract, under penalty of forfeiture of the award, and are as follows:

Clause 1): The undersigned company declares that it is aware of and accepts the express termination clause that provides for the immediate and automatic termination of the contract, or the revocation of the authorization to subcontract or subcontract, should the Prefecture communicate disqualification information pursuant to Article 84 of Legislative Decree no. 159/2011 and subsequent amendments and additions. A similar resolving effect will derive from the ascertained existence of hypotheses of formal and/or substantial connection or agreements with other companies participating in the insolvency proceedings of interest. If the contract has been stipulated pending the acquisition of anti-mafia information, a penalty equal to the value of the contract will also be applied to the company, subject to the subsequent disqualification notice, or, if the same is not determined or determinable, a penalty equal to the value of the services currently performed; The aforementioned penalties will be applied by automatic deduction, by the contracting authority, of the relevant amount from the sums due to the company in relation to the first useful disbursement. In the event that the Prefect issues information pursuant to Article 1septies, Legislative Decree No. 629 of 6 September 1982, converted into Law No. 726 of 12 October 1982, the Contracting Authority reserves the right to assess at its discretion the advisability of excluding the company concerned from the aforementioned information from the procedure and from any subcontract, as well as to proceed with the termination of contracts in progress.

Clause 2): The undersigned undertaking undertakes to communicate to the contracting authority the list and data of the undertakings involved in the award plan with regard to the sectors of activity referred to in Article 2 of the Protocol, as well as any subsequent changes that may occur for any reason.

Clause 3): The undersigned company undertakes to include in all subcontracts/subcontracts the express termination clause in the event that disqualification information emerges, or rejection of the registration in the so-called white list for the sectors of interest, at the expense of the subcontractor/subcontractor.

Clause 4): The undersigned company undertakes to inform the Prefecture without delay, notifying the contracting authority, of any attempt at extortion, intimidation or conditioning of a criminal nature in any form it manifests itself against the entrepreneur, any members of the company structure or their family members (request for bribes, pressure to direct the hiring of personnel or the assignment of work, supplies, services or the like to certain undertakings, damage to or theft of personal property or property on the construction site, etc.). This is without prejudice to the obligation to report the same facts to the Judicial Authority, as per clause no. 5 below. The aforementioned fulfilment is essential for the purposes of the execution of the contract and its non-fulfilment will give rise to the express termination of the contract itself pursuant to art. 1456 c.c.

Clause 5): The undersigned company undertakes to report to the Judicial Authority or to the Police Bodies any unlawful request for money, services or other benefits made to it before the tender and/or the assignment or during the execution of the works, also through its agents, representatives or employees and in any case any unlawful interference in the award procedures or in the execution phase of the works. The Contracting Authority and the Prefecture shall be informed of the complaint, as per clause no. 4 above. The aforementioned fulfilment is essential for the purposes of the execution of the contract and its non-fulfilment will give rise to the express termination of the contract itself pursuant to art. 1456 c.c.

Clause 6): The undersigned company undertakes to assume all charges and expenses, at its own expense, deriving from the agreements/protocols promoted and stipulated by the contracting authority with the competent bodies and/or bodies in the field of security, as well as the repression of crime, aimed at the preventive verification of the program of execution of the works in view of the subsequent monitoring of all phases of execution of the work, the services to be performed and the parties who will perform them, as well as compliance with the obligations arising from these agreements.

Clause 7): The undersigned company undertakes to ensure compliance with this Protocol by subcontractors/subcontractors by inserting contractual clauses similar in content to those contained in this contract.

Clause 8): The undersigned company undertakes to insert in the subcontracts/subcontracts a clause that makes the acceptance and, therefore, the effectiveness of the assignment of receivables made to parties other than those indicated in Legislative Decree no. 50 of 18 April 2016, subject to the prior acquisition by the contracting authority, in the manner set out in Articles 2 and 3 of this Protocol, of the anti-mafia information

referred to in art. 84 and 91 of Legislative Decree no. 159 of 6 September 2011, at the expense of the assignee and to reserve the right to refuse the assignment of the receivable made in favor of assignees for whom the Prefecture provides anti-mafia information of a disqualifying nature. Similar rules must be provided for all subjects, in any capacity involved in the execution of the works, who will enter into an assignment of receivables.

Clause 9): The undersigned company undertakes to proceed with the posting of the workforce, as governed by art. 30 of Legislative Decree no. 276 of 10 September 2003, only with the prior authorization of the contracting authority for the entry of posted workers into the construction site; this authorization is subject exclusively to the prior acquisition, by the contracting authority itself, of the anti-mafia information referred to in art. 84 and 91 of Legislative Decree no. 6 September 2011, No 159, on the posting company. Similar rules must be provided for all those subjects, in any capacity involved in the execution of the works, who will make use of the right to post the workforce.

Clause 10): The contractor undertakes to promptly notify the Prefecture and the Judicial Authority of attempts at bribery that have, in any way, manifested against the entrepreneur, the corporate bodies or the company managers. The aforementioned fulfilment is essential for the execution of the contract and its non-fulfilment will give rise to the express termination of the contract itself, pursuant to art. 1456 of the Italian Civil Code, whenever a precautionary measure has been ordered against public administrators who have exercised functions related to the stipulation and execution of the contract, or an indictment has been made for the offence provided for by art. 317 of the Criminal Code.

Clause 11): The undersigned company declares that it knows and accepts the Contracting Authority undertakes to make use of the express termination clause, referred to in Article 1456 of the Italian Civil Code, whenever precautionary measures have been ordered against the entrepreneur or the members of the corporate structure, or the managers of the company, or have been indicted for any of the crimes referred to in art. 317 of the Criminal Code, 318 of the Criminal Code, 319 of the Criminal Code, 319-bis of the Criminal Code, 319-ter of the Criminal Code, 319-quarter of the Criminal Code, 320 of the Criminal Code, 321 of the Criminal Code, 322 of the Criminal Code, 322-bis of the Criminal Code, 346-bis of the Criminal Code, 353 of the Criminal Code and 353-bis of the Criminal Code.

Clause 12): The undersigned company declares that it is aware of and accepts the express termination clause that provides for the immediate and automatic termination of the contract or the revocation of the authorization to subcontract or subcontract as well as the application of the administrative pecuniary sanctions referred to in Law 136/2010 and subsequent amendments if a financial movement is carried out (incoming or outgoing) without making use of the intermediaries and dedicated accounts referred to in art. 3 of the aforementioned law. The undersigned company declares that it is aware of and accepts the obligation to make collections and payments, relating to the contracts referred to in this Protocol, through dedicated accounts opened with an authorized intermediary by bank or postal transfer, or with other payment instruments suitable

to allow full traceability of the transactions, the non-use of which constitutes cause for termination of the contract; In the event of a breach of this obligation, without justified reason, a penalty of 10% of the value of each individual financial transaction to which the breach refers, automatically deducting the amount from the sums due in relation to the first useful disbursement.

Clause 13): The undersigned company declares that it is aware of and accepts the express clause that provides for the immediate and automatic termination of the contract or the revocation of the authorization of the contract or sub-contract in the event of serious and repeated non-compliance with the provisions on employment, health and safety at work, also with regard to the appointment of the person responsible for safety and protection of workers in contractual and trade union matters. To this end, the following are considered serious breaches: the violation of rules that led to the seizure of the workplace, validated by the Judicial Authority; non-compliance with the requirements imposed by the inspection bodies; the employment of personnel of the individual company not resulting from the records or other mandatory documentation in an amount equal to more than 15% of the total number of workers employed on the site or in the factory.

Clause 14): The undersigned company undertakes to promptly notify the contracting authority of any change in the data contained in its own Chamber of Commerce certificates and those of their subcontractors/subcontractors and, in particular, any change that has occurred after the production of the certificate itself relating to the subjects referred to in Articles 85 and 91, paragraph 4, of Legislative Decree no. 6 September 2011, n. 159 to be subjected to anti-mafia verification. In case of violation, the sanctions provided for by art. 14 of the Protocol.

Clause 15): The undersigned company undertakes to fully comply with all the provisions of the Memorandum of Understanding for the legality and prevention of attempts at criminal infiltration in the legal economy signed between the Prefecture and the Contracting Authority and to be fully aware of and accept the sanctioning system provided for therein.

The contract is also governed by art. 19, paragraphs 4 and 5, of the Regulations for the implementation of Regional Law no. 3 of 27 February 2007 on "Discipline of public works, services and supplies in Campania Discipline of public works, services and supplies in Campania" aimed at protecting the integrity and legality in the phase of execution of works, services and supplies and avoiding the establishment and continuation of contractual relationships with contractors that may be subject to infiltration and unlawful pressure from parties unrelated to the contract or concession relationship, and to facilitate the successful tenderers in reporting facts tending to alter the correct and legal performance of the services, consisting in particular of acts of intimidation or extortion perpetrated against them or to the detriment of subcontractors and which are referred to below:

- if, in the course of the performance of the contract, the contracting authority, including through the offices of the project manager and the works manager, finds, on the basis of concrete factual elements,

the presence of unlawful and multiple pressures on the part of persons unrelated to the contract relationship which tend to condition or alter the proper and lawful performance of the services, represents the situation, without delay and confidentially, to the Prefect responsible for the territory, so that the appropriate investigations are carried out, aimed at verifying the presence of infiltration or pressure against the contractor or any of the subcontractors. The clause itself provides, pursuant to art. 51, paragraph 4, of the Law, the obligation of the successful bidders to report any fact tending to alter the correct and legal performance of the services, as an essential element of the contract.

SELF CLEANING

An economic operator who finds himself in one of the situations referred to in Articles 94 and 95, with the exception of contribution and tax irregularities that have been definitively and not definitively ascertained, may provide evidence that he has taken sufficient measures (so-called self-cleaning) to demonstrate his reliability.

If the ground for exclusion occurred before the submission of the tender, the economic operator shall indicate the ground for exclusion in the ESPD and, alternatively:

- describes the measures taken pursuant to art. 96, paragraph 6 of the Code;
- state the reasons for the impossibility of taking such measures and undertake to act subsequently. The adoption of the measures shall be communicated to the contracting authority.

If the cause of exclusion occurred after the submission of the bid, the economic operator shall take the measures referred to in paragraph 6 of art. 96 of the Code, notifying the contracting authority.

Sufficient measures shall be considered to be compensation or an undertaking to compensate for any damage caused by the offence or offence, proof that the facts and circumstances have been clarified in a comprehensive manner by actively cooperating with the investigating authorities and that concrete technical, organizational or personnel measures have been taken to prevent further offences or offences.

If the measures taken are deemed sufficient and timely, the economic operator shall not be excluded. If such measures are deemed insufficient and untimely, the contracting authority shall inform the economic operator of the reasons for doing so. Self-cleaning may not be used by an economic operator who has been excluded by a final judgment from participating in the award or concession procedures during the period of exclusion resulting from that judgment.

In the event that a group/consortium has ousted or replaced a participant/executor affected by an exclusion clause referred to in Articles 94 and 95 of the Code, the measures taken pursuant to Article 97 of the Code in order to decide on the exclusion shall be assessed.

In the case of the participation of consortia referred to in Article 65(2)(b) and (c) of the Code, the requirements referred to in point 5 are met by the consortium and the consortium members indicated as executors. In the

case of the participation of permanent consortia referred to in Article 65(2)(d) of the Code, the requirements referred to in point 5 are met by the consortium, by the consortium members indicated as executors and by the consortium members who meet the requirements. An economic operator who finds himself in one of the situations referred to in Articles 94 and 95 of the Code, with the exception of contribution and tax irregularities that have been definitively and not definitively ascertained, may provide evidence that he has taken sufficient measures (so-called self-cleaning) to demonstrate his reliability. Pursuant to art. 70, paragraph 4, letter e) of the Code, bids submitted by bidders who do not meet the qualification required by these Regulations are inadmissible.

Economic operators, including those established in other Member States, may submit tenders, provided that they meet the following additional requirements:

(b) compliance, under penalty of exclusion, at the time of submission of the bid, with the employment obligations of persons with disabilities referred to in Law No. 68 of 12 March 1999, pursuant to Article 94, paragraph 5, letter b) of the Code and Article 47 of Legislative Decree 77/2021, converted into Law 108/2021;

(c) the production, under penalty of exclusion, by economic operators employing more than fifty employees, at the time of submission of the bid, of a copy of the latest periodic report on the situation of male and female staff drawn up pursuant to Article 46 of Legislative Decree no. 198 of 2006, with certification of its compliance with that which may have already been sent to the company's trade union representatives and regional equality councilors, i.e., failing that, with certification of its simultaneous transmission to the company trade union representatives and to the regional equality councilor (Article 47, paragraph 3 of Decree-Law no. 77 of 2021 converted into Law 108/2021 and Interministerial Decree of the Minister of Labour and Social Policies and by the Minister of Equal Opportunities and Family of 29 March 2022). **(d)** the production by economic operators employing a number of employees equal to or greater than fifteen and not more than fifty, within six months of the conclusion of the contract, a gender report on the situation of male and female staff in each of the professions, referred to in Article 47, paragraph 3 of Decree-Law No 77 of 2021;

(e) the assumption of the commitment, at the time of submission of the Offer, in the event of the award of the contract, to ensure: a share equal to 30% of the hires necessary for the execution of the contract or for the implementation of activities connected to it or instrumental to both female and youth employment. This is in implementation of the provisions of Article 47, paragraph 4 of Decree-Law No. 77 of 2021, as well as the Ministerial Decree of the Presidency of the Council of Ministers, Department of Equal Opportunities, of 7 December 2021 (Adoption of guidelines aimed at promoting gender and generational equal opportunities, as well as the employment inclusion of people with disabilities in public contracts financed with the resources of the PNRR and PNC), published in the Official Gazette of 30 December 2021, no. 309;

(f) economic operators who employ a number of employees equal to or greater than fifteen and not more than fifty, under penalty of exclusion, must not have omitted, in the twelve months prior to the deadline for

submission of the tender, to produce to the contracting authority a previous contract, financed in whole or in part with funds from the PNRR or the PNC. The report referred to in art. 47, paragraph 3 of Decree-Law no. 77 of 2021;

(g) the assumption of the commitment, under penalty of exclusion, at the time of submission of the bid, to comply with the specific obligations of the PNRR, including the principle of not causing significant harm to the so-called "DO NOT SIGNIFICANT HARM" (DNSH) environmental objectives, pursuant to Article 17 of EU Regulation 2020/852 of the European Parliament and of the Council of 18 June 2020 as well as the principle of contribution to the climate objective.

With reference to the provisions of the Operational Guide for compliance with the principle of not causing significant damage to the environment (so-called "No Significant Damage to the Environment"). DNSH) (RGS circular no. 33 of 13 October 2022), there are no specific sheets relating to the procedure in question, without prejudice to the obligation of the economic operator to comply with the DNSH principles.

BENEFICIAL OWNER

The competitor is required to provide the data necessary for the identification of the beneficial owner of the economic operator itself (referred to in Article 20 of Legislative Decree 231/2007) – see MEF Decree of 11.03.2022, no. 55. In addition, the tenderer and the beneficial owner are required to declare the absence of situations of conflict, even potential, of interests in relation to this procedure and to undertake, if such a situation should arise at a later time, to promptly notify the contracting authority.

7. SPECIAL REQUIREMENTS AND MEANS OF PROOF

Competitors, **under penalty of exclusion**, must meet the requirements set out in the following paragraphs.

The documents required from economic operators for the purpose of demonstrating the requirements must be transmitted through FVOE in accordance with ANAC Resolution no. 262/2023.

Pursuant to art. 70(4)(e) of the Code, tenders submitted by tenderers who do not meet the qualification required by these specifications are inadmissible.

7.1 ELIGIBILITY REQUIREMENTS

a) Registration in the register kept by the Chamber of Commerce, Industry, Crafts and Agriculture or in the register of the provincial commissions for crafts for activities consistent with those covered by this tender procedure.

An economic operator from another Member State that is not resident in Italy is required to declare, pursuant to the Consolidated Law on Laws and Regulations on Administrative Documentation, pursuant to Presidential Decree No. 445 of 28 December 2000, that it is registered in one of the professional or commercial registers referred to in Annex II.11 of Legislative Decree 36/2023.

In order to prove the requirement in the case of operators based in Italy, the Contracting Authority acquires the documents in the possession of Public Administrations ex officio, subject to indication, by the economic operator, of the elements essential for the retrieval of the information or data requested.

In the case of an economic operator from another Member State who is not resident in Italy, the operator is required to document the possession of such registration.

In the case of a temporary grouping, consortium, EEIG consortium or companies adhering to a network contract, the requirement relating to registration in the Register of Companies or in the Register of Craft Enterprises must be met: - by each member of the grouping/consortium/EEIG, even to be established, as well as by the EEIG itself; - by each component of the network aggregation as well as by the common body in the event that it has legal subjectivity

7.2 ECONOMIC AND FINANCIAL STANDING REQUIREMENTS

In order to allow the selection of a reliable operator, with consolidated experience in the sector functionally intended for research activities, which is the subject of the tender, the economic and financial capacity requirements that must be met by the economic operators participating in the tender are listed below.

b) Minimum global turnover referring to the last 3 available financial years (years 2020-2021-2022):

- **Lot no. 1: €809,261.00**
- **Lot no. 2: €5,245,371.00**

For participation in multiple lots, the requirement is given by the sum of the individual requirements required for each participation lot. This requirement responds to the interest of the Contracting Authority to contract with a party that is reliable in relation to the specific commitments that derive from participation in the tender and from the eventual award of the contract.

Proof of the requirement shall be provided by means of one of the following documents:

- for corporations, by means of the financial statements, or extracts thereof, approved on the date of expiry of the deadline for the submission of bids, accompanied by the notes to the financial statements;
- for economic operators established in the form of a sole proprietorship or partnership, by means of a copy of the Single Model or the VAT Return;
- declaration made, pursuant to and for the purposes of Article 47 of the Decree of the President of the Republic no. 445/2000, by the person or body responsible for the accounting control of the company, if present (be it the Board of Statutory Auditors, the auditor or the auditing firm), certifying the amount (amount) and type (reason for invoicing) of the turnover declared at the time of participation.

Where turnover information is not available, for companies that have been in business **for less than 3 years**, the turnover requirements must be related to the period of activity.

An economic operator who is unable to submit the required references for justified reasons may prove his economic and financial standing by means of any other document considered appropriate by the contracting authority. In the case of a temporary grouping, consortium, EEIG consortium or undertakings participating in a network contract, the overall turnover requirement must be met as a whole and fulfilled by the temporary grouping as a whole.

7.3 TECHNICAL AND PROFESSIONAL CAPACITY REQUIREMENTS

c) The tenderer must have carried out, in the last three years (understood as the three years prior to the date of publication of the notice), **one or more supplies similar to the object of the contract** for a minimum total amount equal to the amount indicated as the starting price for each lot, namely:

LOT 1: 809.261,00 €

LOT 2: €5,245,371.00

Similar supplies are defined as:

- Lot 1: Milligram scale mRNA drug manufacturing system;
- Lot 2: mRNA drug production system scale of multiples of grams.

Proof of the requirement shall be provided:

In the case of supplies made to public administrations or public bodies in one of the following ways:

- the original digitally signed by the subscriber, or a certified copy digitally signed by the competitor, of the certificates issued by the contracting authority/entity, indicating the subject, amount and period of execution;
- a copy of the invoices proving the supply of equipment similar to that which is the subject of the present procedure for which they are competing;
- contracts stipulated with public administrations/public bodies, complete with a copy of invoices, receipts or bank documents certifying the payment of the same.

In the case of supplies made to private clients, in one of the following ways:

- the original digitally signed by the subscriber or a certified electronic copy of the certificates issued by the private client, indicating the subject, the amount and the period of execution.
- a copy of the invoices proving the supply of equipment similar to that which is the subject of the present procedure for which they are competing;
- contracts stipulated with private individuals, complete with a copy of the receipted invoices or bank documents certifying the payment of the same.

A competitor who is not established in Italy, but in another Member State or in one of the countries referred to in Article 100, paragraph 3 of the Code and Article 3 of Annex II.12, must submit an affidavit or in

accordance with the procedures in force in the State in which he or she is established for the similar certification.

An economic operator who is unable to submit the required references for reasonable reasons may prove his or her capacity by means of any other document deemed appropriate by the contracting authority.

For participation in more than one lot, the requirement is given by the value of lot no. 2 of greater value (€ 5,245,371.00. This requirement responds to the interest of the Contracting Authority to contract with a party that is reliable in relation to the specific commitments that derive from participation in the tender and from the eventual award of the contract.

7.4 INFORMATION ON SPECIAL REQUIREMENTS IN TEMPORARY GROUPINGS, ORDINARY CONSORTIA, AGGREGATIONS OF NETWORK UNDERTAKINGS, EEIGS

The subjects referred to in Article 65(2)(e), (f), (g) and (h) of the Code must meet the requirements of a special order in the terms indicated below.

Aggregations of network operators, ordinary consortia and EEIGs are subject to the same rules as temporary groupings.

The requirement relating to registration in the register kept by the Chamber of Commerce referred to in point 7.1 letter a) must be met:

- by each member of the grouping/consortium/EEIG, including those to be set up, and by the EEIG itself;
- by each component of the network aggregation as well as by the common body in the event that it has legal entity.

The requirements of economic and financial standing, as well as technical and professional capacity, must be met by the temporary grouping as a whole.

In the event that a group has excluded or replaced a participant in the group because it lacks a special-order requirement referred to in Article 100 of the Code, the measures taken pursuant to Article 97 of the Code in order to decide on the exclusion of the group shall be assessed.

7.5 INFORMATION ON SPECIAL REQUIREMENTS FOR CONSORTIA OF COOPERATIVES AND CRAFT ENTERPRISES AND PERMANENT CONSORTIA

The subjects referred to in art. 65 para. 2, letters b), c) and d) of the Code must meet the requirements for participation in the terms indicated below.

(a) Requirements of professional competence

The requirement relating to registration in the Register of Companies or in the Register of Artisan Enterprises must be met by the consortium and the consortium members indicated as executors;

b) Requirements of economic, financial and technical-professional capacity

The consortia referred to in Article 65(2)(b) and (c) of the Code shall use their own requirements and, in the list of these, shall make use of the resources available to the consortium members that constitute them.

For the consortia referred to in Article 65(2)(d) of the Code, the technical and financial capacity requirements are cumulatively calculated for the consortium, even if they are held by the individual consortium members.

In the event that a consortium has ousted or replaced a consortium member because it does not meet a special-order requirement referred to in Article 100 of the Code, the measures taken pursuant to Article 97 of the Code in order to decide on the exclusion shall be assessed.

8. ENDORSEMENT

The competitor may make use of technical, human and instrumental equipment made available by one or more auxiliary economic operators to demonstrate the possession of the special-order requirements and/or to improve its offer. In the use contract, the parties specify the instrumental and human resources that the auxiliary makes available to the competitor and indicate whether the use is aimed at acquiring the participation requirement or improving the competitor's offer, or if it serves both purposes. In cases where the use is aimed at improving the offer, it is not allowed for both the auxiliary and the operator who makes use of the resources made available by the latter to participate in the same tender, under penalty of exclusion of both subjects. Pursuant to Article 372(4) of the Business Crisis and Insolvency Code, in order to participate in this procedure between the time of filing of the application referred to in Article 40 of the aforementioned Code and the time of filing of the decree provided for in Article 47 of the same Code, it is always necessary to avail oneself of the requirements of another person. Endorsement is not necessary in the event of admission to the composition with creditors. The tenderer and the auxiliary are jointly and severally liable to the contracting authority in relation to the services covered by the contract. It is not allowed to use it to meet the requirements of a general nature and registration with the Chamber of Commerce. The use of more than one auxiliary is permitted. The auxiliary, in turn, may not make use of another person. The auxiliary must: (a) meet the requirements set out in Article 6 and declare them by submitting his or her ESPD, to be completed in the relevant parts; (b) meet the requirements referred to in Article 7.1(a), 7.2(b) and 7.3(c) subject to reliance and declare them in their ESPD, to be completed in the relevant parts; c) undertake, to the tenderer who avails itself and to the contracting authority, to make available, for the entire duration of the contract, the resources (referring to participation and/or bonus requirements) subject to use.

The competitor shall attach to the application form the endorsement contract, which must be digital native and digitally signed by the parties, as well as the declarations of the auxiliary. The failure to produce the auxiliary's declarations can be remedied by means of preliminary assistance. The failure to produce the contract of use can be remedied by means of preliminary assistance, provided that the contract was entered into before the deadline for submission of the tender and that this circumstance can be proven with a certain date prior to the deadline for submission of the tender. It is not possible to remedy - and therefore is a cause of exclusion from the tender - the failure to indicate the resources made available by the auxiliary as a cause

of nullity of the contract of use. If there are grounds for exclusion for the auxiliary or if it does not meet the requirements of the special order, the tenderer shall replace the auxiliary within 10 days of receipt of the request by the contracting authority. At the same time, the competitor produces the documents required for the endorsement. In the event that the auxiliary has been responsible for a false declaration on the possession of the requirements, the contracting authority shall proceed to report to the Authority the conduct of the auxiliary in order to allow the assessments referred to in Article 96, paragraph 15. The economic operator may appoint another auxiliary within ten days, failing which he will be excluded from the tender. Substitution may only be made if it does not lead to a substantial increase in the offer. Failure to comply with the deadline set for substitution will result in the exclusion of the competitor.

9. SUBCONTRACTING

Subcontracting is allowed within the limits set forth in art. 119 of Legislative Decree no. 36/2023, to which reference should be made.

The tenderer must indicate at the time of the tender the services and supplies or parts of services and supplies that it intends to subcontract.

In the absence of any indication of subcontracting, subcontracting is prohibited. The activities referred to in art. 119, par. 3 of the Code.

10. PROVISIONAL WARRANTY

The offer is accompanied by:

(1) **a provisional guarantee**, as defined in Section 106 of the Code, equal to 2% of the total amount of the procedure, namely the following amounts:

- for **Lot no. 1 equal to € 16,942.64**, except as provided for in Article 106, paragraph 8 of the Code;
- for **Lot no. 2 equal to € 111,275.90** except as provided for in Article 106, paragraph 8 of the Code.

In the case of participation in more than one lot, the economic operator may alternatively:

- provide as many distinct and autonomous provisional guarantees as there are lots in which you intend to participate;
- provide a single guarantee for an amount equal to the sum of the amounts established for the lots in which it intends to participate.

The guarantee expressly indicates the individual lots for which it is lent, as well as the detailed amounts of the individual deposits referred to each lot.

The guarantee covers the non-award after the proposal for the award and the failure to sign the contract attributable to any fact attributable to the contractor or resulting from the adoption of anti-mafia interdictory

information issued pursuant to articles 84 and 91 of the code of anti-mafia laws and prevention measures, referred to in the legislative decree of 6 September 2011, No. 159.

The guarantee is automatically released at the time of signing the contract.

The provisional guarantee shall **consist**, at the option of the competitor in the form of a security or surety:

- a) **The deposit is provided by credit**, bank transfer or other electronic payment instruments and channels, to the INTESA SANPAOLO SPA filiale napoli 40 - **IBAN account IT22J0306903594100000046083** specifying as the reason for payment: Provisional guarantee – **GARA ASP, the number of the procedure – indicating CIG, the CUP: E63C22000940007, the CUI: F00876220633202400035**; An electronic copy of the payment must be submitted to the System, indicating the IBAN code of the person who made the payment. It is understood that the competitor must in any case produce the commitment to issue the definitive guarantee for the execution of the contract, if the competitor is successful;
- b) **Bank or insurance guarantee** issued by banking or insurance companies that meet the solvency requirements provided for by the laws governing their respective activities, or by financial intermediaries registered in the register referred to in Article 106 of the Consolidated Law on Banking and Credit, referred to in Legislative Decree No. 385 of 1 September 1993, which exclusively or predominantly carry out activities of issuing guarantees and which are subject to auditing by an auditing firm registered in the appropriate register and which meet the minimum solvency requirements required by current banking and insurance regulations.

The bank or insurance guarantee issued by banking or insurance companies that meet the requirements of art. 106, par. 3 of the Code. In any case, the surety guarantee complies with the standard scheme referred to in art. 117, par. 12 of the Code.

Before proceeding with the subscription, economic operators are required to verify that the guarantor is in possession of the authorization to issue guarantees through access to the following websites:

- (a) <http://www.bancaditalia.it/compiti/vigilanza/intermediari/index.html>
- (b) <http://www.bancaditalia.it/compiti/vigilanza/avvisi-pub/garanzie-finanziarie/>
- (c) http://www.bancaditalia.it/compiti/vigilanza/avvisi-pub/soggetti-nonlegittimati/Intermediari_non_abilitati.pdf
- (d) http://www.ivass.it/ivass/imprese_jsp/HomePage.jsp.

In the case of the provision of a **surety guarantee**, this must:

- 1) contain express mention of the object and the guaranteed entity, the CIG and the CUP;
- 2) be in the name of all the economic operators of the temporary grouping or ordinary consortium or EEIG, or of all the network companies participating in the tender or, in the case of consortia, of the consortium alone;

- 3) comply with the model scheme approved by Decree of the Minister of Economic Development no. 193 of 16 September 2022;
- 4) be valid for 180 days from the deadline for the submission of the bid;
- 5) Expressly provide:
 - a. the waiver of the benefit of the prior enforcement of the principal debtor pursuant to art. 1944 of the Italian Civil Code;
 - b. the waiver of the right to object to the commencement of the terms referred to in art. 1957, paragraph 2, of the Italian Civil Code;
 - c. operation within fifteen days at the simple written request of the contracting authority;
- 6) be accompanied by the guarantor's commitment to renew the guarantee pursuant to art. 106, paragraph 5 of the Code, at the request of the contracting authority for the time necessary to conclude the tender operations, in the event that at the time of its expiry the award has not yet taken place.

The surety must be issued and digitally signed by a person in possession of the necessary powers to bind the guarantor and be verifiable electronically at the issuer by indicating in the application the website where the guarantee can be verified.

In the event of a request for an extension of the duration and validity of the offer and of the surety guarantee, the competitor may produce a new provisional guarantee from another guarantor, in place of the previous one, provided that it has **expressed effect from the date of submission of the bid**.

Pursuant to art. 106, paragraph 8 of the Code, the amount of the guarantee is reduced in the terms indicated below.

- a.** 30% reduction in case of possession of the quality certification in compliance with the European standards of the UNI CEI ISO 9000 series. In the case of participation in an associated form, the reduction is obtained:
- for the entities referred to in Article 65(2)(e), (f), (g) and (h) of the Code, only if all the entities that make up the group, ordinary consortium or EEIG, or all the network companies participating in the tender are in possession of the certification;
 - for the consortia referred to in Article 65(2)(b), (c) and (d) of the Code, if the Consortium has declared during the bidding phase that it intends to carry out with its own resources, only if the Consortium has the aforementioned certification; if the Consortium has indicated during the bid phase that it intends to assign part of the services to one or more consortium members identified in the bid, only if both the Consortium and the designated consortium member possess the aforementioned certification, or alternatively if the Consortium alone possesses the aforementioned certification and the scope of certification of its management system includes the verification that the provision of the service by the consortium member complies with the standards set by the certification.

b. Reduction of 50% in the case of participation of micro, small and medium-sized enterprises and groupings of economic operators or ordinary consortia consisting exclusively of micro, small and medium-sized enterprises. This reduction cannot be combined with that indicated in letter a).

In the case of participation in an associated form, the reduction is obtained:

- for the entities referred to in Article 65(2)(e), (f), (g) and (h) of the Code, if one of the entities that make up the grouping, ordinary consortium or EEIG, or one of the network companies participating in the tender is in possession of the certification;
- for the consortia referred to in Article 65(2)(b), (c) and (d) of the Code, if the consortium or one of the consortium members is in possession of the certification; In order to benefit from the reductions referred to in Article 106, paragraph 8 of the Code, the competitor declares in the application form that he or she is in possession of the certifications and inserts a copy of the certifications held if not already present in the virtual file.

Failure to submit the provisional guarantee may be remedied by means of an inquiry only if it has already been provided that it has already been provided before the submission of the bid. It is the economic operator's burden to prove that these documents were drawn up no later than the deadline for the submission of tenders.

Pursuant to art. 20 of Legislative Decree no. 82/2005, the date and time of creation of the electronic document are enforceable against third parties if affixed in accordance with the technical rules on validation (e.g.: time stamp).

It is also possible to remedy the presentation of a guarantee of a lower value or without one or more of the characteristics indicated above (registration only to some participants in the RTI, lack of mandatory clauses, etc.).

It is not possible to remedy - and therefore it is a cause for exclusion - the signing of the provisional guarantee by a person who is not entitled to issue the guarantee or not authorized to bind the guarantor.

11. INSPECTION

For the purpose of submitting the offer, there is no visit to the sites.

12. PAYMENT OF THE CONTRIBUTION TO ANAC

Competitors shall pay, **under penalty of exclusion**, the contribution required by law in favour of the National Anti-Corruption Authority through the "Tender Contribution Management" (GCG) service, for the amount of: **€ 90.00 for Lot 1** and **€ 220.00 for Lot 2** in compliance with ANAC resolution no. 610 of 19/12/2023 published on the ANAC website in the "contributions during the tender" section.

The contribution is due for each lot for which a bid is submitted according to the amounts described in the table

below:

Lot number	CIG	Amount
1	B2397BBE86	90,00 euro
2	B2397BCF59	220,00 euro

Therefore, the taxpayer who intends to participate in this procedure must generate a payment notice on the pagoPA circuit, through the new "Tender Contributions Management" (GCG) service, and make the payment through the new "Payment Portal of the A. N.AC." The service allows you to generate pagoPA payment notices (identified by the IUV, Unique Payment Identifier) and to pay them in one of the following ways: "Online payment" through the new A.A. N.AC., choosing from the payment channels available on the pagoPA system. "Payment by notice" using the infrastructures made available by a Payment Service Provider (PSP) enabled by pagoPA (ATMs, home banking applications - CBILL and mobile payment service, points of the monopoly sales network - tabacconists, SISAL and Lottomatica, cash desks set up at large-scale retailers, etc.). It should be noted that the new service does not allow payment at PSPs without the payment notice or with the sole indication of the CIG and the tax code of the EO. As proof of the payment of the contribution to A. N.AC., the competitor must send and send to the Administration through the System the payment receipt that will be available in the "Payments made" section of the A.A. Payment Portal. N.AC., upon successful completion of the payment transaction.

The payment of the contribution is a condition for the eligibility of the offer.

The payment is verified by the FVOE.

In the event of a negative outcome of the verification, the preliminary rescue procedure is activated. In the event of failure to regularize the tender within the prescribed period, the tender shall be declared inadmissible.

The contracting authority shall ascertain the payment of the fee by consulting the FVOE for the purpose of admission to the tendering procedure.

If the payment is not recorded in the system, the contracting authority shall require the presentation of the receipt of payment by means of an investigation. An economic operator that does not comply with the request within the time limit set by the contracting authority shall be excluded from the tender procedure due to the inadmissibility of the tender.

13. PROCEDURES FOR SUBMITTING THE OFFER AND SIGNING THE TENDER DOCUMENTS

All documents relating to this procedure up to the award must be sent to the Administration, unless otherwise provided, exclusively electronically through the System, in electronic format and be signed, where required under **penalty of exclusion**, with a digital signature pursuant to Article 1, paragraph 1, letter s) of Legislative Decree no. 82/2005.

The OFFER must be sent by the competitor to the Administration through the System, **no later than the peremptory deadline indicated in the Tender Notice**, under penalty of **inadmissibility of the offer** and in any case its irregularity.

The exact time and date of receipt of bids are determined according to the time of the System.

It should be noted that, in the event of a failure or malfunction of the System such as to prevent the correct submission of bids, the Administration shall take the necessary measures in order to ensure the regularity of the procedure in compliance with the principles set out in Book I Part I of Legislative Decree 36/2023, including by ordering the suspension of the deadline for the receipt of bids for the period of time necessary to restore the normal operation of the means and the extension of the same for a duration proportional to the severity of the failure. In cases of suspension and extension, the System ensures that, until the expiry of the extended term, the secrecy of the tenders sent is maintained. Economic operators who have already submitted their bid are allowed to withdraw it and, if necessary, replace it.

Publicity of this extension shall take place through the timely publication of a specific notice at all available Internet addresses referred to in point I.1 of the Contract Notice.

The "OFFER" consists of:

A – Administrative documentation;

B – Technical offer: one for each Lot for which you intend to participate;

C – Economic offer: one for each Lot for which you intend to participate.

The competitor must produce the above documentation to Sistema in the various sections provided therein on the basis of the rules indicated in the following table:

Document	Section I
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ESPD	ESPD - European Single Procurement Document of the Competing Company
Annex 1 – Application form	Competitor's application form for participation in the competition
Annex A2	Supplementary Declarations
Annex A3	Supplementary Declarations
Annex A4	Supplementary Declarations
Deed of Commitment	Completed Deed of Commitment
Beneficial Owner	Beneficial Ownership Statement
No Beneficial Owner Conflict	Declaration of absence of conflict of interest of the beneficial owner
Proof of payment of the ANAC contribution	Proof of payment of the ANAC contribution
Identification document of the Underwriter	Copy of a valid identity document
Appendix G	Self-declaration of Legislative Decree 231/2001;
ESPD and Model A4	ESPD - European Single Procurement Document for the Ancillary Undertaking and Supplementary Declarations
Model D	Declaration pursuant to Article 85 of Legislative Decree 159/2011
DNSH Card	DNSH Card
Payment of the stamp duty	Proof of payment of stamp duty
Deed of incorporation of RTI or Ordinary Consortium	Any acts relating to R.T.I. or Consortia

Provisional Warranty	Provisional bail and accompanying documentation
Technical Offer	Section II
Technical Offer	Technical Report
Economic Offer <i>[if any]</i> and Time	Section III
Economic offer <i>(generated by the system)</i>	Economic Component Tab

On the website www.acquistinretepa.it, in the appropriate section relating to this procedure, the submission of the OFFER must take place through the execution of procedural steps that allow the preparation and sending of the documents of which the OFFER is composed (i.e.: **Administrative Documentation, Technical Offer, Economic Offer**).

It should be noted that, before sending, all the files that make up the offer, which are not already in .pdf format, must all be converted into .pdf format.

The submission of the OFFER and its submission take place exclusively through the guided procedure provided by the System which can be carried out in subsequent phases, through the saving of the data and the activities carried out, it being understood that the sending of the OFFER must necessarily take place within the expiry of the peremptory deadline for submission established above. The steps must be completed in the sequence established by the System.

The competitor is asked for consistency between the data imputed to the System and those reported in the documentation produced in the OFFER.

It is always possible to modify the steps previously performed: in this case, it is advisable to pay the utmost attention to the procedure for preparing the offer guided by the System, as the changes made may have consequences on the subsequent steps. In any case, it is the responsibility and responsibility of the competitor to constantly update the content of each phase and each step relating to the submission of the OFFER.

The sending of the OFFER, in any case, takes place only with the selection of the appropriate "confirmation and sending" function of the same.

The System used by the Administration adopts a method of execution of the aforementioned actions and activities such as to allow the respect of the utmost secrecy and confidentiality of the OFFER and the documents that compose it, and such as to guarantee the origin, identification and inalterability of the offer itself.

The submission of the OFFER through the System is at the total and exclusive risk of the applicant, who assumes any risk in the event of non-receipt or late receipt of the OFFER, due, by way of example but not limited to, to malfunctions of the telematic tools used, to connection and transmission difficulties, to slow

connections, or to any other reason, Consip S.p.A., the System Operator and the Administration shall not be held liable if, due to delays or technical or other problems, or for any reason, the OFFER is not received within the peremptory deadline.

In any case, without prejudice to the mandatory limits of the law, the competitor exempts Consip S.p.A., the System Operator and the Administration from any liability for malfunctions of any nature, non-functioning or interruptions in the operation of the System. Consip S.p.A. reserves the right, however, to take the measures it deems necessary in the event of a malfunction of the System.

It should also be noted that:

- the OFFER submitted within the deadline for submission of the same is binding for the competitor;
- within the deadline for submission of the OFFER, those who have submitted an OFFER may withdraw it; a withdrawn OFFER will be equivalent to a non-submitted bid;
- **the System does not accept OFFERS submitted after the date and time established as the deadline for the submission of OFFERS, as well as incomplete OFFERS of one or more parties whose presence is necessary and mandatory.**

The competitor is required to attach, as an integral part of the OFFER, **under penalty of exclusion**, the documents specified in the following paragraphs, where required, signed with a digital signature. It is recommended to include these attachments in the relevant section and in particular, **not to indicate or in any case provide the data of the economic offer in a section other than the one relating to the same, under penalty of exclusion from the procedure.**

The competitor is aware, and accepts with the submission of the OFFER, that the System may rename the *files* that the same competitor submits through the System in view only; this modification does not affect the content of the document, nor the original name, which remain, in any case, unchanged.

In addition to the provisions of this document, the operational and explanatory indications present to the System on the internet pages relating to the bid submission procedure remain unaffected.

The competitor who intends to participate in a joint form (e.g. RTI/Consortia, both established and in the process of being established) must indicate the form of participation and indicate the economic operators gathered or in the consortium at the time of submission of the OFFER. The System automatically generates a password dedicated exclusively to the operators gathered, which will be used to allow the indicated subjects to take part (within the limits of the form of participation indicated) in the compilation of the OFFER.

For competitors with registered office in Italy or in one of the countries of the European Union, the self-declarations are drawn up in accordance with articles 46 and 47 of Presidential Decree 445/2000; for competitors who do not have their registered office in one of the countries of the European Union, the self-declarations are made by means of equivalent appropriate documentation according to the legislation of the country to which they belong.

All self-declarations made pursuant to art. 46 and 47 of Presidential Decree 445/2000, including the ESPD, the request for participation, the technical offer and the economic offer must be digitally signed by the legal representative of the competitor or his attorney.

The documentation, unless expressly requested in original, may be produced in certified copy or certified copy pursuant to, respectively, art. 18 and 19 of D.P.R. 445/2000. Unless otherwise specified, simple copying is permitted.

In the case of competitors not established in Italy, the documentation must be produced in an equivalent suitable manner according to the legislation of the country to which they belong; Art. 100, par. 3, of the Code. All the documentation to be produced must be in Italian or, if written in a foreign language, must be accompanied by a sworn translation into Italian. In the event of a conflict between the foreign language text and the Italian text, the Italian language version will prevail, as it is at the competitor's risk to ensure the accuracy of the translation. In the event of lack, incompleteness or irregularity in the translation of the documents contained in the Administrative Documentation, **Section 101 of the Code shall apply.**

Late bids will be excluded as they are inadmissible pursuant to art. 70(4)(b) of the Code. The bid will bind the competitor pursuant to art. 17, par. 4 of the Code for 180 days from the expiry of the deadline indicated for the submission of the bid. In the event that, on the date of expiry of the validity of the tenders, the tender operations are still in progress, the contracting authority may request the bidders, pursuant to art. 17, paragraph 4 of the Code, to confirm the validity of the bid until the date to be indicated and to produce a specific document certifying the validity of the guarantee provided during the tender until the same date. Failure to respond to the request of the contracting authority within the deadline set by the latter or, in any case, in time for the rapid continuation of the procedure shall be considered as a withdrawal by the tenderer from participating in the tender.

Until the day set for the opening, the economic operator may make, through the Platform, a request for correction of a clerical error contained in the technical offer or in the economic offer, of which it has become aware after the expiry of the deadline for their submission.

To this end, it requests to be able to make use of this option, before the deadline set for the opening session of the offer it intends to amend, by sending a specific communication in the Communications Area containing only the expression of interest in rectifying the Technical Offer and/or the Economic Offer. The aforementioned event must be sent only after receipt of the invitation through the Communications Area of the System. Subsequently, competitors, who have sent the expression of interest in amending the Offer in the manner and within the terms described above, may proceed to send the relevant correction. The latter must be sent during the opening session of the relevant Offer, as indicated in the communications setting the opening sessions of

the Technical Offers and the Economic Offers. This correction must be received within the deadline to be specified in the communication from the President of the Commission.

Requests for correction submitted without the prior expression of interest referred to above or sent after the deadline provided for in the notice of scheduling the meeting will not be accepted. The correction must contain all the elements necessary for the Commission to identify the clerical error and, therefore, proceed with the "correction" of the Offer in the interested party. It is understood that the aforementioned correction is made in compliance with the secrecy of the offer and may not entail the submission of a new bid, nor its substantial modification. If the correction is deemed unacceptable because it is substantial, the possibility of declaring the tender inadmissible shall be assessed.

14. PRELIMINARY ASSISTANCE

With the preliminary rescue procedure referred to in art. 101 of the Code, deficiencies in the documentation sent with the request to participate may be remedied, but not those in the documentation that makes up the technical offer and the economic offer.

The same procedure may be used to remedy any omission, inaccuracy or irregularity in the request to participate and in any other document required for participation in the tender procedure, with the exception of the documentation that makes up the technical offer and the economic offer. Omissions, inaccuracies and irregularities that make the identity of the competitor absolutely uncertain cannot be remedied. Specifically, the following rules apply:

- failure to meet the required participation requirements cannot be remedied by means of preliminary assistance and is a cause of exclusion from the tender procedure;
- the omitted or incomplete or irregular submission of declarations on the possession of the requirements for participation and any other lack, incompleteness or irregularity of the application, are remediable, with the exception of false declarations;
- the failure to produce the contract of use, the provisional guarantee, the special collective mandate or the commitment to confer a collective mandate may be the subject of preliminary assistance only if the aforementioned documents are pre-existing and can be proven with a certain date prior to the deadline for submission of the bid;
- the failure to sign the application form, the declarations made and the offer can be remedied;
- failure to indicate the manner in which the operator intends to ensure, in the event of the award of the contract, compliance with the conditions of participation and performance cannot be remedied by means of preliminary assistance;
- the failure to declare that they have fulfilled the obligations referred to in Law 68/1999 and, for competitors employing more than fifty employees, the failure to submit a copy of the latest periodic report on the

situation of male and female staff, drawn up pursuant to Article 46 of Legislative Decree no. 198 of 2006 and the transmission of the same to trade union representatives and regional equality councilors, may be remedied, provided that it is drawn up and sent before the deadline for the submission of tenders;

- Failure to undertake to ensure, in the event of the award of the contract, the employment of young people and women, cannot be remedied by means of preliminary assistance.

For the purposes of the amnesty, the contracting authority shall assign the tenderer a reasonable period - not less than five and not more than ten days - for the necessary declarations to be made, supplemented or regularized, indicating the content and the persons who must make them as well as the section of the platform where the required documentation must be inserted.

If the time limit expires unnecessarily, the contracting authority shall exclude the tenderer from the procedure.

If the tenderer produces declarations or documents that are not perfectly consistent with the request, the contracting authority may request further clarifications or clarifications, setting a peremptory deadline under penalty of exclusion.

The contracting authority may always ask for clarification on the contents of the technical offer and the economic offer and on any of their annexes. The economic operator is required to provide a response within the time limit set by the contracting authority, which will not be less than five days and more than ten days. Clarifications made by the economic operator may not change the content of the offer.

15. CONTENT OF ADMINISTRATIVE DOCUMENTATION

The Administrative Documentation consists of: the application form (which includes the supplementary declarations), the ESPD as well as the accompanying documentation, in relation to the different forms of participation.

15.1 APPLICATION FORM

The application form is drawn up, with stamp duty, preferably on the "Application form A1)" and contains all the following information and declarations.

The application form must be uploaded to the System.

The tenderer shall indicate the individual or associated form in which the undertaking participates in the tendering procedure (sole proprietor, consortium, RTI, aggregation of network undertakings, EEIGs).

In the case of participation in RTIs, ordinary consortiums, aggregations of network companies, EEIGs, the competitor provides the identification data (company name, tax code, registered office) and the role of each company (agent/principal; leader/consortium member).

In the case of a consortium of cooperatives and craft enterprises or a stable consortium referred to in art. 65, par. 2 l. b), c), d) and f) of the Code, the consortium indicates the consortium member for which it is competing in the tender; If the Consortium does not indicate for which consortium member(s) it is competing, it is understood that it participates in its own name and on its own behalf.

The application shall be signed with a digital signature:

- in the case of a temporary grouping or ordinary consortium constituted, by the agent/lead partner;
- in the case of a temporary grouping or ordinary consortium not yet constituted, by all the subjects that will constitute the grouping or consortium;
- In the case of aggregations of companies adhering to the network contract, reference is made to the rules provided for temporary groupings of companies, as compatible.

Especially:

at. if the network has a common body with power of representation and legal subjectivity, pursuant to art. 3, paragraph 4-quarter, of Legislative Decree no. 5 of 10 February 2009, the application for participation must be signed only by the economic operator who performs the function of common body;

b. if the network has a common body with the power of representation but is not a legal entity, pursuant to art. 3, paragraph 4-quarter, of Legislative Decree no. 5 of 10 February 2009, the application for participation must be signed by the company that performs the functions of common body as well as by each of the companies adhering to the network contract participating in the tender;

c. If the network has a common body that does not have the power of representation, or if the network does not have a common body, or if the common body does not meet the qualification requirements for the role of trustee, the application to participate must be signed by the undertaking belonging to the network that has the status of trustee, or, in the case of participation in the forms of the consortium to be formed, by each of the companies adhering to the network contract participating in the tender; - in the case of a consortium of cooperatives and craft enterprises or a permanent consortium referred to in art. 65(2)(b), (c), (d) and (f) of the Code, the application shall be signed by the consortium itself.

With reference to the payment of stamp duty, this is due:

- in the case of RTIs and ordinary consortia constituted/to be established only by the parent agent;
- In the case of stable consortia referred to in art. 65(2)(b), (c), (d) and (f) of the Code, by the consortium itself;
- in the case of Network Aggregations by the common body/agent.
-

The competitor attaches a certified copy of the original of the power of attorney or, only in the event that the competitor's Chamber of Commerce certificate shows an express indication of the representative powers conferred with the power of attorney, the self-declaration made by the attorney/legal representative signatory certifying the existence of the representative powers resulting from the power of attorney.

Method of payment of the stamp duty

The application must be submitted in compliance with the provisions of Presidential Decree 642/1972 regarding the payment of stamp duty. The payment of the aforementioned tax of Euro 16.00 must be made by one of the following methods:

- a. the @e.stamp duty service of the Revenue Agency

As proof of payment, the competitor attaches the electronic payment receipt issued by the @e.stamp duty system or bank transfer.

- b. the use of the F24 Elide model, with specific indication:

In the personal data section, enter:

- University of Naples Federico II – Department of Pharmacy Naples (NA), CF 00876220633;
- Competitor's data (name, municipality, registered office, province, tax code);
- description: Stamp duty relating to the application for participation in the tender procedure "**GARA ASP, the number of the procedure – indicating CIG: _____ the CUP E63C22000940007 - CUI: F00876220633202400035**

For foreign economic operators, the payment of the tax is made by bank transfer using the IBAN code **IT22J0306903594100000046083** and specifying in the reason for payment their name, tax code (if any) and the details of the act to which the payment refers.

It should be noted that, in the event of non-payment of the stamp duty, the Administration will proceed with the reporting to the Revenue Agency pursuant to art. 19 of the Presidential Decree of 26 October 1972 n. 642.

15.2 EUROPEAN SINGLE PROCUREMENT DOCUMENT

The competitor must fill in the ESPD referred to in the scheme attached to the Ministerial Decree of the Ministry of Infrastructure and Transport of 18 July 2016 in electronic format following the following instructions:

Link to the link <https://espd.eop.bg/espd-web/filter?lang=it>

- 1) In the section "Who is filling out the ESPD?"

select "I am an economic operator".

- 2) In the section "What do you want to do?"

Select "Import an ESPD".

- 3) In the "Upload Document" section

click on "Browse" and upload the file with the extension "espd-request.xml" published on the website www.unina.it in the Race section.

- 4) In the section "Where is your company located?"

select the country (example: Italy) and then click on "Next".

"Part I" does not need to be amended as it contains information relating to the tender procedure.

Only the following Parts, relating to information on the Economic Operator, must be completed.

5) After filling in all the fields, click on "Overview", check the correctness of the data entered, then, at the end of the document, click on "Download in format" and select "Both" (PDF and XML) and save the generated "espd-response.zip" file.

6) Open the aforementioned "espd-response.zip" file, extract and save the three files (PDF, XML and TXT).

7) Digitally sign only the "espd-response.pdf" document for forwarding through the System

With reference to the information contained in **Sect. A - Information on the Economic Operator**, the following clarifications are provided:

(1) Box **"SME Economic Operator"**. The turnover to be indicated is that accrued in the three-year period prior to the date on which the procedure was initiated, pursuant to Article 100, paragraph 11, of the Code.

2) **"Registration in official lists"** box. This is where the relevant declarations of economic operators registered in official lists of entrepreneurs, suppliers, or service providers or who are in possession of a certification issued by accredited bodies are included.

The possession of a qualification certificate issued by the Attestation Bodies (SOAs) pursuant to Article 100 of the Code, as well as by the qualification systems in special sectors pursuant to Article 162 of the same Code, must be declared by the economic operators in this box, indicating, in particular,

- the details of the attestation (name of the Attestation Body or Qualification System, number and date of the attestation) under "Provide the name of the list or certificate and the relevant registration or certification number, if applicable";
- if the attestation of qualification is available electronically, the web address, the issuing authority or body, the precise reference of the documentation under "If the certificate of registration or certification is available electronically, please indicate where";
- if relevant, the categories of qualification to which the attestation refers under the heading "Indicate the references on which the registration or certification is based and, where applicable, the classification obtained in the official list".

If the above registration, certification or attestation does not meet all the required selection criteria, the information to be provided regarding the selection criteria not met in the above documentation must be included in Part IV, Sections A, B or C.

3) **"Form of participation" box**. In the case of participation of the consortia referred to in art. 65(2)(b)(c) and (d) and Article 66(1)(g) of the Code, the ESPD shall be completed separately by the consortium and the executing consortium members indicated therein. Therefore, this box must indicate the names of the economic operators who are part of a consortium referred to in the aforementioned Article 65, paragraph 2 letters b) c) d) or of a Society of professionals referred to in the aforementioned Article 66, paragraph 1 letter g) who perform the services covered by the contract.

The form of participation of economic operators must be specified in the application form.

With regard to **Sec. B - Information on the representatives of the economic operator**, it is specified that the declaration to be included in this section must refer to all the subjects listed in Article 94, paragraph 3 of the Code and that, in the event that the shareholder is a legal person, the directors of the same must be indicated.

In the event of recourse to the endorsement, the completion of section C is required

The competitor shall indicate the name of the ancillary economic operator and the requirements to be met.

In particular, the competitor, for each auxiliary, shall attach:

(1) ESPD in electronic format, signed by the Auxiliary, containing the information referred to: in Part II, Sections A and B, in Part III, in Part IV, in relation to the requirements to be applied, and in Part VI;

2) self-declaration pursuant to art. 104, paragraph 4 of the Code, signed with a digital signature by a person with appropriate powers of the auxiliary, by which the latter undertakes, towards the competitor and the contracting authority, to make available, for the entire duration of the contract, the necessary resources that the competitor lacks (in accordance with Annex A4);

3) self-declaration pursuant to art. 104, par. 12 of the Code, signed with a digital signature by a person with appropriate powers of the auxiliary, with which the latter certifies that it does not participate in the tender on its own or as an associate or consortium member (in accordance with Annex A4). A declaration signed by the ancillary undertaking to the tenderer and to the contracting authority to make available, for the entire duration of the contract, the necessary resources which the tenderer lacks, cannot be regarded as included in the ESPD. This declaration must be attached to the documentation submitted by the competitor.

(4) an original or certified copy of the contract of use, by virtue of which the auxiliary undertakes, vis-à-vis the tenderer, to provide the requisites and to make available the necessary resources, which must be described in detail, for the entire duration of the contract. To this end, the contract of use shall contain, **under penalty of nullity**, pursuant to Article 104 of the Code, a specification of the requirements provided and the resources made available by the auxiliary; in the case of the provision of educational and professional qualifications and relevant professional experience, the economic operator who directly performs the service for which such skills are required must be indicated;

In the case of auxiliary economic operators having their registered office, residence or domicile in the countries included in the so-called "black lists"

5) declaration by the digitally signed auxiliary of the possession of the valid authorization issued pursuant to the Ministerial Decree of 14 December 2010 of the Ministry of Economy and Finance pursuant to (art. 37 of Legislative Decree 78/2010, conv. in law 122/2010) **or** declaration by the digitally signed auxiliary to have submitted an application for authorization pursuant to art. 1 paragraph 3 of the Ministerial Decree of 14.12.2010 with attachment copy of the application for authorisation sent to the Ministry.

In the case of subcontracting, section D is required.

The tenderer, failing which it will not be possible to subcontract, shall indicate the list of services which he intends to subcontract with the relative percentage share of the total amount of the contract.

Part III – Grounds for exclusion

The competitor declares that he/she does not meet the conditions set out in point 6 of these regulations. In addition, the competitor who intends to make the substitute declarations pursuant to Article 94, paragraphs 1 and 2 of the Code also on behalf of the subjects listed in Art. 94, par. 3 of the Code, must preferably use the facsimile A2 form). Only in the event that the legal representative/attorney of the competitor does not intend to make the substitute declarations pursuant to Article 94, paragraphs 1 and 2 of the Code also on behalf of the aforementioned subjects, the latter are required to fill in the declaration pursuant to Article 94, paragraphs 1 and 2 of the Code, preferably using the facsimile Form A3) and attaching a photocopy of the valid identity document.

Part IV – Selection criteria

The competitor declares that he/she meets all the requirements of the selection criteria referred to in points 7.1, 7.2 and 7.3, preferably using the facsimile form A2) or by filling in the following sections of Part IV of the ESPD:

- (a) Section A to declare that the professional competence requirement referred to in point 7.1 of these specifications is met;
- b) Section B to declare the possession of the requirement relating to economic and financial standing referred to in paragraph 7.2 of these specifications;
- (c) Section C to declare that the requirement relating to professional and technical capacity referred to in paragraph 7.3 of these specifications is met.

Part VI – Final Declarations

The competitor shall provide all the required information by filling in the relevant parts.

The ESPD must be submitted:

- in the case of temporary groupings, ordinary consortia, EEIGs, by each of the economic operators participating in the procedure jointly;
- in the case of aggregations of network undertakings by each of the network undertakings, if the entire network participates, or by the joint body and by the individual network undertakings indicated;
- in the case of cooperative consortia, artisan consortia and permanent consortia, by the consortium and the consortium members on whose behalf the consortium competes.

In the event of incorporation, corporate merger or transfer of a business, the declarations referred to in art. 94, par. 1, 2 and art. 98, par. 3, l. f) of the Code, must also refer to the subjects referred to in art. 94, par. 3 of the

Code who have worked with the company that has been merged, merged or sold the company in the year prior to the date of publication of the call for tenders.

15.3 SUPPLEMENTARY DECLARATIONS AND ACCOMPANYING DOCUMENTATION

15.3.1 Additional Statements

Each competitor makes the following declarations, preferably on the facsimile form A2) pursuant to art. 46 and 47 of D.P.R. 445/2000, with which:

1. declares that he/she does not incur the grounds for exclusion referred to in 94(5)(d), (e) of the Code;
1. **bis** hereby declares, with regard to the grounds for exclusion referred to in Article 95:
 - the serious infringements referred to in Article 95(1)(a) committed in the three years preceding the date of publication of the contract notice;
 - the acts by which the Public Prosecutor's Office carries out the criminal prosecution pursuant to Article 407-bis, paragraph 1, of the Code of Criminal Procedure (formulation of the indictment or request for indictment) and the personal or real precautionary measures of the criminal court, if prior to the prosecution, adopted in relation to the alleged commission of the offences referred to in Article 94, paragraph 1 of the Code and the alleged or ascertained commission of the offences referred to in Article 98(4)(h) of the Code, issued in the three years prior to the date of publication of the call for tenders;
 - enforceable sanctions imposed by the Italian Competition Authority or by other sector authorities, adopted in the three years prior to the date of publication of the call for tenders;
 - all other conduct referred to in Article 98 committed within the three years preceding the date of publication of the contract notice.

The above declaration must also be made in the event of a court appeal against the relevant measures.

The economic operator shall declare the existence of the grounds for exclusion that occurred before the submission of the tender and indicate the self-cleaning measures taken, or demonstrate the impossibility of taking such measures before the submission of the tender. The economic operator shall take the self-cleaning measures that it was unable to take before the submission of the tender and those relating to grounds for exclusion that occurred after that time. If the economic operator fails to inform the contracting authority of the existence of the facts and measures which may constitute grounds for exclusion within the meaning of Articles 94 and 95 of the Code and those facts or measures do not appear in the FVOE, the three-year period shall begin to run from the date on which the contracting authority acquired them, rather than by the commission of the act or the adoption of the measure.

2. declares the identification data (name, surname, date and place of birth, tax code, municipality of residence, etc.) of the subjects referred to in 94, paragraph 3 of the Code, or indicates the official database or public register from which the same can be obtained in an updated manner on the date of submission of the bid;

3. Declares the financial offer submitted to be remunerative, since it has taken note of and considered the following in formulating it:

(a) the contractual conditions and charges, including any related obligations relating to safety, insurance, working conditions and social security and assistance, in force at the place where the services are to be provided;

(b) all general, particular and local circumstances, none excluded or excepted, which may have influenced or influence both the provision of the services and the determination of its offer;

4. accepts, without any condition or reservation, all the rules and provisions contained in the tender documentation;

5. agrees to comply with the obligations of traceability of financial flows pursuant to Law no. 136/2010 and accepts the clauses of the Legality Protocol of the Prefecture of Naples, to which the University adhered on 10.12.2021, following resolution of the Board of Directors no. 34 of 27.10.2021, attached to the tender documentation (art. 1, paragraph 17 of Law 190/2012);

5bis. declares to observe and to ensure that its employees and collaborators comply with the aforementioned Legality Protocol, under penalty of exclusion from the tender or termination of the contract;

6. declares that it is aware that the contract is governed by the current Integrated Plan of Activities and Organisation of the University, by the National and University Codes of Conduct available on the www.unina.it website and undertakes, in the event of award, to observe and ensure that its employees and collaborators comply with the aforementioned codes of conduct, as far as applicable, under penalty of termination of the contract;

ARTICLE 7. to be an economic operator referred to in Article 47, paragraph 2 of Legislative Decree 77/2021 and to be required to draw up the report on the situation of personnel, pursuant to Article 46 of Legislative Decree No. 198 of 11 April 2006, as well as to have produced, at the time of submission of the application for participation, a copy of the last report drawn up, with certification of its compliance with the one sent to the company trade union representatives and to the regional councilor of equality pursuant to the second paragraph of the aforementioned Article 46, or, in the event of non-compliance with the terms provided for in paragraph 1 of the same Article 46, with certification of its simultaneous transmission to the company trade union representatives and to the regional equality councilor; That is, to be an economic operator referred to in Article 47, paragraph 3 of Legislative Decree 77/2021 and to employ a number equal to or greater than fifteen employees, committing themselves, within six months of the conclusion of the contract, to deliver to the administration a gender report on the situation of the staff as specified in the aforementioned rule;

8. to have fulfilled, at the time of submission of the bid, the obligations regarding the employment of persons with disabilities referred to in Law no. 68 of 12 March 1999 (art. 47, paragraph 4, Decree-Law 77/2021 converted into Law 108/21);

9.To commit to complying with the specific obligations of the NRRP, including the principle of not doing significant harm to the so-called environmental objectives. "Do No Significant Harm" (DNSH) pursuant to Article 17 of Regulation (EU) 2020/852 of the European Parliament and of the Council of 18 June 2020;

10. For economic operators with registered office, residence or domicile in the countries included in the so-called "black lists": declares to be in possession of a valid authorization issued pursuant to the Ministerial Decree of 14 December 2010 of the Ministry of Economy and Finance pursuant to art. 37 of Legislative Decree 78/2010, conv. in Law 122/2010 **or** declares that he/she has submitted an application for authorization pursuant to art. 1 paragraph 3 of the Ministerial Decree of 14.12.2010 and attaches a certified copy of the application for authorization sent to the Ministry;

11. For non-resident economic operators without a permanent establishment in Italy: undertakes to comply, in the event of an award, with the rules set out in Articles 17, paragraph 2, and 53, paragraph 3 of Presidential Decree 633/1972 and to notify the contracting authority of the appointment of its tax representative, in the forms required by law;

12. indicates the following data: tax domicile; tax code, VAT number; indicates the certified email address **or**, only in the case of competitors based in other Member States, the e-mail address for the purposes of the communications referred to in art. 90, paragraph 1 of the Code;

13. authorize, where a participant in the tendering procedure exercises the right of "access to the documents", the contracting authority to issue a copy of all the documentation submitted for participation in the tendering procedure **or** , if a participant in the tendering procedure exercises the right of "access to the documents", authorizes the contracting authority to issue a copy of the technical tender and of the explanations that may be required during the verification of anomalous tenders, as they are covered by technical/commercial secrecy. This declaration must be adequately motivated and substantiated pursuant to art. 35(4)(a) of the Code; In particular, in order to ensure, on the one hand, adequate protection of the interests of competitors and, on the other hand, compliance with the provisions of art. 35 of Legislative Decree 36/2023 and subsequent amendments without slowing down or aggravating the procedure, it is the responsibility of the competitor who intends to remove individual parts of the technical offer from access by other competitors to attach to the offer a reasoned declaration, proven with appropriate documentation, relating to the possible existence of technical or commercial secrets. Similarly, the competitor who intends to exempt from the right of access certain information contained in the justifications or in the further clarifications, must attach to them a reasoned declaration, substantiated by appropriate documentation, relating to the possible existence of technical or commercial secrets. In this regard, it should be noted that art. 35, paragraph 4, of Legislative Decree 36/2023 and subsequent amendments, in excluding the right of access and any form of disclosure in relation to *'the information provided in the context of the offer or to justify the same, which constitutes, according to the reasoned and proven declaration of the bidder, technical or commercial secrets'* – is in line with the consolidated orientation according to which the prescription contained therein does not refer to generic confidential information, specific to each company, but to specific secrets, such as those deriving from patents or patents.

In this regard, it should be noted that art. Article 98 of the Industrial Property Code defines " *technical and commercial secrets*" as the set of company information and technical-industrial experience, including commercial ones, subject to the legitimate control of its holder and specifies that such information is worthy of protection where: 'a) *it is secret, in the sense that it is not as a whole or in the precise configuration and combination of its elements generally known or easily accessible to experts and operators in the sector;* (b) *have economic value because they are secret;* (c) *are subject, by the persons to whose lawful control they are subject, to such measures as may reasonably be considered appropriate to keep them secret.*' Therefore, the competitor who wishes to remove from access those parts of his technical offer that he intends to keep confidential, must make express reference to the elements listed in Article 98 of the Industrial Property Code, with an explanation, therefore, of their secret nature, the estimate (even approximate) of their economic value, as well as, by documenting it appropriately, the indication of the relative security measures adopted in the company to protect the own *know-how*. In the absence of the above-mentioned reasoned and documented declarations, the Administration will allow the other tenderers access to the full text of the bid and the justifications without making any prior communication to the counter-interested tenderer. In the presence of generic declarations of confidentiality, without justification and documentation, the Administration will allow the other competitors access to the full text of the bid, the justifications, at the same time giving notice, for mere information, to the competitor concerned.

14. Certifies that he/she is informed, pursuant to and for the purposes of Article 13 of Legislative Decree No. 196 of 30 June 2003, that the personal data collected will be processed, including by electronic means, exclusively in the context of this tender, as well as of the existence of the rights referred to in Article 7 of the same Legislative Decree.

For economic operators admitted to the composition with creditors with business continuity pursuant to art. 186 bis of Royal Decree no. 267 of 16 March 1942

15. indicates, in addition to what is indicated in Part III, Section C, letter d) of the ESPD, the following details of the decision to admit to the composition with creditors and of the measure authorizing participation in the tendering procedures with an indication of the tender procedures and of the Court which issued that decision, and declares that it does not participate in the tendering procedure as the agent of a temporary grouping of undertakings and that the other undertakings belonging to the consortium are not subject to insolvency proceedings pursuant to art. 186 *bis*, paragraph 6 of Royal Decree no. 267 of 16 March 1942.

15.4 ACCOMPANYING DOCUMENTATION

The competitor attaches:

- proof of payment of the stamp duty of € 16.00 according to the aforementioned procedures;
- receipt of payment of the ANAC contribution;

- document certifying the provisional guarantee referred to in Article 106 of the Code;
- For economic operators who present the provisional security in a reduced amount, pursuant to art. 106, paragraph 8, of the Code, certified copy of the certification referred to in art. 106 paragraph 8 of the Code which justifies the reduction of the amount of the deposit.

15.4 ADDITIONAL DOCUMENTATION AND DECLARATIONS FOR ASSOCIATED ENTITIES

The declarations referred to in this paragraph shall be signed in accordance with the procedures set out in point 15.

For temporary groupings that have already been formed

- Certified copy of the irrevocable collective mandate with representation conferred on the agent by public deed or notarized private deed.
- Declaration indicating, pursuant to art. 68, paragraph 2 of the Code, the parts of the service, or the percentage in the case of indivisible services, which will be performed by the individual economic operators united or in consortium.

For ordinary consortia or EEIGs already set up

- the deed of incorporation and articles of association of the consortium or EEIG, in certified copy, indicating the person designated as lead partner.
- Declaration indicating, pursuant to art. 68, paragraph 2 of the Code, the parts of the service or the percentage in the case of an indivisible service, which will be carried out by the individual economic operators in the consortium.

For temporary groupings or ordinary consortia or EEIGs not yet established

- Declaration stating:
 - a. the economic operator who, in the event of an award, will be given a special mandate with representation or functions as group leader;
 - b. the commitment, in the event of award, to comply with the regulations in force with regard to temporary groupings or consortia or EEIGs pursuant to art. 68, paragraph 1 of the Code, by conferring a special collective mandate with representation to the member qualified as an agent who will enter into the contract in the name and on behalf of the principals/consortium members;
 - c. Declaration indicating, pursuant to art. 68, paragraph 2 of the Code, the parts of the supply, or the percentage in the case of indivisible supplies, which will be carried out by the individual economic operators united or in consortium.

For aggregations of companies adhering to the network contract: if the network has a common body with power of representation and legal subjectivity

- certified copy or certified copy of the network contract, drawn up by public deed or notarized private deed, or by digitally signed deed pursuant to art. 25 of Legislative Decree no. 82/2005, with an indication of the common body acting on behalf of the network;

- a declaration, signed by the legal representative of the Joint Body, indicating for which companies the network is competing;
- A statement indicating the parts of the supply, i.e. the percentage in the case of indivisible supplies, which will be carried out by the individual economic operators aggregated in the network.

For aggregations of companies adhering to the network contract: if the network has a common body with power of representation but is not legally subject

- certified copy of the network contract, drawn up by public deed or notarized private deed, or by digitally signed deed pursuant to art. 25 of Legislative Decree no. 82/2005, containing the irrevocable collective mandate with representation conferred on the mandated company; If the network contract has been drawn up with a mere digital signature that is not authenticated pursuant to art. 24 of Legislative Decree no. 82/2005, the mandate in the network contract cannot be considered sufficient and it will be mandatory to confer a new mandate in the form of a notarized private deed, also pursuant to art. 25 of Legislative Decree no. 82/2005;
- A statement indicating the parts of the supply, i.e. the percentage in the case of indivisible supplies, which will be carried out by the individual economic operators aggregated in the network.

For aggregations of companies adhering to the network contract: if the network has a common body without the power of representation or if the network does not have a common body, or, if the common body does not meet the required qualification requirements, it participates in the form of the RTI established or constituting:

- **in the case of an established RTI:** certified copy of the network contract, drawn up by public deed or notarized private deed or by digitally signed deed pursuant to art. 25 of Legislative Decree 82/2005 with attached the irrevocable collective mandate with representation conferred on the agent, indicating the person designated as agent and the parties to the supply, or the percentage in the case of indivisible supplies, which will be carried out by the individual economic operators aggregated in the network; If the network contract has been drawn up with a mere digital signature that is not authenticated pursuant to art. 24 of Legislative Decree no. 82/2005, the mandate must take the form of a public deed or a notarized private deed, also pursuant to art. 25 of Legislative Decree no. 82/2005;
- **in the case of RTIs, constituting:** an authentic copy of the network contract, drawn up by public deed or notarized private deed, or by digitally signed deed pursuant to art. 25 of Legislative Decree 82/2005, with attached declarations, made by each competitor adhering to the network contract, certifying:
 - a. which competitor, in the event of being awarded, will be given a special mandate with representation or functions of group leader;
 - b. the commitment, in the event of award, to comply with the regulations in force on temporary groupings;
 - c. the parts of the supply, i.e. the percentage in the case of indivisible supplies, which will be carried out by the individual economic operators aggregated in the network.

The irrevocable collective mandate with representation may be conferred on the agent by private deed.

If the network contract has been drawn up with a mere digital signature that is not authenticated pursuant to art. 24 of Legislative Decree no. 82/2005, the mandate must take the form of a public deed or a notarized private deed, also pursuant to art. 25 of Legislative Decree no. 82/2005.

15.5 DOCUMENTATION IN CASE OF USE

The ancillary undertaking shall make declarations on the fulfilment of the general requirements by filling in the appropriate section of the ESPD. The competitor, for each auxiliary, shall attach:

- 1) the declaration of endorsement;
- 2) the contract of use.

In the case of use aimed at improving the offer, the contract for the use of the contract is presented in the technical offer.

Collaboratively:

Self-declaration for the purpose of verification pursuant to Legislative Decree 159/2011 and subsequent amendments drawn up according to the facsimile Model D), containing:

- Declaration made by all the subjects referred to in art. 85 of Legislative Decree 159/2011 and subsequent amendments, with the indication of the adult family members living together and complete with personal data, tax code and domicile and/or residence.

16. DEED OF COMMITMENT

The deed of commitment, which complies with the form attached to the tender documentation, must be digitally signed by the legal representative of the competitor or by the attorney of the same, appropriate special power of attorney.

By this Act, the competitor declares:

1. to have full knowledge of the Documentation relating to the tender procedure, to accept and comply with them

all the provisions contained therein;

2. to undertake (if it employs a number equal to or greater than fifty employees and is required to draw up the report on the situation of personnel pursuant to Article 46 of Legislative Decree no. 198 of 11 April 2006), to produce, under penalty of exclusion, a copy of the last report drawn up, with certification of its conformity with the one sent to the company trade union representatives and to the regional equality councillor, or, in the event of non-compliance with the terms provided for in paragraph 1 of the same Article 46, with certification of its simultaneous transmission to the company trade union representatives and to the regional equality councillor;

3. to undertake (if it employs a number equal to or greater than fifteen employees and not more than fifty and is not required to draw up a report on the situation of personnel, pursuant to Article 46 of Legislative Decree No 198 of 11 April 2006) to deliver, within six months of the conclusion of the contract, a gender report on the situation of male and female staff in each of the professions and in relation to the state of recruitment, training, professional promotion, levels, changes in category or qualification, other mobility phenomena, the intervention of the Wage Guarantee Fund, dismissals, early retirements and retirements, the remuneration actually paid and to transmit the aforesaid to the company trade union representatives and to the regional equality councillor, under penalty of the application of the penalties referred to in Article 47, paragraph 6 of Decree-Law No. 77 of 31 May 2021, converted with amendments by Law No. 108 of 29 July 2021;

4. to undertake (if it employs fifteen or more employees) to deliver, within six months of the conclusion of the contract, a report clarifying the fulfilment of the obligations imposed on the undertakings by Law no. 68 of 12 March 1999, and illustrating any sanctions and measures imposed on the undertakings in the three years preceding the deadline for the submission of tenders. The economic operator is also required to send the report to the company's trade union representatives, under penalty of the application of the penalties referred to in art. 47, paragraph 6, of Decree-Law No. 77 of 31 May 2021, converted with amendments by Law No. 108 of 29 July 2021; 5. to undertake (in the event of the award of the tender procedure in its favour) to ensure:

- a quota equal to 30% of the recruitments necessary for the execution of the contract or for the implementation of high-quality activities.

related to or instrumental to youth employment (under 36 years of age);

- a quota equal to 30% of the recruitment necessary for the execution of the contract or for the implementation of activities related to it or instrumental to the employment of women.

6. To commit to complying with the specific obligations of the NRRP, including the principle of not causing significant harm to the so-called environmental objectives. "Do No Significant Harm" (DNSH) pursuant to Article 17 of Regulation (EU) 2020/852 of the European Parliament and of the Council of 18 June 2020, as well as with reference to the "Operational Guide" referred to in MEF Circular No. 32 of 30 December 2021.

16.1. Declaration of Beneficial Ownership and Declaration of Absence of Conflict of Interest.

The competitor is required to provide the data necessary for the identification of the beneficial owner of the economic operator itself (pursuant to Article 20 of Law 231/2007) – see MEF Decree of 11.03.2022, no. 55. To this end, a form shall be made available in the tender documents to be completed and signed.

The competitor and the beneficial owner are required to declare the absence of situations of conflict, even potential, of interests in relation to this procedure and to undertake, if such a situation should occur at a later time, to promptly notify the contracting station. To this end, a form shall be made available in the tender documents to be completed and signed.

17. CONTENT OF THE TECHNICAL OFFER

With reference to this procedure, the competitor must, **under penalty of exclusion** from the tender, send and submit to the Administration a ***Technical Offer***, **for each lot in which he intends to participate**, according to the following procedure:

- sending through the System the *digitally signed Technical Report*, which contains a technical-organizational proposal that illustrates, with reference to the evaluation criteria indicated below:

The report should consist of the following parts:

1. **Lot 1** "*Automated mRNA Production System at scale suitable for drug discovery and preclinical development with Critical Reagent Supply and Processing System*" in which the competitor will have to illustrate the characteristics, dimensions and all the accessories of the automated solution for the production of mRNA drugs at scale suitable for drug discovery and preclinical development.

In addition, the competitor will have to deepen and illustrate the topics covered by criteria A-I.

At. Time required, such as manual labor, in front of the machine during a batch production.

B. Yield of mRNA obtained during the production of a specific construct; variety of DNA constructs and complexity supported by process and system.

C. The quality of the mRNA produced, assessed by the percentage of mRNA integrity, its capping efficiency, the length of the Poly-A tail, and the amount of dsRNA and residual plasmid DNA in the final product.

D. Time required for manual work in front of the machine to obtain the final mRNA that meets the quality criteria; reproducibility of the quality attributes of the mRNA produced.

And. Number of different mRNA sequences that can be produced in parallel; range of different batch sizes that can be made by the system.

F. Time required to produce a certain amount of mRNA and meet quality attributes.

G. Footprint of the system and other materials related to the process;

H. Amount of electricity consumed by the system during standby and during production; Amount of water and solvents used to produce a given amount of mRNA; Amount of waste produced by the system.

The. Product contamination, transfer of the final product into the environment, and risk to the operator.

The report should consist of the following parts:

Lot 2 "*Automated System for GMP mRNA production at scale for clinical stages and commercial production with Critical*" in which the competitor will have to illustrate the characteristics, dimensions and all the accessories of the automated solution for the GMP production of mRNA drugs for clinical trials.

In addition, the competitor will have to deepen and illustrate the topics covered by criteria A-K.

- A. Time required, such as manual labor, in front of the machine during a batch production.
- B. Yield of mRNA obtained during the production of a specific construct; variety of DNA constructs and complexity supported by process and system.
- C. The quality of the mRNA produced, assessed by the percentage of mRNA integrity, its capping efficiency, the length of the Poly-A tail, and the amount of dsRNA and residual plasmid DNA in the final product.
- D. Time required for manual work in front of the machine to obtain the final mRNA that meets the quality criteria; reproducibility of the quality attributes of the mRNA produced
- E. Range of different batch sizes feasible by one equipment.
- F. Time required to produce a certain amount of mRNA and meet quality attributes.
- G. Footprint of the system and other materials related to the process;
- H. Amount of electricity consumed by the system during standby and during production; Amount of water and solvents used to produce a given amount of mRNA; Amount of waste produced by the system.
- I. Product contamination, transfer of the final product into the environment, and risk to the operator.
- J. Impact of cost/mg on an annual mRNA production compared to conventional processes.
- K. Number and type of certifications and qualifications provided for the system, process, reagents, and single-use materials.

Each part of the report should contain a specific summary paragraph in the form of a list of the improvements proposed for each individual criterion.

The Report in question, including any technical data sheets and/or information leaflets, drawn up in Times New Roman font size 12 and using line spacing 1, must consist of a maximum of 100 pages (excluded/beyond the cover), for each lot. The Competition Commission will not evaluate pages in excess of those indicated above.

The technical offer must comply with the minimum characteristics set out in the technical document, **under penalty of exclusion** from the tender procedure, in compliance with the principle of equivalence referred to in Article 79 and Annex II.5 to the Code.

The technical offer, **under penalty of exclusion**, must be digitally signed by the legal representative of the competitor or by his attorney.

In the case of associated competitors, the offer must be signed in the manner indicated for the subscription of the application referred to in point 15.

The economic operator shall attach a signed statement containing the details of the tender covered by confidentiality, giving an appropriate explanation of the reasons why any parts of the offer should be kept secret. To this end, the competitor shall also attach a signed copy of the technical report, suitably redacted in the parts deemed to constitute technical and commercial secrets. This is without prejudice to the right of the contracting authority to assess the merits of the reasons given and to ask the competitor to demonstrate the tangible existence of any technical and commercial secrets.

18. CONTENT OF THE ECONOMIC OFFER

With reference to this procedure, the competitor must generate the economic offer **for each lot** directly from the system, according to the following procedure and methods:

1. Insertion in the appropriate section of the System of the **percentage discount on the price** and the **price offered** in figures only; these values will be reported on an offer declaration generated by the System in .pdf "Economic Offer" format, which the competitor must send and send to the Administration through the System after having downloaded and saved it on their PC; (iii) digitally signed.

The Economic Offer contains, under penalty of exclusion, the following elements:

1. Total price;
2. an indication of the percentage discount offered;
3. the following headings:
 - PRF: the price that the competitor offers for each good to be supplied for the lot in which it intends to participate;
 - RPU: percentage discount on the price;
 - PTO: The total price offered.

The average percentage discount (abbreviated RPU) must report a maximum of three decimal places with consequent truncation of the discounts formulated with a greater number of decimal places (example: discount indicated 1.2449% will be understood as 1.244%) and must be formulated on the price that the competitor offers for the realization of the supply - PRF. If the competitor does not indicate the three decimal places, the missing ones will be considered zero (example: discount indicated 1% will mean 1,000%).

If there is no indication of the average percentage discount offered, the competitor will be automatically excluded from the tender.

The Administration, through the Sole Project Manager, will in any case ascertain the adequacy of the Offer, which must be congruous in relation to the provisions of art. 110 of Legislative Decree no. 36/2023 and subsequent amendments and additions.

The economic offer will include the improved supplies offered by the competitor.

Economic offers at or in excess of the basic contract amount are not permitted, even if supplemented by supplies offered by the competitor in increase.

The economic offer, **under penalty of exclusion**, is signed in the manner indicated for the subscription of the application referred to in the previous paragraphs.

Should one or more values indicated by the competitor be found to be discordant with each other, the most convenient one for the Administration will be taken into consideration.

19. AWARD CRITERIA

The award is made according to the criterion of the most economically advantageous offer identified on the basis of the best quality/price ratio pursuant to art. 108 paragraph 1 of Legislative Decree 36/2023

The bids will be judged by a special Commission, on the basis of the evaluation criteria and the relative weighting factors indicated below.

	MAXIMUM SCORE
Technical Offer	80
Economic offer	20
TOTAL	100

On the basis of the scores obtained as specified in the following paragraphs, the Selection Board will compile the ranking for the purpose of awarding the contract, given by the sum of the technical score assigned to each competitor (max 80 points) and the economic score attributed to the same competitor (max 20 points). The descriptions and indications given in the report and in everything that is presented in support of the technical offer, will be an integral and substantial part of the offer and therefore the economic operator, if awarded the contract, will be required to guarantee and provide them during the execution of the contract. In this sense, the technical offer submitted by the tenderer will have to consider the economic situation and the expected duration of the contract.

19.1 CRITERIA FOR EVALUATING THE TECHNICAL OFFER

The score of the technical offer is assigned on the basis of the evaluation parameters listed in the table below with the relative distribution of the scores.

In the "Type of parameter" column, it is indicated whether the relative points are attributed:

- by reason of the exercise of the discretion of the Selection Board (Discretionary scores);
- by applying a mathematical formula (Quantitative Scores);
- due to the offer or non-offer of what is specifically requested (Table Scores).

Automated mRNA Production System at scale suitable for drug discovery and preclinical development with Critical Reagent Supply and Processing System – Lot 1



N°	Evaluation parameter	Type of parameter	Max Score
At	The system must automate the production of mRNA batches with consistent quality to reduce human error and provide fast turnaround times.	Tabular	10
B	The system shall demonstrate process efficiency (mRNA yield) on different sizes of mRNA constructs and be adaptable to the specificities of RNA constructs.	Tabular	8
C	The system must produce an RNA that meets the quality criteria (capping efficacy, percentage of integrity, poly-A tail size) and contains nucleic acid impurities (amount of dsRNA and residual DNA) at the lowest possible level.	Discretionary	8
D	The system must ensure reproducible process performance in terms of yield and quality of the final product and limit the number of hours of manual work and operators (human effort).	Discretionary	10
And	The system must provide flexibility, allowing the production of multiple constructs in parallel at the mg scale; or a single construct on a larger scale	Tabular	10
F	The system must deliver the final purified mRNA product with the highest level of quality in the shortest possible time.	Discretionary	10
G	The space required by the solution should be limited as much as possible	Discretionary	8
H	The process must be environmentally friendly, consuming less energy, water, and solvents, and creating less waste.	Discretionary	8
The	The system must avoid contamination of the substance, the environment and the operator.	Discretionary	8
	TOTAL		80

ASSESSMENT CRITERION C

The offer with the best quality criteria (capping efficacy, percentage of integrity, poly-A tail size) and the lowest level of nucleic acid impurities (amount of dsRNA and residual DNA) will be evaluated as the best;

ASSESSMENT CRITERION D

The best offer will be evaluated as offering the best reproducible performance of the process in terms of yield and quality of the final product and able to limit the number of hours of manual work and operators (human effort);

ASSESSMENT CRITERION F

The best offer presenting the final purified mRNA product with the highest level of quality in the shortest possible time will be evaluated;

ASSESSMENT CRITERION G

The best offer will be evaluated if it presents the space required by the solution as limited as possible;

EVALUATION CRITERION H

The most environmentally friendly process, consuming less energy, water and solvents and creating less waste, will be evaluated as the best;

ASSESSMENT CRITERION I

The best offer will be considered if it presents a system that avoids contamination of the substance, the environment and the operator.

Automated System for GMP mRNA production at scale for clinical stages and commercial production with Critical – Lot 2

N°	Evaluation parameter	Type of Parameter	Score
At	The system needs to automate the production of mRNA batches in GMP with consistent quality to reduce human error and provide fast turnaround times.	Tabular	10
B	The system shall demonstrate process efficiency (mRNA yield) on different sizes of mRNA constructs and be adaptable to the specificities of RNA constructs.	Tabular	6



C	The system must produce an RNA that meets the quality criteria (capping efficacy, percentage of integrity, poly-A tail size) and contains nucleic acid impurities (amount of dsRNA and residual DNA) at the lowest possible level.	Discretionary	6
D	The system must ensure reproducible process performance in terms of yield and quality of the final product and limit the number of hours of manual work and operators (human effort).	Discretionary	8
And	The system must guarantee flexibility, allowing the production of batches of different sizes. Production scales must meet the quantities required for clinical development (Phase I, Phase II, Phase III).	Tabular	10
F	The system must deliver the final purified mRNA product with the highest level of quality in the shortest possible time.	Discretionary	8
G	The space required by the solution should be limited as much as possible	Discretionary	8
H	The process must be environmentally friendly, consuming less energy, water, and solvents, and creating less waste.	Discretionary	6
The	The system must avoid contamination of the substance, the environment and the operator.	Discretionary	6
J	The manufacturing process must provide economic benefits in terms of cost/mg or cost/stroke.	Discretionary	6
K	The system is GMP compliant, operates under a quality management system (QMS), and is subject to comprehensive IQ/OQ, FAT, and SAT protocols.	Tabular	6
	TOTAL		80

ASSESSMENT CRITERION C

The offer with the best quality criteria (capping efficacy, percentage of integrity, poly-A tail size) and the lowest level of nucleic acid impurities (amount of dsRNA and residual DNA) will be evaluated as the best;

ASSESSMENT CRITERION D

The best offer will be evaluated as offering the best reproducible performance of the process in terms of yield and quality of the final product and able to limit the number of hours of manual work and operators (human effort);

ASSESSMENT CRITERION F

The best offer presenting the final purified mRNA product with the highest level of quality in the shortest possible time will be evaluated;

ASSESSMENT CRITERION G

The best offer will be evaluated if it presents the space required by the solution as limited as possible;

EVALUATION CRITERION H

The most environmentally friendly process, consuming less energy, water and solvents and creating less waste, will be evaluated as the best;

ASSESSMENT CRITERION I

The best offer will be evaluated if it presents the system capable of avoiding contamination of the substance, the environment and the operator;

ASSESSMENT CRITERION J

The best offer will be evaluated as the production process that can provide economic advantages in terms of cost/mg or cost/stroke.

19.2 METHOD OF ASSIGNING THE COEFFICIENT FOR CALCULATING THE SCORE OF THE TECHNICAL OFFER

With regard to the items to which a **tabular score** identified by column "T" of the table is assigned, the relative score is assigned, automatically and in absolute value, on the basis of the presence or absence in the tender, of the requested element.

Each of the **qualitative elements** to which a discretionary score is assigned in column "D" of the table is assigned a coefficient on the basis of the pairwise comparison method applied to each criterion through the method of transformation into coefficients varying between zero and one of the sum of the values assigned by the individual commissioners, as specified below:

The coefficients, which vary between 0 and 1, for the evaluation of each qualitative element of the various tenders are

determined using the triangular table (see below), where the letters A, B, C, D, E, F,....., N represent the tenders, element by element, of each tenderer.

The table contains as many boxes as there are possible combinations between all the bids taken two by two.

Each commissioner assesses which of the two elements that make up each pair is preferable. In addition, considering that the preference between one element and another can be more or less strong, it assigns a score ranging from 1 (tie), to 2 (minimum preference), to 3 (small preference), to 4 (medium preference), to 5 (large preference), to 6 (maximum preference). In case of uncertainty in the evaluation, intermediate scores are awarded.

In each box, the letter corresponding to the element that has been preferred with the relative degree of preference is placed, and in the event of a tie, the letters of the two elements in comparison are placed in the box, assigning a point to both.

	B	C	D	E	F	N
At							
B							
C							
D							
E							
A							
...							
N - 1							

Maximum preference	= 6
Large preference	= 5
Medium preference	= 4
Small preference	= 3
Minimum preference	= 2
parity	= 1

For the purposes of determining the coefficients relating to the qualitative evaluation elements for the aforementioned criteria, if the tenders to be evaluated are less than three, it should be noted that they will be determined by means of the average of the coefficients assigned at the discretion of the individual commissioners. In this case, the evaluation of the criteria will take place with the attribution of a score by the individual commissioners that will vary from "excellent", "good", "sufficient", "minimum", "absolutely not adequate", based on the level of professionalism that best meets the objective of guaranteeing the performance of the task in the highest compliance with quality standards and the best organizational conception and technical-organizational structure offered. In particular, the Commission, at its sole discretion, will evaluate the bids by assigning the score to each evaluation criterion, according to the following parameters:

Evaluation	Description	Score Weight
Very good	The requirement is dealt with in a completely exhaustive way and what is proposed responds in an absolutely improved way to expectations.	1



Good	The requirement is dealt with comprehensively and what is proposed fully meets expectations	0,75
Sufficient	The requirement is dealt with in an acceptable manner and what is proposed satisfactorily meets expectations	0,50
Minimum	The requirement is barely sufficiently dealt with and what is proposed is barely adequate to meet expectations	0,25
Absolutely inadequate	Absolutely inadequate	0

In the event that a technical offer is partial, due to the failure to submit improvement proposals relating to one or more of the evaluation criteria, the relative competitor is mandatorily assigned the coefficient "zero" in correspondence with the evaluation criterion not presented, and the same criterion not presented is not subject to evaluation.

For the purpose of evaluating tenders, scores will be expressed to two decimal places, rounded to the next unit if the third decimal place is equal to or greater than five.

This criterion will be used for all the mathematical operations carried out for the attribution of scores to all elements of the Offer.

At the end of the pair comparisons, the commission will assign the scores relating to the individual criteria on the basis of the following criterion:

- For each commissioner, the sum of the coefficients assigned by means of the "pairwise comparison" is transformed into coefficients varying between zero and one and the average of the coefficients of each commissioner is calculated, attributing one to the competitor who obtained the highest average coefficient and to the other competitors a score consequently proportional to the coefficient achieved.

The sum of the scores obtained in this phase will be used for the evaluation of the anomaly of the offer.

At the end of the evaluation process and the definition of the ranking of the qualitative elements, the Commission will proceed to adjust the scores for each criterion, assigning the maximum score of the criterion to the economic operator that has obtained the maximum score of the tender, and to the second competitor by proportionally adjusting the score obtained by the same with respect to the best one.

More specifically, the reparation will take place on the single criterion, with the aim being that the best offer, obtains the maximum partial score provided.

19.2 CRITERIA FOR ASSIGNING ECONOMIC POINTS

As far as the economic offer is concerned, a coefficient is attributed to the economic element, varying from zero to one, calculated by:

Linear Interpolation Formula

$$There = Ra/Rmax$$

where:

There = coefficient attributed to the *i*-th competitor;

Ra = percentage discount of the offer of the *i*-th competitor;

Rmax = Percentage discount of the cheapest offer

19.4 METHOD FOR CALCULATING FINAL SCORES

Once the coefficients have been assigned, the Commission will proceed, in relation to each bid, to assign the scores for each individual criterion according to the following method: AGGREGATIVE COMPENSATOR.

The score is given by the following formula:

$$Pi = Cai \times Pa + Cbi \times Pb + \dots + Cni \times Pn$$

Where:

Pi = concurrent score i;

Cai = coefficient of evaluation criterion a, of the competitor i;

Cbi = coefficient of evaluation criterion b, of competitor i;

Cni = coefficient of evaluation criterion n, of the competitor i;

Pa = weight evaluation criterion a;

Pb = weight evaluation criterion b;

Pn = weight evaluation criterion n.

The final score will be given by the sum of the scores assigned to the technical offer and the economic offer.

20. CONDUCT OF TENDER OPERATIONS

The System allows the performance of the competition sessions pre-arranged for the exam:

- administrative documentation;
- technical offers;
- economic offers.

The System guarantees compliance with the provisions of the Code on the confidentiality of transactions and information relating to the tender procedure, as well as compliance with the principles of transparency. It should be noted that each competitor will be able to attend the public sessions by connecting remotely to the System through its own IT infrastructure. Public sessions will be held remotely through the Microsoft Teams application. These operating procedures will be used for all public sessions of the Competition Seat and the Competition Commission. It should be noted that each competitor will be able to attend the public session by connecting to the link indicated in the notice of the public session. It should be noted that it is necessary to

identify the delegates of the economic operators who intend to attend the meeting by uploading the proxy and a photocopy of an identification document to the email address dip.farmacia@unina.it.

Notices of all public sessions will be announced by the Administration through a notice published on the University Notice Board and in the Competitions section, on the University website www.unina.it, as well as by communication made to competitors on the website www.acquistinretepa.it with even one day's notice. Therefore, competitors are invited to consult the website constantly. In the event that it is necessary to postpone this date, notice of the postponement will be given by notice with at least one day's notice by means of communication made to the competitors on the www.acquistinretepa.it website and on the website www.unina.it at the link of the tender procedure

22. CONDUCT OF TENDER OPERATIONS: VERIFICATION OF ADMINISTRATIVE DOCUMENTATION

On the day and at the time indicated in the attached Announcement, a competition station will proceed, in public session, operating through the System, to carry out the following activities:

- (a) verification of the receipt of tenders submitted in good time. The timeliness of the receipt of the offers and that the same offers are composed of Administrative Documentation, Technical Offer, Economic Offer and Time Offer is verified by the presence of the same offers in the System since, as better established in the previous paragraphs, any untimely and incomplete offers (i.e., lacking one or more necessary and mandatory parts) are not accepted by the System itself and therefore no offer is present at the same time. System;
- b) subsequently, the tender station will proceed through the System to open the bids submitted and, therefore, to access the area containing the "Administrative Documentation" of each individual bid submitted, while the Technical Bids, the Economic Bids will remain secret, closed/blocked to the System and, therefore, the related content will not be visible either to the Office or to the Tender Commission, neither to the Department of Pharmacy of the University of Naples Federico II, nor to Consip S.p.A., nor to competitors, nor to third parties; therefore, the System will allow access to the administrative documentation and the tender station responsible for examining the administrative documentation will proceed to verify the presence of the documents requested and contained therein;
- c) verify the compliance of the administrative documentation with the requirements of these specifications;
- d) activate the procedure for any preliminary assistance;
- e) draw up, through the Rogante Officer of the University or his deputy, a specific report relating to the activities carried out;
- (f) adopt the measure determining the exclusions and admissions from the tender procedure.

The system will proceed to carry out the communications referred to in art. 90(1)(d) of the Code.

The inclusion of price elements in documents contained in the administrative documentation results in **the exclusion of the tenderer from the tendering procedure**. The Competition Seat will proceed as indicated above in letter f).

It should be noted that each competitor will be able to attend the public session by connecting to the link provided with public notice. It should be noted that it is necessary to identify the delegates of the economic operators who intend to attend the meeting by sending the proxy and a photocopy of an identification document through the System (Communications with suppliers' section) or to the **certified email address: dip.farmacia@pec.unina.it**.

This is without prejudice to the possibility of requiring the tenderer, at any time during the procedure, to submit all or part of the additional documents, if this is necessary to ensure the proper conduct of the procedure.

The verification of the administrative documentation will take place, pursuant to art. 24 of the Code, through the use of the FVOE 2.0 system, made available by ANAC.

For the purposes of registration with the FVOE, non-resident Economic Operators without a permanent establishment in Italy must have a certified e-mail address or a similar tool in other Member States.

21. SELECTION BOARD

The Selection Board is appointed, pursuant to art. 93 of the Code, after the expiry of the deadline for the submission of tenders and is composed of 3 members (two of whom are professors, researchers of the Federico II University of Naples, with skills and professionalism in the sector covered by the contract), experts in the specific sector to which the subject of the contract refers. There must be no grounds for the commissioners to prevent their appointment pursuant to art. 93, paragraph 5 of the Code. To this end, they issue the declarations required for this purpose by the current Integrated Plan of Activities and Organization of the University.

The Selection Board is responsible for the evaluation of the technical and economic offers of the competitors and aids the RUP in the evaluation of the adequacy of the technical offers and must conclude its work as follows:

Number of bids received	Number of days allotted for evaluation
1 to 5 offers	Total days 15
From 5 offers to 10 offers	Total 20 days

If the number of Bids to be examined is higher than the maximum indicated in the Table above, the undersigned will evaluate and communicate the time to be assigned to the Commission for the conclusion of its work. This period may be extended only once at the reasoned request of the President of the Commission.

22. OPENING AND EVALUATION OF TECHNICAL AND ECONOMIC OFFERS

At the end of the examination of the administrative documentation, the Selection Committee, in a public session, the date of which will be communicated to the competitors admitted through the System, will proceed to open the technical offer and verify the presence of the documents required by these specifications.

For the procedures for carrying out public sessions, reference should be made to the provisions of Article 19 above.

In one or more reserved sessions, to be carried out in accordance with the operating procedures referred to in art. 19, the commission will proceed with the examination and evaluation of the technical offers submitted and the assignment of the relative scores by applying the criteria and formulas indicated in the announcement and in these specifications.

Subsequently, the Commission will proceed, in a session open to the public, the date of which will be communicated in advance through the System to the admitted competitors, as well as through publication on the University website at the opening of the Economic Offers.

In the same session open to the public, the Commission will make visible to competitors through the System:

- (a) the "technical scores" (PT) awarded to the individual technical tenders submitted for each lot;
- (b) as a result of the unblocking and opening of economic tenders, the percentage discount offered by competitors. The relevant evaluation will be carried out automatically by the system, according to the procedures described in point 18;

The fulfilment of the obligations referred to in art. 90, paragraph 1, letter d) of the Code will be delegated to the RUP which will proceed through the system. The contracting authority will then proceed to identify the single final numerical parameter for the formulation of the ranking, pursuant to art. 108, paragraph 4 of the Code.

In the event that the bids of two or more competitors obtain the same overall score, but different partial scores, the competitor who has obtained the best score on the technical offer will be placed first in the ranking. In the event that the bids of two or more competitors obtain the same overall score and the same partial scores, the procedure will be carried out in accordance with art. 77 of R.D. 827/1924 and, in the alternative, by drawing lots in public session. If a competitor or an auxiliary company has declared the existence of a situation of control within the meaning of art. 2359 of the Italian Civil Code with another competitor, the Commission, after the aforementioned public session, will proceed, in a subsequent private session, to the relevant checks, with admission to the continuation or exclusion of the competitors involved. In this case, the documentation necessary for verification will be requested through the system (or by certified email). The results of the audit will be communicated in a subsequent public session.

At the end of the above operations, the commission, in a public session, draws up the ranking list and proceeds in accordance with the provisions of point 23. If you identify offers that exceed the anomaly threshold referred to in art. 110 of the Code, and in any other case in which, on the basis of specific elements, the bid appears abnormally low, the commission closes the public session by notifying the RUP, which will proceed as indicated

in paragraph 22 below. At any stage of the evaluation of technical and economic offers, the commission shall promptly communicate any exclusions to be ordered for:

- **failure to separate the economic offer and the time offer from the technical offer, or the inclusion of elements concerning the price in documents contained in the technical offer;**
- **submission of partial, multiple, conditional or alternative offers;**
- **submission of inadmissible bids, pursuant to art. 70, paragraph 4 of the Code.**

At any stage of the tender process, the Tender Chair shall promptly communicate, through the Office responsible for the tender procedure, pursuant to Article 90(1) of the Code, the cases of **exclusion** for:

- submission of partial, multiple, conditional or alternative offers;
- submission of inadmissible tenders.

24. VERIFICATION OF ANOMALY OF THE OFFERS

If the conditions set out in art. 110 of the Code and in any other case in which, on the basis of specific elements, the tender appears abnormally low, the RUP, making use, if deemed necessary, of the commission, assesses the adequacy, seriousness, sustainability and feasibility of the offers that appear abnormally low.

We proceed to check the first best abnormally low bid. If this offer is anomalous, the same procedure is used for subsequent bids, until the best bid deemed not anomalous is identified. The contracting authority shall have the right to proceed at the same time to verify the adequacy of all abnormally low tenders.

The RUP shall request the tenderer to submit written explanations in writing, indicating where appropriate the specific components of the tender deemed to be anomalous.

To this end, it shall set a deadline of not less than fifteen days from receipt of the request.

The RUP, with the support of the Commission, examines the explanations provided by the tenderer in a confidential session and, if it considers them insufficient to rule out the anomaly, may request, also by means of an oral hearing, further clarifications, assigning a maximum deadline for response.

The results of the RUP's evaluations are transmitted to the Tender Committee, which will make them known in a subsequent public session, as specified in paragraph 25 below.

25. AWARD OF THE CONTRACT AND CONCLUSION OF THE CONTRACT

The award proposal is made by the Selection Board in favor of the tenderer who has submitted the best tender. With this fulfilment, the Commission closes the tendering operations.

If there has been verification of the adequacy of the anomalous bids referred to in Article 22 by the Single Project Manager, the results of the checks carried out by the latter shall be transmitted to the Commission, which shall take the consequent decisions in public session.

If no offer is convenient or suitable in relation to the object of the contract, the Administration reserves the right not to proceed with the award pursuant to art. 108, par. 10 of the Code.

The Administration reserves the right to award the tender even if only one bid is received within the submission deadline, as well as to suspend, re-call and/or not award the tender for reasons.

The Administration also reserves the right not to enter into the contract and not to authorize subcontracting or subcontracting if, downstream of the checks referred to in the combined provisions of art. 84 and 91 of Legislative Decree 159/2011 (Anti-Mafia Code), the application of the measures referred to in art. 67 of the aforementioned code or any attempts at mafia infiltration.

The verification of the general and special requirements will take place, pursuant to art. 99 of the Code, on the tenderer to whom the contracting authority has decided to award the contract.

Prior to the award, the Administration shall:

1) request, pursuant to art. 90 of the Code, to the competitor to whom he has decided to award the tender the documents, for the purpose of proving the absence of the grounds for exclusion referred to in art. 94 et seq. of the Code (with the exception, with reference to subcontractors, of Article 94, paragraph 6 of the Code) and compliance with the selection criteria referred to in Art. 100 of the same Code. The acquisition of the aforementioned documents will take place through the use of the FVOE system.

2) request - if the fairness of the offer has not been verified - the documents necessary for the verification referred to in art. 110 of the Code of Competence of the Project Manager.

The competent body, subject to approval of the relevant award proposal, pursuant to art. 17, paragraph 5 of the Code, awards the tender.

Starting from the award, the contracting authority shall, within five days, proceed with the communications referred to in art. 90(1)(b) and (c) of the Code.

The award becomes effective, pursuant to art. 17, paragraph 5 of the Code upon positive outcome of the verification of the possession of the requirements referred to in no. 1 above).

Pursuant to Article 17, paragraph 8 of the Code, the Administration may authorize the execution of the contract as a matter of urgency pending verification of the requirements referred to in Art. 94 and 95 of the Code, as well as the qualification requirements for participation in this procedure.

In the event of a negative outcome of the checks, or failure to prove the requirements, the winning company will be declared forfeited from the award by order of the competent Manager, with reporting of the fact to ANAC and with the right to act for compensation for any further damage.

The Administration will proceed, in the manner indicated above, with regard to the second graduate. In the event that the tender cannot be awarded to the latter either, the Administration will proceed, in the same manner as mentioned above, by scrolling through the ranking.

Pursuant to art. 106, paragraphs 6 and 10 of the Code, the provisional guarantee will be released to the successful bidder automatically at the time of signing the contract; to the other competitors, it will be released promptly and in any case within thirty days from the communication of the award.

Once the award has become effective, the winning company must deliver to the Budget and Accounting Office of the Department of Pharmacy of the University the documentation required for the stipulation of the

contract, within the deadline indicated by the Administration, starting from the date of receipt, by certified email, of the relevant communication.

The stipulation of the contract is subject to the positive outcome of the checks provided for by current legislation on the fight against the mafia (Legislative Decree 159/2011 so-called Anti-Mafia Code), without prejudice to the provisions of art. 88 paragraph 4-bis and 89 and art. 92 paragraph 3 of Legislative Decree no. 159/2011. In particular, the current legislation on the fight against the mafia (Legislative Decree 159/2011 so-called Anti-Mafia Code) applies. In addition, pursuant to the provisions of Article 3 of Law No. 120 of 11 September 2020, converting Decree-Law No. 76, following consultation of the database, the contracting authority shall proceed with the stipulation of the contract for which the provisional release information is issued, provided that the situations referred to in Articles 67 and 84 do not arise with regard to the subjects subject to anti-mafia checks, paragraph 4(a), (b) and (c) of Legislative Decree no. 159 of 6 September 2011.

The stipulation of the contract, pursuant to the provisions of the aforementioned article, will be subject to a termination condition, without prejudice to further checks for the purpose of issuing anti-mafia documentation to be completed within sixty days.

This is without prejudice to the subsequent withdrawal from the contract if elements relating to mafia infiltration attempts are subsequently ascertained pursuant to art. 92, paragraph 4 of Legislative Decree no. 159/2011.

The contract, pursuant to Section 18, paragraph 3 of the Code, may not be entered into before 35 days (*stand still*) from the sending of the last of the aforementioned award notices.

The stipulation must take place, pursuant to art. 18, paragraph 2 of the Code, within the following 60 days from the effective date of the award, without prejudice to the exercise of the powers of self-protection in the cases permitted by the regulations in force and without prejudice to the hypothesis of deferral expressly agreed with the successful tenderer, provided that it is in any case justified by the interest in the prompt execution of the contract.

At the time of stipulation of the contract, the successful bidder must present the final guarantee to be calculated on the contract amount, in accordance with the measures and procedures provided for by art. 117 of the Code.

The contract is stipulated electronically, in public administrative form by the Rogue Officer or his deputy, in case of absence or impediment. It should be noted that an express termination clause will be included in the contract relating to the hypothesis of annulment of the award following a court order. In addition, the contract will contain a specific clause by which the contractor declares to have read and become aware of the aforementioned acts and to be aware of the right for the University to terminate the contract in the event of violation of the obligations deriving from the National and University Codes of Conduct. It should also be noted that a specific '*anti-pantouflage*' clause will be included in the contract in accordance with the provisions of the current Integrated Plan of University Activities and Organization.

The successful tenderer shall file, before or at the same time as the signing of the contract, the continuous cooperation, service and/or supply contracts referred to in art. 119, paragraph 3, letter d) of the Code.

If the documentation required for the stipulation of the contract is not complete or complies with what is required or is not received within the deadline established in the Administration's request sent by certified email, without prejudice to the Administration's right to request additional documentation and grant extensions for specific and proven needs - in any case within the limits of compatibility with any emergencies of the Administration - the winning company will be declared forfeited from the award and the Administration reserves the right to award the contract to the second company in the ranking and to take action for compensation for any further damage.

The contract is subject to the obligations regarding the traceability of financial flows pursuant to Law no. 136 of 13 August 2010.

Pursuant to art. 119, paragraph 2 of the Code, the contractor shall communicate, for each sub-contract that does not constitute a subcontract, the amount and object of the same, as well as the name of the sub-contractor, before the start of the service.

In the cases referred to in art. 124, paragraph 1 of the Code, the contracting authority shall progressively consult the parties who have participated in the tender procedure, resulting from the relative ranking, in order to stipulate a new contract for the assignment of the assignment or for the completion of the service.

The expenses relating to the publication of the notice and the notice on the results of the award procedure, pursuant to art. 225, paragraph 1 of the Code and of the Ministerial Decree of 2 December 2016 (OJ 25.1.2017 n. 20), will be reimbursed by the successful bidder to the contracting authority within sixty days of the Administration's request, the contracting authority will communicate to the successful bidders the actual amount of the aforementioned expenses, providing the supporting documents, as well as the related payment methods. The successful bidder shall also be responsible for all contractual expenses, tax charges such as taxes and duties - including registration fees where due - relating to the conclusion of the contract.

Finally, it should be noted that, in implementation of the provisions of the current Integrated Plan of Activities and Organisation of the University, the conditions for carrying out the service offered by the successful bidder will be published on the University website (after verification of the reasoned and documented declarations made at the time of the bid regarding the presence of technical or commercial secrets).

26. OBLIGATIONS RELATING TO THE TRACEABILITY OF FINANCIAL FLOWS

The contract is subject to the obligations regarding the traceability of financial flows pursuant to Law no. 136 of 13 August 2010.

The contractor must inform the contracting authority:

- the identification details of the dedicated bank or postal accounts, with an indication of the work/service/supply to which they are dedicated;
- the personal details and tax code of the persons delegated to operate on them;

- any changes to the data transmitted.

The notification must be made within seven days of the opening of the current account or, in the case of existing current accounts, of their first use in financial transactions relating to a public contract. In the case of legal persons, the communication in question must be signed by a legal representative or by a person with a specific power of attorney. Omitted, late or incomplete communication of information will result in the application of an administrative fine of between 500 and 3,000 euros to be imposed on the defaulting party. Failure to comply with the obligations for the traceability of the financial flows relating to the contract will result in the termination of the contract by law.

On the occasion of each payment to the contractor or subsequent control interventions, the fulfilment of the obligations relating to the traceability of financial flows is verified.

The contract is subject to the condition of termination in all cases in which the transactions have been carried out without the use of banks or Poste Italiane S.p.a. companies or even without instruments other than bank or postal transfer that are suitable to guarantee full traceability of the transactions for the consideration due under this contract.

27. CODE OF CONDUCT

In carrying out the activities covered by the contract, the successful bidder of each lot must comply with the principles and, as far as compatible, the duties of conduct referred to in the Decree of the President of the Republic of 13 June 2023 no. 81 and in the Code of Conduct of this contracting authority and in the University Integrity and Organisation Plan.

Following the notification of the award and before the contract is signed, the successful bidder of each lot is responsible for viewing the aforementioned documents published on the contracting authority's website.

28. ACCESS TO DOCUMENTS

Access to the documents of the procedure is ensured digitally through the direct acquisition of the data and information entered in the e-procurement platforms, in compliance with the provisions of Article 35 of the Code and the current provisions on the right of access to administrative documents, in accordance with the procedures indicated in Article 36 of the Code.

29. SETTLEMENT OF DISPUTES

Disputes arising from the contract are subject to the jurisdiction of the Court of Naples, with the possibility of arbitration expressly excluded.

30. PROCESSING OF PERSONAL DATA

Pursuant to art. 13 of EU Regulation no. 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (hereinafter also referred to as the "EU

Regulation" or "GDPR"), the Administration provides the following information on the processing of personal data.

Purpose of the processing

- The data provided by the competitors are collected and processed by the Administration to verify the existence of the requirements required by law for the purposes of participation in the tender and, in particular, for the purpose of verifying the administrative and technical-economic capacities of these subjects, as well as for the purposes of awarding, in compliance with precise legal obligations deriving from the legislation on public procurement and contracts;
- The data provided by the successful bidder are acquired by the Administration for the purpose of stipulating the Contract, for the fulfilment of the legal obligations connected to it, as well as for the management and economic and administrative execution of the Agreement itself.
- All data acquired by the Administration may also be processed for study and statistical purposes in compliance with the rules set forth in the EU Regulation.

Legal basis and nature of the provision

The Competitor is required to provide the data to the Administration, due to the legal obligations deriving from the legislation on public procurement and contracts. Refusal to provide the data requested by the Administration could determine, depending on the case, the impossibility of admitting the competitor to participate in the tender or its exclusion from it or the forfeiture of the award, as well as the impossibility of stipulating the contract.

Nature of the data processed

The data processed for the purposes specified above are of the following nature: i) common personal data (e.g. personal data and contact details); ii) data relating to criminal convictions and offences (so-called criminal convictions). "judicial") pursuant to art. 10 of the EU Regulation, limited to the sole purpose of assessing the possession of the requirements and qualities provided for by the current applicable legislation for the purposes of participation in the tender and award. On the other hand, data falling within the "special categories of personal data" (so-called "special categories of personal data") are not requested. "sensitive"), pursuant to art. 9 EU Regulation.

Methods of data processing

The processing of data will be carried out by the Administration in such a way as to guarantee the necessary security and confidentiality and may be carried out using manual, paper, computer and telematic tools suitable for processing the data in compliance with the security measures provided for by the EU Regulation.

Scope of communication and dissemination of data

The data may be:

- processed by the staff of the Administration that takes care of the tender procedure and the execution of the Contract, by the staff of other offices of the same that carry out related activities, as well as by the offices that deal with activities for study and statistical purposes;

- communicated to self-employed collaborators, professionals, consultants, who provide advice or assistance to the Administration with regard to the tender procedure and the execution of the Contract, also for any protection in court, or for sector studies or statistical purposes;
- communicated to any external parties, who are part of the Adjudication and Testing Commissions that will be set up from time to time;
- communicated to other competitors who request access to the tender documents within the limits allowed pursuant to Law no. 241 of 7 August 1990;
- communicated to the National Anti-Corruption Authority, in compliance with the provisions of AVCP Resolution no. 1 of 10/01/2008.

The name of the successful bidder and the price awarded the contract will be published on the www.unina.it website. In addition to the above, in compliance with the legal obligations that impose administrative transparency (art. 1, paragraph 16, letter b, and paragraph 32 of Law 190/2012; art. 35 of Legislative Decree no. 33/2012; as well as art. 20 of Legislative Decree 36/2023), the competitor/contractor acknowledges and consents that the data and documentation that the law requires to be published, are published and disseminated, under the conditions of the same, through the website www.unina.it, "Transparency" section. The data may be transferred to an international organization, in compliance with legal obligations; in this case, the transfer will take place in compliance with the requirements of the EU Regulation.

Data Retention Period

The data retention period is 10 years from the conclusion of the execution of the Contract, due to the potential legal actions that can be exercised. In addition, the data may be stored, also in aggregate form, for study or statistical purposes in compliance with art. 89 of the EU Regulation.

Automated decision-making

As part of the tender phase, there is no automated decision-making.

Rights of the competitor/data subject

"Data subject" means any natural person whose data is transferred by the competitor to the Administration. The interested party is entitled to the rights referred to in Articles 15 to 23 of the EU Regulation. In particular, the interested party has the right to: *i)* obtain, at any time, confirmation as to whether or not personal data concerning him or her are being processed; *iii)* the right of access to their personal data in order to know: the purpose of the processing, the category of data processed, the recipients or categories of recipients to whom the data are or will be communicated, the period of storage of the same or the criteria used to determine this period; *iiii)* the right to request, and if necessary obtain, the rectification and, where possible, the cancellation or, again, the limitation of processing and, finally, the right to object, for legitimate reasons, to their processing; *iv)* the right to data portability, which will be applicable within the limits set out in Article 20 of the EU Regulation.

If, in the event of the exercise of the right of access and related rights, the response to the request is not received within the terms of the law and/or is not satisfactory, the interested party may assert his or her rights

before the judicial authority or by contacting the Guarantor for the protection of personal data by means of a specific complaint, appeal or report.

Data Controller and Data Protection Officer

The Data Controller is the University of Naples Federico II, which has appointed its own Data Protection Officer. Any request regarding the processing of personal data provided and the exercise of rights must be addressed to the Data Protection Officer (DPO) who can be contacted at the following e-mail address: uff.privacy@pec.unina.it.

Consent to the processing of personal data

Having acquired the above information, with the submission of the offer and/or the signing of the Contract, the pro tempore legal representative of the Competitor/successful bidder acknowledges and expressly consents to the processing as defined above of the personal data, including judicial data, concerning him/her. The competitor undertakes to comply with the obligations of information and consent, where necessary, towards the natural persons (Data Subjects) whose personal data are provided as part of the assignment procedure, with regard to the processing of their Personal Data, including judicial data, by the Administration for the purposes described above.

31. DECLARATIONS REQUIRED BY THE CURRENT PIAO

In compliance with the current PIAO cod. id. B12 have been rendered:

- On 12 March 2024 and acquired in the protocol with no. PG/2024/29803 of 12/03/2024 the declarations of the RUP and the Director of the Department of Pharmacy, Prof. Angela Zampella with which it was attested:
 - a) not to be aware of situations of conflict, even potential, of interests provided for by the current Code of Conduct, without prejudice to the obligation to refrain if it becomes aware of them at a later time or in any other case in which there are serious reasons of convenience;
 - b) that he has not been convicted, not even with a sentence that has not become final, for the crimes provided for in Chapter I of Title II of Book Two of the Criminal Code – pursuant to art. 35-bis, paragraph 1, letter c) of Legislative Decree no. 165/2001 and subsequent amendments – and therefore not to be in the conditions of incompatibility referred to in Law no. 190/2012 (the so-called Anti-Corruption Law) and Legislative Decree no. 39/2013;
 - c) to undertake, if one of the conditions of incompatibility or abstention referred to in the aforementioned rules occurs at a time after taking office, to immediately abstain from the office and to promptly notify the Office responsible for the tender procedure;
 - d) not to be in the conditions referred to in art. 16, paragraph 1 of Legislative Decree 36/2023.



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UNIVERSITÀ DEGLI STUDI DI NAPOLI
FEDERICO II

The Director

Prof. Angela Zampella

Department of Pharmacy

Director: Prof. Angela Zampella

Organisational unit responsible for the award procedure:

Budget and Accounting Office

Person in charge: Mariarosaria Persico