

**PNRR Mission 4, Component 2, Investment 1.4 "Strengthening of research and research facilities"
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

Development of gene therapy and drugs with RNA technology

MUR project code: CN00000041 – CUP UNINA: E63C22000940007

UNIVERSITY OF NAPLES FEDERICO II



DEPARTMENT OF PHARMACY

SPECIFICATIONS FOR OPEN PROCEDURE

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. 36/2023 as amended and supplemented 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"*.

CUP: E63C22000940007

CUI: F00876220633202400035

CIG: B3C107603D

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DISCIPLINARY Open procedure with 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. 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"*.

1. PREMISES

With determination to contract no. 1004 of 11/10/2024, this Administration has launched a 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"***.

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, paragraph 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 Development of gene therapy and drugs with RNA technology, with a specific Milestone dedicated to the creation of a plant for the production of therapeutic RNA, intends to purchase an automated system for the production of mRNA with critical supply of reagents and processing system. This requires high-performance instrumentation that can automatically synthesize mRNA at a scale suitable for drug discovery and preclinical development. The mRNA production steps that must be performed automatically and with high repeatability are transcription from a DNA template, 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 assignment in question is financed with resources PNRR Mission 4, Component 2, Investment 1.4 "Strengthening 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" – Investment 1.4 – Notice "National Centres" – D.D.n.3138 of 16 December 2021 corrected with D. Dn. 3175 of 18 December 2021.

The place of delivery of the supply is Department of Pharmacy of the University of Naples Federico II, via Tommaso De Amicis floor -1 (NA) (NUTS code ITF33).

The Sole Project Manager, 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 as amended, nor tenders 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 Sole Project Manager also communicated that: *"Due to the specific type of purchase, there are no minimum environmental criteria (CAM) applicable to the contract"*.

NUTS code: ITF33;

CUPS: E63C22000940007;

CUI: F00876220633202400035

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 the Rules) - in particular, of EU Regulation no. 910/2014 (hereinafter eIDAS Regulation - electronic IDentification Authentication and Signature), of Legislative Decree no. 82/2005 containing the Digital Administration Code (CAD) and of the AGID Guidelines, as well as what has been 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 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 submitting the application, malfunctioning, damages, prejudices to the economic operator, from:

- malfunctions of the equipment and connection systems and programs used by the individual economic operator for connection 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 non-operation or non-operation of the system. correct functioning, considering the seriousness of the same. The contracting authority reserves the right to act in this way even when, excluding the negligence of the economic operator, it is not possible to ascertain the cause of the failure or malfunction. The activities and operations carried out within the System are recorded and attributed to the economic operator and are fully proven against the users of the System. These system recordings are confidential and will not be disclosed to third parties, except by order of the judge or in the event of a legitimate request for access to the records, pursuant to current legislation. The activities and operations carried out within the

System are considered to have been carried out at the time and on the day resulting from the system recordings. The operating system of the System is synchronized on the national time scale referred to in Decree of the Minister of Industry, Commerce and Crafts no. 591 of 30 November 1993, using the 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 not materially attached and available on the website 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, PEC box or in any case a qualified certified electronic delivery service address, as well as connections for access to the Internet, remain the exclusive responsibility of the economic operator. The System is normally accessible 24 hours a day, seven days a week. Access to the System may in any case be slowed down, hindered or prevented due to scheduled maintenance interventions on the System or technical problems, which will, where possible, be reported to users with appropriate notice. 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 attachments, of 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 the provisions of the other parts of these Tender Regulations, the MEF, Consip S.p.A. and the System Operator, each within their respective areas of competence, reserve the right to act for compensation for damages, direct and indirect, patrimonial and image, possibly suffered.

1.2. TECHNICAL EQUIPMENT

For the purposes of participating in this procedure, each economic operator must equip itself, at its own expense, expense and responsibility with technical and IT equipment in accordance with that indicated in these specifications 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:

- 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 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 issued by:
- a body included in the public list of certifiers kept by the Agency for Digital Italy (provided for by Article 29 of Legislative Decree no. 82/05);
- a certifier operating on the basis of a licence or authorisation issued by a Member State of the European Union and meeting the requirements set out in 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 set out in 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 the 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 person, with the necessary powers to commit the economic operator on whose behalf he intends to operate, accesses the System after a specific Registration.

Access to the System is free of charge and is allowed following online identification that 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 an 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 users without the 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, with the registration and, in any case, with the submission of the offer, gives as valid and acknowledges without any dispute what has been put in place within the System by the user attributable to the economic operator himself; 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 Manager (i.e. the entity indicated on the website www.acquistinretepa.it the winner of the public tender procedure carried out for this purpose) also in charge of the technical management services of the IT applications necessary for the functioning of the System, assuming all responsibility in this regard. The System Manager is responsible for checking the main operating parameters of the System itself, reporting any anomalies of 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 suitable 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 report;
- Economic framework;
- Special tender specifications;
- Call for Tenders;
- Tender regulations;
- ESPD;
- Annex A1): Application form;
- Annexes: A2), A3), A4), D);
- Declaration of Legislative Decree no. 231 of 2001;
- DNSH Sheet No. 3;
- Declaration of beneficial owner;

- Declaration of absence of conflict of interest of the beneficial owner;
- Deed of commitment;
- Draft contract;
- Operating instructions for accessing the Platform and technical rules for using the same Rules of the e-Procurement system;
- Code of Conduct for Public Employees;
- University Code of Conduct contained in the current Integrated Plan of Activities and Organization 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>;
- University corruption prevention rules 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 on 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 attempts at criminal infiltration into the legal economy (hereinafter: Legality Protocol), 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 Transparency Administration, Calls for Tenders and Contracts section. If one or more of the above-mentioned documents are not correctly viewable, interested parties can send an immediate report to the Head of the Public Relations Office, via certified email to the address: urp@pec.unina.it.

To read the digitally signed documentation, it is necessary to equip oneself with 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. On these websites, the electronic version of the documentation is available in PDF/Word/Excel format that is not digitally signed. In the event of discrepancy between the two electronic versions, the digitally signed version will prevail.

2.2 CLARIFICATIONS

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

Requests for clarification must be made exclusively in Italian.

Pursuant to art. 88, paragraph 3 of the Code, the responses 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 publication anonymously on the University website.

Telephone clarifications are not allowed.

2.3. COMMUNICATIONS

Pursuant to art. 29 of the Code, the economic operator, with the submission of the offer, automatically elects domicile in the appropriate "Communication 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, to the extent not provided for by the same, 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 indexes 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 companies or ordinary consortia, even if not yet formally established, the communication delivered to the agent/lead partner is considered validly given to all grouped, aggregated or consortium economic operators. In the case of consortia referred to in art. 65, paragraph 2, letters b), c) and d) of the Code, the communication delivered to the consortium is considered validly made to all consortium members. In the event of endorsement, the communication delivered to the tenderer is considered validly made to all auxiliary economic operators.

3. OBJECT, AMOUNT AND SUBDIVISION INTO LOTS

In accordance with art. 58 paragraph 2 of Legislative Decree no. 36/2023, the tender cannot be divided into lots given the technical characteristics of the asset being supplied, which do not allow the subdivision of the instrumentation, therefore it is not possible to proceed with the division of the contract into lots.

Table no. 1 – Description of the lots

Number of lots	Object of the lot	CIG
1	Automated mRNA Production System at scale suitable for drug discovery and preclinical development with Critical Reagent Supply and Processing System;	B3C107603D

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

Table no. 2 – Object of the contract - Lot 1 – CIG B3C107603D

n.	Object of the lot	CPV	P (main)	Amount
1	Automated mRNA Production System at scale suitable for drug discovery and preclinical development with Critical Reagent Supply and Processing System	3800000-5	P	809.261,00 €

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 amount of the tender was calculated by considering the market reference prices between the companies producing the requested good. The basic tender amount was calculated by taking into account the average of those prices.

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

The supply must be made **within 4 months** from the signing of the contract (or from the report of early execution, pursuant to Articles 17 par. 8, 9 of Legislative Decree 36/2023 as amended, and from 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 contingencies and options), is equal to € 847,132.14 € net of VAT and/or other taxes and contributions required by law, including security charges due to zero interference risks and is determined as follows:

- Starting price: € 809,261.00, plus VAT;
- amount for contingencies and options: € 37,871.14, plus VAT.

It should be noted that the above-mentioned maximum estimated value is relevant exclusively for the purposes of quantifying the Contribution in favour of ANAC and has been estimated in compliance with the provisions of art. 14, paragraph 4 of the Code.

5. INDIVIDUAL AND ASSOCIATED ADMITTED SUBJECTS AND CONDITIONS OF PARTICIPATION

Economic operators, including those established in other Member States, may participate in this tender individually or in association, in accordance with the provisions of art. 65 of the Code, provided that they meet the requirements prescribed by the following articles.

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

It is forbidden for competitors to participate in the tender in more than one temporary grouping or ordinary consortium of competitors or aggregation of companies adhering to the network contract (hereinafter, aggregation of network companies).

It is forbidden for the competitor who participates in the tender in a group or ordinary 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 individually or in association.

The consortia referred to in art. 65, paragraph 2 of the Code are required to indicate, at the time of bidding, for which consortium members the consortium is competing; The consortium members designated by the consortium for the execution of the contract cannot, in turn, in cascade, indicate another subject for the execution, except in the case where the consortium member designated is, in turn, a consortium referred to in art. 65, paragraph 2 required by law to indicate, at the time of the bid, the consortium members for which it competes; the latter are prohibited from participating, in any other form, in this tender. In the event of 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 shall apply.

Aggregations between companies adhering to the network contract referred to in art. 65, para., 2 letter g) of the Code, comply with the rules provided for temporary groupings of companies as compatible. Especially:

- a) **In the event that the network has a common body with 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 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 submit a request for participation 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 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 companies participates in the form of a consortium established or constituting, with full application of the relevant rules (cf. ANAC Determination 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 purposes included in the common programme, while the duration of the same must be commensurate with the time taken to complete the contract (cf. ANAC Determination no. 3 of 23 April 2013). The role of principal/agent of a temporary grouping of companies can also be assumed by a consortium referred to in art. 65, paragraph 2, l. b), c) d) and f) or by a sub-association, in the form of an RTI or ordinary consortium established or an aggregation of network companies.

To this end, if the network has a common body with power of representation (with or without legal subjectivity), this body will take on 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 as a going concern may also compete as a joint venture provided that it does not have the status of agent and provided that the other companies belonging to the joint venture are not subject to insolvency proceedings.

6. GENERAL REQUIREMENTS

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

The existence of the automatic causes of exclusion referred to in Article 94 entails direct exclusion, while the existence of the non-automatic causes of exclusion referred to in Article 95 must be ascertained after an adversarial hearing with the economic operator.

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

Economic operators for which there are grounds for exclusion pursuant to 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** are excluded.

Economic operators with headquarters, residence or domicile in the countries included in the so-called "Tax Authorities". **The 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 a valid authorization issued pursuant to 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 converted into Law no. 122/2010) or the application for authorization 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 **grounds 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 signing the contract or subcontract, under penalty of forfeiture of the award, and are as follows:

Clause 1): The undersigned company declares to be aware of and accept the express termination clause which provides for the immediate and automatic termination of the contract, or the revocation of the authorization for subcontracting or subcontracting, should the Prefecture communicate interdictory information pursuant to art. 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 10% of 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 of the issue by the Prefect of information pursuant to Article 1septies, Legislative Decree No. 629 of 6 September 1982, converted by Law No. 726 of 12 October 1982, the Contracting Authority reserves the right to assess at its discretion the opportunity to exclude the company concerned from the aforementioned information from the procedure and from any subcontract, as well as to terminate the contracts in progress.

Clause 2): The undersigned company undertakes to communicate to the contracting authority the list and data of the companies involved in the award plan with regard to the sectors of activity referred to in art. 2 of the Protocol, as well as any subsequent changes for any reason.

Clause 3): The undersigned company undertakes to include in all subcontracts/subcontracts the express termination clause in the event that interdictory 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 that may occur against the entrepreneur, any members of the corporate structure or their families (request for bribes, pressure to direct the hiring of personnel or the assignment of work, supplies, services or similar to certain companies, damage or theft of personal property or on the construction site, etc.). The obligation to report the same facts to the Judicial Authority remains unaffected, as per clause no. 5 below. The aforementioned fulfilment is essential for the performance of the contract and the related non-fulfilment will give rise to the express termination of the contract itself referred to in art. 1456 of the Italian Civil Code.

Clause 5): The undersigned company undertakes to report to the Judicial Authority or to the Police any unlawful request for money, performance or other benefit formulated 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 performance of the contract and the related non-fulfilment will give rise to the express termination of the contract itself referred to in art. 1456 of the Italian Civil Code.

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 execution program of the works in view of the subsequent monitoring of all phases of execution of the work, of the services to be performed and of the subjects who will carry them out, as well as compliance with the obligations deriving from these agreements.

Clause 7): The undersigned company undertakes to ensure that this Protocol is respected by subcontractors/subcontractors, through the inclusion of contractual clauses with similar content to those contained in this contract.

Clause 8): The undersigned company undertakes to include in the subcontracts/subcontracts a clause that makes the acceptance and, therefore, the effectiveness of the assignment of receivables made against 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, against the transferee and to reserve the right to refuse the assignment of the credit made in favour of assignees for whom the Prefecture provides anti-mafia information of a prohibitive 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 secondment of the workforce, as governed by Article 30 of Legislative Decree No. 276 of 10 September 2003, only subject to the authorization of the Contracting Authority for the entry of the 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 Articles 84 and 91 of Legislative Decree 6 September 2011, no. 159, on the posting company. Similar regulations 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 secondment of the workforce.

Clause 10): The contractor undertakes to promptly notify the Prefecture and the judicial authorities of attempts at bribery that have been manifested in any way against the entrepreneur, the corporate bodies or the company managers. The aforementioned fulfilment is essential for the performance of the contract and the

related non-fulfilment will give rise to the express termination of the contract itself, pursuant to art. 1456 of the Civil Code, whenever a precautionary measure has been ordered against public administrators who have exercised functions relating to the stipulation and execution of the contract, or an indictment has been imposed for the offence provided for by art. 317 of the Criminal Code.

Clause 11): The undersigned company declares that it is aware of and accepts the contracting authority and undertakes to avail itself of the express termination clause, referred to in Article 1456 of the Italian Civil Code, whenever a precautionary measure has been ordered against the entrepreneur or the members of the corporate structure, or the managers of the company, or an indictment has been made for any of the crimes referred to in Article 317 of the Italian 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 to be aware of and accept the express termination clause which provides for the immediate and automatic termination of the contract or the revocation of the authorization for subcontracting or subcontracting as well as the application of the administrative fines 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 for allowing full traceability of the transactions, the non-use of which constitutes cause for termination of the contract; In the event of violation of this obligation, without justified reason, a penalty will be applied to the extent of 10% of the value of each individual financial transaction to which the violation 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 placement, 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, in any case, a serious non-compliance: 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 to an extent 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 reported in its own Chamber of Commerce certificates and those of their subcontractors/subcontractors and, in particular, any change that occurs after the production of the certificate itself relating to the subjects referred to in art. 85 and 91, paragraph 4, of Legislative Decree 6 September 2011, no. 159 to be subjected to anti-mafia verification. In the event of violation, the penalties 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 into 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 regulated by art. 19, paragraphs 4 and 5, of the Implementing Regulation of Regional Law no. 3 of 27 February 2007 on "Regulation of public works, services and supplies in Campania Regulation of public works, services and supplies in Campania" aimed at protecting the integrity and legality in the execution phase of works, services and supplies and avoiding the establishment and continuation of contractual relationships with contractors who may be subject to infiltration and unlawful pressure from parties unrelated to the contract or concession relationship, and to facilitate the contractors in reporting facts tending to alter the correct and legal performance of the services, consisting in particular in intimidating or extortionate acts perpetrated against them or against subcontractors and which are referred to below:

- if, during 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, tending to condition or alter the correct and legal performance of the services, represents the situation, without delay and confidentially, to the Prefect responsible for the territory, so that the appropriate investigations can be 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 contractors 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 cause of exclusion occurred before the submission of the tender, the economic operator shall indicate in the ESPD the impediment and, alternatively:

- describes the measures adopted pursuant to art. 96, paragraph 6 of the Code;
- justifies the impossibility of adopting such measures and undertakes 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 tender, the economic operator shall adopt 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 crime or misconduct, proof that you have clarified the facts and circumstances comprehensively by actively cooperating with the investigating authorities, and that you have taken concrete technical, organizational or personnel measures to prevent further criminal or unlawful acts.

If the measures taken are deemed sufficient and timely, the economic operator is not excluded. If these measures are deemed insufficient and untimely, the contracting authority shall communicate the reasons to the economic operator. The economic operator excluded by a final judgment from participating in the award or concession procedures, during the period of exclusion resulting from that judgment, may not make use of self-cleaning.

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

In the case of 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 participation of permanent consortia referred to in Article 65, paragraph 2, letter 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 without the qualification required by these Regulations are inadmissible.

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

(b) compliance, at the time of submission of the offer, with the employment obligations of people with disabilities pursuant to 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 tender, 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 any report already sent to the company trade union representatives and regional equality councilors, or, 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 the Minister of Equal Opportunities and the Family of 29 March 2022). **(d)** the production by economic operators employing a number of employees equal to or greater than fifteen and not exceeding 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 quota equal to 30% of the hires necessary for the execution of the contract or for the implementation of activities connected or instrumental to both female employment 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 PNRR and PNC resources), published in the Official Gazette of 30 December 2021, no. 309;

(f) economic operators employing a number of employees equal to or greater than fifteen and not exceeding fifty, under penalty of exclusion, must not have failed, in the twelve months prior to the deadline for submitting the bid, 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 offer, to comply with the specific obligations of the PNRR, including the principle of not causing significant damage to the so-called "DO NOT SIGNIFICAT 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 "Operational Guide"). 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 no. 55 of 11.03.2022. 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, should such a situation occur 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 by FVOE in accordance with ANAC resolution no. 262/2023.

Pursuant to art. 70, paragraph 4, letter e) of the Code, tenders submitted by tenderers without 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.

The economic operator of another Member State not resident in Italy is required to declare pursuant to the consolidated text of the legislative and regulatory provisions on administrative documentation, referred to in Presidential Decree No. 445 of 28 December 2000, that he is registered in one of the professional or commercial registers referred to in Annex II.11 of Legislative Decree 36/2023.

To prove the requirement in the case of operators based in Italy, the Contracting Authority acquires ex officio the documents in the possession of Public Administrations, 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 not resident in Italy, the operator is required to document the possession of this 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 group/consortium/EEIG, including those 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, subject to 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 three years prior to the publication of the call (years 2021-2022-2023) must be a total of € 809,261.00;

This requirement responds to the interest of the Contracting Authority to contract with a party that is reliable in relation to the specific commitments deriving from participation in the tender and the possible award of the contract.

Proof of the requirement is 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 Form or the VAT Return;
- declaration made, pursuant to and for the purposes of Article 47 of Presidential Decree no. 445/2000, by the person or body responsible for auditing the company, where present (whether it is the Board of Statutory Auditors, the auditor or the auditing firm), certifying the amount (amount) and the 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.

The economic operator, who for justified reasons is unable to submit the required references, may prove its economic and financial standing by means of any other document considered suitable by the contracting authority. In the case of a temporary grouping, consortium, EEIG consortium or network contract undertakings, the overall turnover requirement must be met as a whole and possessed by the temporary consortium 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-year period prior to the date of the month prior to the publication of the notice), **one or more supplies similar to the subject of the contract with a** minimum total amount equal to the amount indicated in the starting price, i.e. **€ 809,261.00**.

Similar supplies shall mean:

- mRNA drug production system milligram scale;

Proof of the requirement is provided:

In the case of supplies provided to public administrations or public bodies by one of the following methods:

- original digitally signed by the signatory, or certified copy digitally signed by the tenderer, of the certificates issued by the contracting administration/body, indicating the subject, amount and period of performance;
- copy of the invoices proving the supply of equipment similar to that subject to this procedure for which they compete;
- contracts entered into with public administrations/public bodies, complete with copies of invoices, receipts or bank documents certifying their payment.

In the case of supplies provided to private customers, by one of the following methods:

- original digitally signed by the subscriber or certified electronic copy of the certificates issued by the private client, indicating the subject, amount and period of execution.
- copy of the invoices proving the supply of equipment similar to that subject to this procedure for which they compete;
- contracts entered into with private individuals, complete with copies of receipted invoices or bank documents certifying their payment.

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 it is established for the similar certification.

The economic operator, who for justified reasons is unable to submit the required references, may prove its capacity by means of any other document considered suitable by the contracting authority.

7.4 INDICATIONS ON SPECIAL REQUIREMENTS IN TEMPORARY GROUPINGS, ORDINARY CONSORTIA, AGGREGATIONS OF NETWORK COMPANIES, EEIGS

The persons referred to in Article 65, paragraph 2, letters e), f), g) and h) of the Code must meet the special requirements within the terms indicated below.

The rules laid down for temporary groupings apply to aggregations of network operators, ordinary consortia and EEIGs.

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 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.

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

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

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

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

(a) Occupational competence requirements

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

(b) Economic, financial and technical-professional capacity requirements

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

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

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

8. ENDORSEMENT

The competitor may make use of technical equipment, human and instrumental resources 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 endorsement contract, the parties shall specify the instrumental and human resources that the auxiliary makes available to the competitor and indicate whether the endorsement is aimed at acquiring the participation requirement or improving the tenderer's offer, or whether 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 him to participate in the same tender, under penalty of exclusion of both parties. Pursuant to Article 372, paragraph 4 of the Business Crisis and Insolvency Code, in order to participate in this procedure between the time of filing the application referred to in Article 40 of the aforementioned Code and the time of filing the decree provided for in Article 47 of the same Code, it is always necessary to avail oneself of the requirements of another person. The endorsement is not necessary in the event of admission to the arrangement with creditors. The tenderer and the auxiliary are jointly and

severally liable towards the contracting authority in relation to the services covered by the contract. Reliance is not allowed to meet the general requirements and registration with the Chamber of Commerce. The use of more than one auxiliary is allowed. The auxiliary may not in turn make use of another person. The auxiliary must: a) meet the requirements set out in Article 6 and declare them by submitting his own ESPD, to be completed in the relevant parts; b) meet the requirements referred to in Article 7.1 letter a), 7.2 letter b) and 7.3 letter c) subject to reliance and declare them in their ESPD, to be completed in the relevant parts; c) undertake, towards the tenderer who makes use of it and towards the contracting authority, to make available, for the entire duration of the contract, the resources (referring to participation and/or bonus requirements) subject to validation.

The competitor shall attach to the application for participation 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 declarations of the auxiliary can be remedied, by means of preliminary assistance. Failure to produce the endorsement contract can be remedied by means of preliminary assistance provided that the contract was stipulated before the deadline for submitting the offer and that this circumstance can be proven with a certain date prior to the deadline for submitting the offer. Failure to indicate the resources made available by the auxiliary company cannot be remedied - and therefore is cause for exclusion from the tender - as a cause of nullity of the endorsement contract. If there are grounds for exclusion for the auxiliary or where it does not meet the special order requirements, the tenderer replaces 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 validation. In the event that the auxiliary has been responsible for a false declaration on the possession of the requirements, the contracting authority shall report to the Authority the conduct of the auxiliary to allow the assessments referred to in Article 96, paragraph 15. The economic operator may indicate another auxiliary within ten days, under penalty of exclusion from the tender. The replacement can only be carried out if it does not lead to a substantial of the offer. Failure to comply with the deadline set for the replacement will result in the exclusion of the competitor.

9. SUBCONTRACTING

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

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

In the absence of indications regarding subcontracting, subcontracting is prohibited. The activities referred to in art. 119, paragraph 3 of the Code.

10. PROVISIONAL WARRANTY

The offer is accompanied by:

1) **a provisional guarantee**, as defined by section 106 of the Code, equal to 2% of the total amount of the procedure, namely the amount equal to the following amount:

- **€ 16,942.64** except as provided for in art. 106, paragraph 8 of the Code;

The guarantee covers the non-award after the award proposal and the failure to sign the contract attributable to any fact attributable to the contractor or consequent to the adoption of interdictory anti-mafia 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 choice of the competitor, in the form of a security or surety:

- a) **The deposit is constituted by crediting**, by bank transfer or with other electronic payment instruments and channels, to the INTESA SANPAOLO SPA FILIALE NAPOLI 40 account - **IBAN IT22J0306903594100000046083** specifying as the reason: Provisional guarantee - **ASP TENDER, the number of the procedure - indicating CIG B3C107603D - the CUP: E63C22000940007, the CUI: F00876220633202400035**; an electronic informed copy of the payment must be submitted to the System with an indication of 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 awarded;
- 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 carry out exclusively or mainly the activity of issuing guarantees and which are subject to the audit by an auditing firm registered in the appropriate register and who 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, paragraph 3 of the Code. In any case, the surety guarantee complies with the standard scheme referred to in art. 117, paragraph 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 by accessing 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-non-entitled/Intermediari_non_abilitati.pdf
- d) <http://www.ivass.it/ivass/impreses.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 subject, the CIG and the CUP;
- 2) be in the name of all the economic operators of the constituted/constituting temporary grouping or ordinary consortium or EEIG, or to all the network companies participating in the tender or, in the case of consortia, to the consortium alone;
- 3) comply with the model scheme approved by Decree of the Minister of Economic Development of 16 September 2022 no. 193;
- 4) be valid for 180 days from the deadline for submitting 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 Civil Code;
 - b. the waiver of the right to object to the start of the terms referred to in art. 1957, paragraph 2, of the 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 the award has not yet been made at the time of its expiry.

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 the surety guarantee, the competitor may produce a new provisional guarantee from another guarantor, replacing the previous one, provided that it is **expressly effective from the date of submission of the offer**.

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 accordance 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 consortia referred to in Article 65(2)(b), (c) and (d) of the Code, if the Consortium has declared at the bid stage that it intends to carry out the activities with its own resources, only if the Consortium has the

aforementioned certification; if the Consortium has indicated at the stage of the bid 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 verification that the provision of the service by the consortium member complies with the standards set by the certification.

b. 50% reduction 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 constituting the group, ordinary consortium or EEIG, or one of the network companies participating in the tender, is in possession of the certification;
- for consortia referred to in Article 65, paragraph 2, letters b), c), d) of the Code, whether 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 the 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 can be remedied by means of preliminary assistance only on condition that it has already been established before the submission of the bid. It is the responsibility of the economic operator to prove that these documents are produced on a date 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 stamping).

The presentation of a guarantee of a lower value or without one or more of the characteristics indicated above (registered only to some participants in the RTI, lack of mandatory clauses, etc.) can also be remedied.

It is not remediable - and therefore is a cause of exclusion - the signing of the provisional guarantee by a person who is not entitled to issue the guarantee or who is not authorised to bind the guarantor.

11. INSPECTION

For the purposes of submitting the offer, no visit to the places is planned.

12. PAYMENT OF THE CONTRIBUTION IN FAVOUR OF 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, in the amount of: **€ 90.00** in compliance with ANAC resolution no. 610 of 19/12/2023 published on the ANAC website in the "tender contributions" section.

The contribution is due according to the amounts described in the table below:

Lot number	CIG	Amount
1	B3C107603D	90,00 euro

Therefore, the taxpayer who is an economic operator who intends to participate in this procedure must generate a payment notice on the pagoPA circuit, through the new "Tender Contribution Management" (GCG) service, and make the payment through the new "Portal of payments of the A. N.AC." The service allows you to generate pagoPA payment notices (identified by the IUUV, Unique Payment Identifier) and to pay them in one of the following ways: "Online payment" through the new 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 for pagoPA (ATMs, home banking applications - CBILL and mobile payment service, points of the monopoly sales network - tobacconists, SISAL and Lottomatica, cash desks set up at large-scale retail outlets, 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 OE. As proof of the payment of the contribution to the 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. N.AC., at the conclusion of the payment transaction with a positive outcome.

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

Payment is verified by the FVOE.

In the event of a negative outcome of the verification, the preliminary assistance procedure is activated. In the event of failure to regularise within the deadline assigned, the tender is declared inadmissible.

The contracting authority ascertains the payment of the fee by consulting the FVOE for the purposes of admission to the tender.

If the payment is not recorded in the system, the contracting authority shall request, by means of preliminary assistance, the presentation of the receipt of payment. An economic operator that does not comply with the request within the deadline 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 until 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 art. 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 preemptory 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, also by providing for 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 seriousness of the non-operation. In the event 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 the offer are allowed to withdraw it and replace it if necessary.

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

The "OFFER" consists of:

A – Administrative documentation;

B – Technical offer;

C – Economic offer.

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
Competitor's ESPD	ESPD - European Single Procurement Document of the Competing Company
Annex 1 – Application form	Application for participation in the tender by the competitor
Annex A2	Supplementary declarations
Annex A3	Supplementary declarations
Annex A4	Supplementary declarations
Deed of commitment	Completed deed of commitment
Beneficial owner	Beneficial Owner Declaration
No beneficial owner conflict	Declaration of no 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 identification document
Coach G	Self-declaration of Legislative Decree 231/2001;
ESPD of the auxiliary and Form A4	ESPD - European Single Procurement Document of the Auxiliary Company and Supplementary Declarations
Model D	Declaration pursuant to Article 85 of Legislative Decree 159/2011
DNSH Tab	DNSH Tab

Payment of the road tax	Proof of payment of stamp duty
Deed of incorporation of RTI or Ordinary Consortium	Any deeds relating to R.T.I. or Consortia
Provisional warranty	Provisional deposit and accompanying documentation
Technical offer	Section II
Technical offer	Technical report
Economic offer	Section III
Economic offer	Economic offer (<i>generated by the system</i>)

On the [www.acquistinretepa.it website](http://www.acquistinretepa.it), in the appropriate section relating to this procedure, the presentation 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 presentation of the OFFER and its submission take place exclusively through the guided procedure provided by the System which can be carried out in successive phases, through the saving of the data and 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 to be consistent 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 presentation 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 compliance with 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 proceeding party, who assumes any risk in the event of non-receipt or late receipt of the OFFER itself, due, by way of example but not limited to, to malfunctions of the telematic tools used, connection and transmission difficulties, slowness of connections, or any other reason, any liability of Consip S.p.A., the System Operator and the Administration is excluded if, due to delay or technical or other errors, or for any reason, the OFFER is not received within the peremptory deadline envisaged.

In any case, without prejudice to the mandatory limits of the law, the competitor exempts Consip S.p.a., the System Manager and the Administration from any liability for malfunctions of any nature, failure to function or interruptions in the operation of the System. Consip S.p.A. reserves the right, however, to adopt 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 the submission of the same is binding on the tenderer;
- within the deadline for submitting the OFFER, those who have submitted an OFFER may withdraw it; a withdrawn OFFER will be equivalent to a non-submitted offer;
- **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 from 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 insert 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 that 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 presents through the System in view only; this modification does not concern the content of the document, nor the original name which remain, in any case, unaltered.

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

The competitor who intends to participate in a joint form (e.g. RTI/Consortia, both established and to be established) must indicate the form of participation and indicate the united or consortium economic operators when submitting the OFFER. The System automatically generates a password dedicated exclusively to the united operators, 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 substitute declarations are drawn up pursuant to Articles 46 and 47 of Presidential Decree 445/2000; for competitors not having their registered office in one of the countries of the European Union, the self-declarations are made by means of equivalent suitable documentation according to the legislation of the country of origin.

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

The documentation, if not expressly requested in original, may be produced in certified copy or in certified copy pursuant to, respectively, art. 18 and 19 of Presidential Decree 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 of origin; art. 100, paragraph 3, of the Code.

All 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 text in a foreign language and the text in Italian, the Italian version will prevail, as it is at the risk of the competitor to ensure the fidelity 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 inadmissible pursuant to art. 70, paragraph 4, letter b) of the Code. The offer will bind the competitor pursuant to art. 17, paragraph 4 of the Code for 180 days from the expiry of the deadline indicated for the submission of the bid. In the event that the tender operations are still in progress on the date of expiry of the validity of the bids, the contracting authority may require the bidders, pursuant to art. 17, paragraph 4 of the Code, to confirm the validity of the bid until the date that will 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 the tenderer's waiver of participation 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, which 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 rectify, by sending a specific communication in the Communications Area containing only the expression of interest in correcting the Technical Offer and/or the Economic Offer. The aforementioned event must be sent only after receipt of the invitation through the Communication Area of the

System. Subsequently, the competitors, who have sent the expression of interest to rectify the Offer in the manner and 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. The aforementioned correction must be received within the deadline that will be indicated in the specific communication of the President of the Commission.

Requests for rectification submitted without the prior expression of interest referred to above or sent after the deadline set in the communication for the scheduling of the meeting for the submission of 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 part. It is understood that the aforementioned correction is carried out in compliance with the secrecy of the offer and cannot involve the submission of a new offer, nor its substantial modification. If the correction is deemed unacceptable because it is substantial, the possibility of declaring the offer inadmissible is assessed.

14. PRELIMINARY ASSISTANCE

With the preliminary assistance procedure referred to in art. 101 of the Code, the deficiencies of the documentation transmitted with the application for participation can be remedied but not those of 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 application for participation and 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 prescribed requirements for participation cannot be remedied by means of preliminary assistance and is cause for exclusion from the tender procedure;
- the omitted or incomplete as well as irregular submission of declarations on the possession of the participation requirements and any other deficiency, incompleteness or irregularity of the application, can be remedied, with the exception of false declarations;
- failure to produce the contract of validation, the provisional guarantee, the special collective mandate or the commitment to confer a collective mandate can 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 for participation, the declarations made and the offer can be remedied;

- failure to indicate the methods by 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 on having 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 councillors, may be remedied; provided that it is drawn up and transmitted before the deadline for the submission of tenders;
- the failure to undertake to ensure, in the event of the award of the contract, the assumption of a quota of youth and female employment cannot be remedied by means of preliminary assistance.

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

In the event of unnecessary expiry of the deadline, the contracting authority shall proceed to 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 deadline set by the contracting authority, which will be not less than five days and more than ten days. The clarifications provided by the economic operator cannot 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 FOR PARTICIPATION

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

The application form must be uploaded to the System.

The competitor indicates the individual or associated form with which the company participates in the tender (single company, consortium, RTI, aggregation of network companies, EEIG).

In the case of participation in RTI, ordinary consortium, aggregation of network companies, EEIG, the competitor provides the identification data (company name, tax code, headquarters) and the role of each company (agent/principal; leader/consortium member).

In the case of a consortium of cooperatives and craft enterprises or a permanent consortium referred to in art. 65, paragraph 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 which consortium member(s) it is competing for, it is understood that the consortium participates in its own name and on its own behalf.

The application is signed with a digital signature:

- in the case of a temporary grouping or ordinary consortium established, by the agent/leader;
- in the case of a temporary grouping or ordinary consortium not yet established, 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 regulations provided for temporary groupings of companies, as compatible.

Especially:

at. if the network has a common body with power of representation and 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 only by the economic operator who performs the function of common body;

b. if the network has a common body with power of representation but is devoid of 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 that participate in the tender;

c. 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 qualification requirements to assume the role of agent, the application for participation must be signed by the company belonging to the network which has the status of agent, or, in the case of participation in the forms of the consortium to be established, by each of the companies adhering to the network contract that participates in the tender; - in the case of a consortium of cooperatives and artisan enterprises or a permanent consortium referred to in art. 65, para. 2 l. b), c), d) and f) of the Code, the application is signed by the consortium itself.

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

- in the case of RTI and ordinary consortia established/being established only by the parent company;
- in the case of permanent consortia referred to in art. 65, paragraph 2 letters 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 shall attach a certified copy to 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 substitute declaration made by the signatory attorney/legal representative certifying the existence of the representative powers resulting from the search.

Method of payment of the vignette

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 in one of the following ways:

- 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 form, with specific indication:

In the part relating to personal data, enter:

- University of Naples Federico II – Department of Pharmacy Naples (NA), CF 00876220633;
- Data of the competitor (name, municipality, registered office, province, tax code);
- description: Stamp duty relating to the application for participation in the tender procedure "**ASP TENDER**", **the number of the procedure - indicating CIG B3C107603D - 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 your name, tax code (if any) and the details of the deed 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 report to the Revenue Agency pursuant to art. 19 of the Presidential Decree no. 642 of 26 October 1972.

15.2 EUROPEAN SINGLE PROCUREMENT DOCUMENT

The competitor fills 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:

Connect 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 a DGUE".
- 3) In the "Upload the document" section

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

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

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

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

Only the following Parts, relating to the 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 **Sec. A - Information on the Economic Operator**, the following clarifications are provided:

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

2) Box "**Registration in official lists**". Here 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 entered.

The possession of a qualification certificate issued by certification bodies (SOAs) pursuant to Article 100 of the Code, as well as by qualification systems in special sectors pursuant to Article 162 of the same Code, must be declared by 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 "Please provide the name of the list or certificate and the relevant registration or certification number, if applicable";
- if the certificate 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";
- where relevant, the qualification categories 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 registration, certification or attestation indicated above does not meet all the required selection criteria, the information to be provided regarding the selection criteria not met in the aforementioned 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)(d) and Article 66(1)(g) of the Code, the ESPD shall be drawn up, separately, by the consortium and the executing consortium members indicated therein. Therefore, the name of the economic operators belonging to a

consortium referred to in the aforementioned Article 65, paragraph 2, letters b), c) d) or of a professional company referred to in the aforementioned Article 66, paragraph 1, letter g) that perform the services covered by the contract must be indicated in this box.

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

With regard to **Section 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 tenderer shall indicate the name of the auxiliary economic operator and the requirements to be used.

In particular, the competitor, for each auxiliary, attaches:

- 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 subject to validation, 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 suitable 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, paragraph 12 of the Code signed with a digital signature by a person with suitable 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 auxiliary undertaking by which the latter undertakes to the tenderer and to the contracting authority to make available, for the entire duration of the contract, the necessary resources that the tenderer lacks cannot be considered to be included in the ESPD. This declaration must be attached to the documentation submitted by the competitor.
- 4) original or certified copy of the contract of validation, by virtue of which the auxiliary undertakes, towards the tenderer, to provide the requirements and to make available the necessary resources, which must be described in detail, for the entire duration of the contract. To this end, the reliance contract contains, **under penalty of nullity**, pursuant to Section 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 relevant educational and professional qualifications and 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 headquarters, residence or domicile in the countries included in the so-called "black lists"

5) digitally signed declaration 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, converted into Law 122/2010) **or** digitally signed declaration of the auxiliary that it has submitted an application for authorization pursuant to art. 1 paragraph 3 of the Ministerial Decree of 14.12.2010 with attached copy of the authorization application sent to the Ministry.

In the event of recourse to subcontracting, the completion of section D is required.

The tenderer, under penalty of being unable to resort to subcontracting, shall indicate the list of services 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 or 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, paragraph 3 of the Code, must preferably use the facsimile form A2). In the only 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 possession of the requirement relating to professional competence referred to in point 7.1 of these specifications;
- b) section B to declare possession of the requirement relating to economic and financial capacity referred to in paragraph 7.2 of these specifications;
- c) section C to declare the possession of the requirement relating to professional and technical capacity referred to in paragraph 7.3 of these specifications.

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 companies, by each of the network companies, if the entire network participates, or by the common body and the individual network companies indicated;
- in the case of cooperative consortia, craft consortia and permanent consortia, by the consortium and by the consortium members on whose behalf the consortium competes.

In the event of incorporation, corporate merger or sale of a business, the declarations referred to in art. 94, par. 1, 2 and art. 98, para. 3, l. f) of the Code, must also refer to the subjects referred to in art. 94, paragraph 3 of the Code who operated at the merged company, 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 Supplementary Declarations

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

1. declares that he/she does not incur the causes of exclusion referred to in Article 94(5)(d) and (e) of the Code;

1.bis states, with regard to the grounds for exclusion referred to in Article 95:

- serious infringements referred to in Article 95(1)(a) committed in the three years prior to the date of publication of the contract notice;
- the acts by which the public prosecutor 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 contract notice;
- the executive sanctioning measures imposed by the Italian Competition Authority or by another sector authority, 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 in the three years prior to the date of publication of the call for tenders.

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

The economic operator declares the existence of the causes of exclusion that occurred before the submission of the tender and indicates the self-cleaning measures adopted, or demonstrates the impossibility of adopting such measures before the submission of the tender. The economic operator shall adopt the self-cleaning measures that it was unable to adopt before the submission of the tender and those relating to causes of exclusion that occurred after that moment. If the economic operator fails to inform the contracting authority of the existence of the facts and measures that may constitute a cause for exclusion pursuant to Articles 94 and 95 of the Code and such facts or measures are not included 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 by 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 economic offer submitted remunerative, since for its formulation it has taken note of and considered:

a) the contractual conditions and charges, including any related ones relating to safety, insurance, working conditions and social security and assistance in force in the place where the services are to be carried out;

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

4. accepts, without 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 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 Organization 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 observe, as far as applicable, the aforementioned codes of conduct, under penalty of termination of the contract;

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 Decree-Law 77/2021 and to employ a number equal to or greater than fifteen employees, committing, 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 complied, at the time of submission of the offer, with the obligations regarding the work of people with disabilities pursuant to Law no. 68 of 12 March 1999 (art. 47, paragraph 4, Legislative Decree 77/2021 converted into Law 108/21);

9. To commit to complying with the specific obligations of the NRRP, including the principle of not causing significant damage 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 headquarters, residence or domicile in the countries included in the so-called "black list": declares to be in 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, converted into Law 122/2010 **or** declares that it 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 authorization application sent to the Ministry;

11. For non-resident economic operators without a permanent establishment in Italy: undertakes to comply, in the event of 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 PEC address **or**, only in the case of competitors based in other Member States, the e-mail address for the purposes of communications pursuant to art. 90, paragraph 1 of the Code;

13. authorizes, if a participant in the tender exercises the right of "access to the documents", the contracting authority to issue a copy of all the documentation submitted for participation in the tender **or** does not authorize, if a participant in the tender exercises the right of "access to the documents", the contracting authority to issue a copy of the technical offer and any explanations that may be requested during the verification of anomalous tenders, as they are covered by technical/commercial secrecy. This declaration must be adequately motivated and proven pursuant to art. 35, paragraph 4, letter 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, compliance with the provisions of art. 35 of Legislative Decree 36/2023 as amended, 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 itself a reasoned declaration, proven by appropriate documentation, relating to the possible existence of technical or commercial secrets. Similarly, the competitor who intends to remove from the right of access certain information contained in the justifications or in the further clarifications, must attach to them a reasoned declaration, proven 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 as amended, in excluding the right of access and any form of disclosure in relation to *'the information provided as part of the offer or in justification of the same, which constitutes, according to the reasoned and proven declaration of the bidder, technical or commercial secrets'* –

is part of the consolidated orientation according to which the prescription contained therein does not refer to generic confidential information, of each company, but to real specific secrets, such as those deriving from patents or property rights. 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 information, 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 known accessible to experts and operators in the sector; b) have economic value as secret; c) are subject, by the persons to whose legitimate control they are subject, to measures that are considered reasonably adequate 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 expressly refer to the elements listed above in Article 98 of the Industrial Property Code, thus explaining their secret nature, the estimate (even approximate) of their economic value, as well as, documenting it appropriately, the indication of the relative security measures adopted in the company to protect the know-how. In the absence of the aforementioned reasoned and documented declarations, the Administration will allow the other competitors access to the full text of the offer and the justifications without making any prior communication to the counter-interested competitor. In the presence of generic declarations of confidentiality, without motivation 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 counterparty competitor.

14. Certifies that it 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 arrangement with creditors with business continuity referred to in 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 DGUE, the following details of the decision of admission to the composition with creditors and of the measure of authorization to participate in the tenders with an indication of the tender procedures and of the Court that issued said measure, as well as declares that it does not participate in the tender as agent of a temporary group of companies and that the other companies belonging to the group are not subject to an insolvency procedure 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 submit the provisional security in a reduced amount, pursuant to art. 106, paragraph 8, of the Code, a 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 PARTIES

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 established

- certified copy of the irrevocable collective mandate with representation conferred on the agent by public deed or authenticated 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 gathered or consortium.

For ordinary consortia or EEIGs already established

- deed of incorporation and statute of the consortium or EEIG, in certified copy, with an indication of the entity designated as leader.
- 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 performed 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 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 EEIG 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 gathered or consortium.

For business combinations 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 authenticated 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;
- declaration, signed by the legal representative of the common body, indicating for which companies the network competes;
- declaration indicating the parts of 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.

For business combinations adhering to the network contract: if the network has a common body with power of representation but is devoid of legal subjectivity

- certified copy of the network contract, drawn up by public deed or authenticated 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 unauthenticated digital signature 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 an authenticated private deed, also pursuant to art. 25 of Legislative Decree no. 82/2005;
- declaration indicating the parts of 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.

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 forms 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 authenticated 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 unauthenticated digital signature pursuant to art. 24 of Legislative Decree no. 82/2005, the mandate must take the form of a public deed or authenticated private deed, also pursuant to art. 25 of Legislative Decree no. 82/2005;
- **in the case of an RTI constituting:** an authentic copy of the network contract, drawn up by public deed or authenticated 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 award, 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 unauthenticated digital signature pursuant to art. 24 of Legislative Decree no. 82/2005, the mandate must take the form of a public deed or authenticated private deed, also pursuant to art. 25 of Legislative Decree no. 82/2005.

15.5 DOCUMENTATION IN THE EVENT OF ENDORSEMENT

The auxiliary undertaking makes declarations on the possession of the general requirements by filling in the appropriate section of the ESPD. The competitor, for each auxiliary, attaches:

- 1) the declaration of validation;
- 2) the contract of validation.

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

Collaboratively:

Substitute declaration aimed at verifying pursuant to Legislative Decree 159/2011 and subsequent amendments drawn up according to the facsimile Form 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 family members of legal age living together and complete with personal data, tax code and domicile and/or residence.

16. DEED OF COMMITMENT

The deed of commitment, punctually compliant with the form attached to the tender documentation, must be digitally signed by the legal representative of the competitor or by the latter's attorney, just special power of attorney.

With this Deed, the competitor declares:

1. to have full knowledge of the Documentation relating to the tender procedure, to accept and comply with it 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 compliance with any report 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 does not exceed 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 aforementioned 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 a number equal to or greater than fifteen) to deliver, within six months of the conclusion of the contract, a report clarifying the fulfilment of the obligations provided for by Law no. 68 of 12 March 1999, and illustrating any sanctions and measures imposed on companies in the three years preceding the deadline for the submission of tenders. The economic operator is also required to transmit the report to the company 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 hires necessary for the execution of the contract or for the implementation of activities in the

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

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

6. to commit to complying with the specific obligations of the PNRR, including the principle of not causing significant damage 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 owner 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 to be completed and signed is made available among the tender documents.

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, should such a situation occur at a later date, to promptly notify the contracting authority. To this end, a form to be completed and signed is made available among the tender documents.

17. CONTENT OF THE TECHNICAL OFFER

With reference to this procedure, the competitor must, **under penalty of exclusion** from the tender, send and send to the Administration a **Technical Offer**, according to the following procedure:

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

The report must consist of the following parts:

"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 features, dimensions and all accessories of the automated solution for the production of mRNA drugs at scale suitable for drug discovery and preclinical development.

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

At. Time required, 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 the process and system.

C. The quality of the mRNA produced, as assessed by the percentage of mRNA integrity, its capping efficiency, the length of the Poly-A tail, and the amount of dsRNA and plasmid DNA remaining 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 produced by the system.

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

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

H. The amount of electricity consumed by the system in 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.

Each part of the report must 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 brochures, drawn up in Times new Roman font size 12 and using line spacing 1, must consist of a maximum of 100 pages (excluding/beyond the cover). The Tender Commission will not evaluate pages exceeding those indicated above.

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

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

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

The economic operator shall attach a signed declaration containing the details of the tender covered by confidentiality, arguing in an appropriate manner the reasons why any parts of the tender are to be secreted. To this end, the tenderer shall also attach a signed copy of the technical report adequately obscured in the parts deemed to constitute technical and commercial secrets. The contracting authority has the right to assess the validity of the reasons given and to ask the tenderer to demonstrate the tangible existence of any technical and commercial secrets.

18. CONTENT OF THE ECONOMIC OFFER

With reference to this procedure, the tenderer must generate the economic offer directly from the system, according to the procedure and methods that follow:

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 *i)* downloaded and saved it on his PC; *ii)* digitally signed.

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

1. total price offered;
2. the indication of the percentage discount offered;
3. the indication of the following items:
 - PRF: the price that the competitor offers for the supply;
 - RPU: percentage discount on the price;
 - PTO: The total price offered.

The average percentage discount (abbreviated RPU) must contain a maximum of three decimal places with the 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 be understood as 1,000%).

If the indication of the average percentage discount offered is completely missing, 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 as amended.

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

Economic offers that are higher than the basic amount of the contract are not allowed, even if supplemented by supplies offered by the competitor in increase.

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

If one or more values indicated by the competitor should be in conflict with each other, the most convenient one for the Administration will be taken into consideration.

19. AWARD CRITERION

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 related 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 Committee will compile the ranking list 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 reported 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 it is awarded the contract, will be required to guarantee and provide them during the execution of the contract. In this sense, the technical offer made by the competitor will have to take into account 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 scores.

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

- due to 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

N°	Rating 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 must demonstrate the efficiency of the process (mRNA yield) on different sizes of mRNA constructs and be adaptable to the specificities of the RNA constructs.	Tabular	8
C	The system must produce RNA that meets the quality criteria (capping efficacy, integrity percentage, 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 and operator work (human effort).	Discretionary	10
And	The system must ensure flexibility, allowing the production of multiple constructs in parallel on a mg scale; or a single construct on a larger scale	Tabular	10

F	The system must deliver the purified mRNA final 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

EVALUATION CRITERION C

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

EVALUATION CRITERION D

The best offer that presents 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) will be evaluated;

EVALUATION CRITERION F

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

EVALUATION CRITERION G

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

EVALUATION CRITERION H

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

EVALUATION CRITERIA I

The best offer that presents a system capable of avoiding contamination of the substance, the environment and the operator will be evaluated.

19.2 METHOD OF ATTRIBUTION OF THE COEFFICIENT FOR THE CALCULATION OF THE SCORE OF THE TECHNICAL OFFER

As for the elements 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 determination of the coefficients, varying between 0 and 1, for the evaluation of each qualitative element of the various tenders is carried out using the triangular table (see ultra), 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 offers taken two by two.

Each commissioner assesses which of the two elements that make up each pair is to be preferred. Furthermore, taking into account that the preference between one element and another can be more or less strong, it gives a score that varies from 1 (parity), to 2 (minimum preference), to 3 (small preference), to 4 (medium preference), to 5 (large preference), to 6 (maximum preference). In the event of uncertainty in the evaluation, intermediate scores are awarded.

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

	B	C	D	And	F	...	N
At							
B							
C							
D							
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 the same will be determined by 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 which will vary from "excellent", "good", "sufficient", "minimum", "absolutely inadequate", 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
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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 in a comprehensive manner and what is proposed fully meets expectations	0,75
Sufficient	The requirement is treated in an acceptable way and what is proposed satisfactorily meets expectations	0,50
Minimum	The requirement is barely dealt with sufficiently and what is proposed is barely adequate to expectations	0,25
Absolutely not adequate	Absolutely not adequate	0

In the event that a technical offer is partial, due to the failure to submit proposals for improvements 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 submitted, and the same criterion not presented is not subject to evaluation.

For the purposes of evaluating the tenders, the scores will be expressed with two decimal places, rounded to the next unit if the third ci between decimals is equal to or greater than five.

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

At the end of the pairs, 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 through the "pairwise comparison" is transformed into coefficients varying between zero and one and the average of the coefficients of each commissioner is calculated by 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 with the reparameterization of the scores for each criterion, assigning the maximum score of the criterion to the economic operator that has obtained the maximum tender score, and to the *i*th competitor, proportionally reparameterizing the score obtained by the same with respect to the best one.

More specifically, the reparameterization will take place on the individual criterion, since it must be obtained that the best offer obtains the maximum partial score envisaged.

19.2 CRITERIA FOR AWARDING THE ECONOMIC SCORE

As regards the economic offer, 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 bid of the *i*-th competitor;
Rmax = percentage discount of the cheapest offer

19.4 METHOD FOR CALCULATING FINAL SCORES

The Committee, once the attribution of the coefficients has been completed, will proceed, in relation to each offer, to assign the scores for each individual criterion according to the following method: COMPENSATORY AGGREGATION.

The score is given by the following formula:

$$P_i = C_{ai} \times P_a + C_{bi} \times P_b + \dots + C_{ni} \times P_n$$

Where:

P_i = competitor score *i*;
 C_{ai} = coefficient of evaluation criterion *a*, of competitor *i*;
 C_{bi} = coefficient evaluation criterion *b*, of competitor *i*;
 C_{ni} = coefficient of evaluation criterion *n*, of competitor *i*;
 P_a = weight evaluation criterion *a*;
 P_b = weight evaluation criterion *b*;
 P_n = 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 competition sessions to be carried out as preordained for the exam:

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

The System ensures compliance with the provisions of the Code regarding 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 their own IT infrastructure. Public sessions will be held remotely through the Microsoft Teams application. These operating methods will be used for all public sessions of the Tender Seat and the Tender Commission. It should be noted that each competitor may 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.

The notices of all public sessions will be made known by the Administration through a notice published on the University Notice Board and in the Tenders section, on the University website www.unina.it, as well as by communication made to the competitors on the www.acquistinretepa.it website with even one day's notice. Therefore, competitors are invited to consult the website regularly. 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 www.unina.it website 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 Notice, a tender station will proceed, in public session, operating through the System, to carry out the following activities:

- a) the verification of the receipt of the tenders submitted in a timely manner. 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 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 in 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 Seat 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 of any preliminary assistance;
- e) to draw up, through the University Rogating Officer or his substitute, a special 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 make the communications referred to in art. 90, paragraph 1, letter d) of the Code. The inclusion of elements concerning the price in documents contained in the administrative documentation determines **the exclusion of the competitor from the tender procedure**. The Tender Seat will proceed as indicated above in letter f).

It should be noted that each competitor may attend the public session by connecting to the link provided with the 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 **PEC address: dip.farmacia@pec.unina.it**.

This is without prejudice to the possibility of asking the tenderer, at any time during the procedure, to submit all or part of the additional documents, if this is necessary to ensure the smooth running 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 registering 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 COMMITTEE

The Selection Committee 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 members chosen from 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. For the commissioners, there must be no causes preventing the 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 Committee is responsible for the evaluation of the technical and economic offers of the competitors and provides support to the RUP in assessing the adequacy of the technical offers and must conclude its work as follows:

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

If the number of Offers to be examined is greater than the maximum indicated in the Table above, the writer will evaluate and communicate the time to be assigned to the Commission for the conclusion of its work. This deadline may be extended only once upon a reasoned request from 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 admitted candidates through the System, will proceed to open the technical offer and verify the presence of the documents required by these regulations.

For the procedures for carrying out public sessions, please refer to the provisions of Article 19 above.

In one or more reserved sessions, to be carried out according to 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 regulations.

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 the competitors through the System:

a) the "technical scores" (PT) attributed to the technical offer submitted.

b) following the activities of unblocking and opening the economic offers, the total price offered and the percentage discount offered by the competitors. The relevant assessment 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 who will proceed through the system. The contracting authority will therefore proceed to identify the only 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 bid 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 pursuant to art. 77 of Royal Decree 827/1924 and, in the alternative, by drawing lots in a public session. If a competitor or an auxiliary undertaking had declared the existence of a situation of control pursuant to art. 2359 of the Italian Civil Code with another competitor, the Commission, after the aforementioned public session, will proceed, in a subsequent reserved 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 verification will be communicated in a subsequent public session.

At the end of the above operations, the commission, in 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 point 22 below. At any stage of the evaluation of the technical and economic offers, the commission shall promptly communicate any exclusions to be made 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 and alternative offers;**
- **submission of inadmissible bids, pursuant to art. 70, paragraph 4 of the Code.**

At any stage of the tender operations, the Tender Seat shall promptly communicate, through the Office responsible for the tender procedure, pursuant to Article 90, paragraph 1 of the Code, the cases of **exclusion** for:

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

24. VERIFICATION OF ANOMALIES IN THE OFFERS

When 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, availing himself, if deemed necessary, of the commission, assesses the adequacy, seriousness, sustainability and feasibility of the tenders that appear abnormally low.

The first best abnormally low bid is verified. If this offer is anomalous, the same procedure is followed for subsequent offers, until the best offer deemed non-anomalous is identified. The contracting authority has the right to proceed at the same time with the verification of the adequacy of all abnormally low tenders.

The RUP shall request the tenderer in writing to submit, in writing, explanations, if necessary indicating the specific components of the tender considered 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 bidder in a confidential session and, if it considers them not sufficient to exclude the anomaly, may request, also by means of an oral hearing, further clarifications, assigning a maximum deadline for the response.

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

25. AWARD OF THE CONTRACT AND CONCLUSION OF THE CONTRACT

The award proposal is formulated by the Selection Committee in favour of the competitor who has submitted the best bid. With this fulfilment, the Commission closes the tender operations.

If there has been verification of the adequacy of the anomalous bids referred to in Article 22 by the Sole 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 subject of the contract, the Administration reserves the right not to proceed with the award pursuant to art. 108, paragraph 10 of the Code.

The Administration reserves the right to award the tender even if there is only one bid received within the submission deadline, as well as to suspend, re-announce and/or not award the tender with good reason.

The Administration also reserves the right not to enter into the contract and not to authorise subcontracting or subcontracting if, following 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.

Before the award, the Administration proceeds to:

- 1) request, pursuant to art. 90 of the Code, to the competitor to whom it 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 art. 94, para. 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 - where the verification of the adequacy of the offer has not been carried out - the documents necessary for the verification referred to in art. 110 of the Code of Competence of the Sole 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 proceed, within five days, with the communications referred to in art. 90, paragraph 1, letters b) and c) of the Code.

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

Pursuant to Article 17, paragraph 8 of the Code, the Administration may authorise the execution of the contract as a matter of urgency pending verification of the requirements referred to in Articles. 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 notification of the fact to ANAC and with the right to take action 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, 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 term 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 the 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 notice is issued, provided that the situations referred to in Articles 67 and 84 do not emerge with regard to the subjects subject to anti-mafia checks, paragraph 4, letters 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 the anti-mafia documentation to be completed within sixty days.

This is without prejudice to the subsequent withdrawal from the contract where elements relating to attempts at mafia infiltration referred to in art. 92, paragraph 4 of Legislative Decree no. 159/2011.

The contract, pursuant to Article 18, paragraph 3 of the Code, cannot be stipulated 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 except in the case of deferral expressly agreed with the successful tenderer, provided that it is in any case justified by the interest in the prompt performance of the contract.

At the time of stipulation of the contract, the successful tenderer must submit the final guarantee to be calculated on the contract amount, according to the measures and procedures provided for by art. 117 of the Code.

The contract is stipulated electronically, in public administrative form by the Rogante Officer or his substitute, 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 with which the contractor declares that he has read and is aware of the aforementioned acts and that he is 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 special '*antipantouflage*' clause will be included in the contract in accordance with the provisions of the University's current Integrated Plan of Activities and Organization.

The successful bidder 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 compliant with what is required or does not arrive 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 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 subcontracting, the amount and object of the same, as well as the name of the subcontractor, before the start of the service.

In the cases referred to in art. 124, paragraph 1 of the Code, the contracting authority progressively consults the parties who 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 no. 20), will be reimbursed by the successful bidder to the contracting authority within sixty days of the request of the Administration, 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 fees - including registration fees where due - relating to the stipulation of the contract.

Finally, it should be noted that, in implementation of the provisions of the University's current Integrated Plan of Activities and Organization, the conditions for carrying out the service offered by the successful bidder will be published on the University website (subject to 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 communicate to the contracting authority:

- the identification details of the dedicated bank or postal current 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 relating to the data transmitted.

The communication 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 the information elements will result in the application of an administrative fine of between 500 and 3,000 euros to the defaulting party.

Failure to comply with the obligations for the traceability of 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 termination condition in all cases in which the transactions have been carried out without making use of banks or Poste Italiane S.p.a. companies or even without instruments other than bank or postal transfers that are suitable for guaranteeing 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 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 no. 81 of 13 June 2023 and in the Code of Conduct of this contracting authority and in the University Integrity and Organization Plan.

Following the notification of the award and before the conclusion of the contract, the successful tenderer is responsible for viewing the aforementioned documents published on the website of the contracting authority

28. ACCESS TO DOCUMENTS

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

29. SETTLEMENT OF DISPUTES

For disputes arising from the contract, the Court of Naples has jurisdiction, with the express exclusion of arbitration compromise.

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 related 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 provided for by 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. The 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 his exclusion from this 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 and contact details); ii) data relating to criminal convictions and offences (so-called "criminal convictions"). "judicial") referred to in art. 10 EU Regulation, limited to the sole purpose of assessing the possession of the requirements and qualities provided for by the current legislation applicable 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 implemented using manual, paper, computer and telematic tools suitable for processing 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 independent collaborators, professionals, consultants, who provide consultancy or assistance to the Administration regarding the tender procedure and the execution of the Contract, also for possible 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 established from time to time;
- communicated to other competitors who request access to the tender documents within the limits permitted pursuant to Law no. 241 of 7 August 1990;

– communicated to the National Anti-Corruption Authority, in compliance with the provisions of AVCP Determination no. 1 of 10/01/2008.

The name of the successful bidder and the contract award price will be published on the www.unina.it website.

In addition to the above, in compliance with the legal obligations that require 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 agrees that the data and documentation that the law requires to be published, are published and disseminated, if the conditions are met, through the www.unina.it website, "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, even 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 are transferred by the competitor to the Administration. The data subject is granted the rights referred to in articles 15 to 23 of the EU Regulation. In particular, the data subject has the right to: *i)* obtain, at any time, confirmation as to whether or not personal data concerning him or her is being processed; *ii)* the right of access to their personal data 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; *iii)* the right to request, and if necessary obtain, rectification and, where possible, erasure or, again, limitation of processing and, finally, may 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 exercising the right of access and related rights, the response to the request is not received within the legal deadlines and/or is not satisfactory, the data subject 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 the 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 bid 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 award 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 were rendered:

- On 11 October 2024 and acquired at the protocol with no PG/2024/127684 the declarations of the RUP and the Director of the Department of Pharmacy, Prof. Angela Zampella and staff units involved in the tender process, Dott.ssa Maria Colangelo, Dott. Pasquale Capasso, Dott.ssa Francesca Formica with which it was certified:
 - 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 abstain if it becomes aware of it 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 II of the Criminal Code - pursuant to art. 35-bis, paragraph 1, letter c) of Legislative Decree no. 165/2001 as amended – 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 at a time subsequent to the assumption of the assignment, one of the conditions of incompatibility or abstention referred to in the aforementioned rules occurs, to immediately abstain from the function and to promptly inform the Office responsible for the tender procedure;
 - d) that they do not meet the conditions referred to in art. 16, paragraph 1 of Legislative Decree 36/2023.

The Director

Prof. Angela Zampella

Department of Pharmacy Director: Prof. Angela Zampella Organisational unit responsible for the award procedure: Budget and Accounting Office Head: Mariarosaria Persico
