

***SPECIAL CONTRACT SPECIFICATIONS FOR THE SUPPLY OF MEDICAL EQUIPMENT TO THE XOOGGA
HOSPITAL IN MOGADISHU.***

(Art. 87, paragraph 2 and Art. 32 of Annex I.7 of Legislative Decree No. 36/2023)

RECITALS

This document, drawn up pursuant to articles. 22, paragraph 4, letter. m) and 32 of Annex I.7 to Legislative Decree 31 March 2023, n. 36 and art. 43 paragraph 2 of the Presidential Decree 05/10/2010 n. 207, concerns the technical and detailed requirements to be applied to the subject of the contract.

In the following and in the other contractual documents they will be defined as follows:

- ❖ The Procurement Code: Legislative Decree 31 March 2023, n. 36 "Public contracts code implementing article 1 of law 21 June 2022, no. 78, containing delegation to the Government regarding public contracts";
- ❖ The Implementing Regulation: the Presidential Decree 5 October 2010, n. 207 "Execution and implementation regulation implementing directives 2004/17/EC and 2004/18/EC" for the articles still in force.
- ❖ The General Tender Specifications: the Ministerial Decree. 19 April 2000, n. 145 "Regulations containing the General Specifications for the procurement of public works, and subsequent amendments", in the parts still in force.

The Contracting Authority: Defense Industries Agency.

The Contractor: the company carrying out the supply.

The Project Manager (RUP): Gen.D. Giorgio RAINO'

The Director of Contract Execution (DEC): Ten.Col. Massimo DECANDIA

Art. 1 – Object of supply

Il presente capitolato disciplina la procedura di gara aperta per Attrezzature da destinare alle FORZE ARMATE DELLA SOMALIA in relazione alla Misura di assistenza EPF a seguito della raccomandazione dell'Alto Commissario accettata dal Political and Security Committee del 16 aprile 2024.

The supply of the aforementioned material/equipment must comply with European and national regulations, in particular:

- EU Regulation 2017/745 (MDR): This regulation regulates the production, marketing and compliance of medical devices. It is essential that medical equipment is certified according to CE standards and complies with safety and performance requirements;
- Legislative Decree. . 46/97: Italian legislation transposing the European directives on medical devices, integrated by the MDR;

and comply with the CEI EN 60601-1 Standard (European Standard for the safety of electro-medical equipment) and comply with the risk management and safety requirements defined by the MDR.

In particular, the following products are required:

- ❖ See list of materials called "Supply list", divided into n. 2 Lots to be the basis of the tender referred to in "Annex A".

Art. 2 – Value and Duration of Contract

The starting bid amount (subject to reduction) is set respectively as follows:

- Lotto 1 pari ad euro €. 875.000,00;
- Lotto 2 pari ad euro €. 113.800,00;

Since this is a mere supply, risks of interference are not present.

Art. 3 – Governing Rules

The supply of the aforementioned material/equipment must comply with European and national regulations, in particular:

- EU Regulation 2017/745 (MDR): This regulation regulates the production, marketing and compliance of medical devices. It is essential that medical equipment is certified according to CE standards and complies with safety and performance requirements;
- Legislative Decree. . 46/97: Italian legislation transposing the European directives on medical devices, integrated by the MDR;
- CEI EN 60601-1 standard (European standard for the safety of electro-medical equipment);
- Sector regulations regarding public procurement;
- Civil Code and other regulatory provisions in force regarding private law contracts;

and comply with the risk management and safety requirements defined by the MDR.

All equipment and materials must fully comply with current technical regulations as well as those regarding safety.

The economic operators participating in this tender, in drawing up their offer, must comply with all the provisions of the Laws, Regulations and Standards in force regarding safety, construction, operation and installation, applicable to the supply covered by the tender, even when not explicitly mentioned in the tender documents.

The technical and functional specifications described in the "Supply List", an integral part of these Specifications, are considered by the contracting authority as minimum characteristics of the products to be supplied by the economic operators and have been defined and accepted by the beneficiary. When producing the offer, economic operators must refer to the provisions of the "Supply list" attached to this document and from which the characteristics of the products and the related accessories required, the quantities and the estimated maximum price of each element can be deduced.

Economic operators will be able to propose products and related accessories required to accompany them with performance characteristics equivalent to or superior to the minimum ones.

Art. 4 – Technical Equivalence and Interoperability Criteria of the Products Offered

Economic operators participating in the tender may propose, at the time of submission, alternative products and related accessories to those indicated in “Annex A”, provided that such products feature **technical and performance characteristics that are equivalent to or superior** to those required.

The assessment of equivalence will be carried out based on the following minimum parameters:

- correspondence to the specified functional performances;
- compliance with the cited technical standards;
- adherence to dimensional and weight requirements, if declared as binding;
- possession of quality or compliance certifications issued by accredited bodies.

In any case, the alternative products offered must ensure full technical, operational, and logistical interoperability with the models indicated by way of example in “Annex A”.

The economic operator must submit, as part of the technical offer:

- Detailed technical data sheets and supporting documentation of the performance;
- A comparative table between the exemplary product listed in the technical annex and the proposed one, highlighting compliance with minimum requirements and full equivalence;
- A formal declaration of compatibility and interoperability, signed by the legal representative.

The evaluation of interoperability will be carried out by the Contracting Authority, also through requests for technical clarifications and/or demonstration tests, and constitutes an essential condition for the admissibility of the technical offer.

Art. 5 – Supply Condition

The supply of the material must be carried out at the Military Chemical Pharmaceutical Establishment of Florence, within the following deadlines:

- For Lots 1 and 2 : 180 calendar days from the date of signature of the Contract.

The delivery of all materials must be accompanied by transport documentation and carried out at the warehouse located in:

Address: Via Reginaldo Giuliani, 201, 50141 Firenze (FI)

Contacts: Email: scfm@aid.difesa.it

Certified eMail: scfm.aid@postacert.difesa.it

Phone: +39 055 45561

subject to prior agreements with the contracting authority.

All materials supplied must be provided with closed and intact packaging and must be accompanied by technical data sheets, declarations of Conformity and Performance, as indicated in the items on the Supply List and delivered according to the dimensions on pallets or in containers suitable for air/sea transport.

If materials falling within the common list of military equipment of the European Union are delivered, the contracting company must present appropriate documentation relating to the nationality of the suppliers/subcontractors as well as the origin of the goods supplied.

The Supplier is responsible for all charges, expenses and risks relating to the performance of the activities covered by the Supply, meaning they are remunerated with the contractual fee, as well as any activity that may be necessary for their activation and performance or, in any case, appropriate for the correct and complete fulfillment of the obligations envisaged, including those relating to any transport, travel and mission expenses for the personnel assigned to the contractual execution.

The Supplier guarantees the execution of the Supply in a perfect workmanlike manner, in compliance with the regulations in force and according to the conditions, methods, terms and provisions contained in these Specifications, under penalty of legal termination of the contractual relationship.

The contractual services must necessarily comply with the technical characteristics and specifications indicated in the Special Specifications and in the tender documents referred to in the premises. In any case, the Supplier undertakes to observe, in the execution of contractual services, all the regulations and all technical and safety requirements in force.

The Supplier expressly undertakes to indemnify and hold harmless the contracting authority from all consequences arising from any failure to comply with the technical, safety, hygiene and health regulations and requirements in force.

The supplier must make the delivery at his own risk, assuming all expenses of any kind (port, packaging, transfer to the premises indicated at the time of delivery, etc.). In the event that the supplier is unable to deliver even one of the awarded products, even for limited periods of time, he is required to immediately

notify the administration. Checks of the ordered quantities and contractual compliance of the delivered goods are carried out at the warehouse.

The judgment on the acceptability of the supply is left to the personnel in charge of control. Acceptance of the goods does not relieve the supplier from the responsibility of his obligations regarding apparent or hidden defects in the goods delivered, not detected at the time of delivery.

Supply conditions that provide for a billable minimum are not accepted. Therefore, the contracting company is required to deliver the ordered material, whatever the amount of the orders, under penalty of forfeiture of the award and without prejudice to any action to protect against any damage suffered.

Each individual product delivery, accompanied by the transport document, is considered accepted subject to verification of the goods delivered.

The returned materials must be returned by the Administration in the original packaging and complete with any accompanying accessories. The shipping costs to the Supplier will be borne by the Administration, those of sending the replaced materials to the Administration will be borne by the Supplier. The maximum time for returning materials is set at 30 days from delivery.

Art. 6 - Verification of conformity and functionality tests.

The contracting authority will ascertain: the number and type of products and materials supplied, the conformity of the products supplied, the execution and results of the functionality tests. The tests and verifications of functionality and conformity will have as reference the technical specifications and "targets" indicated in the Special Specifications.

The execution of the functionality tests of the Supply is the responsibility of the contracting authority, under the supervision of the Contract Execution Director.

The contracting authority reserves the right to refuse supplies in all those cases in which from the verification and testing operations:

- a) discrepancies should emerge on the technical or regulatory specifications;
- b) the Supply is incomplete or irregular even for just one element.

If the non-correspondence of the products supplied by the awarded company is found, in whole or in part, the latter will be required to replace the same within 30 natural and consecutive days from the communication from the contracting authority, without this entailing any cost for the same and without prejudice to the application of the penalties referred to in the art. 8.

The contracting authority, on the basis of the tests and checks carried out, can accept the products or reject them or declare them revisable. Supplies that are found to be defective or in any way not compliant with the technical requirements will be rejected. Even those with minor defects can be declared reviewable. Regular testing of the products and declarations of acceptance do not, however, exonerate the Supplier for any defects or imperfections that did not emerge at the time of testing, but are subsequently ascertained. In this case, the Supplier is invited by the contracting authority to attend, through their representatives, any assessment visits, having to respond to any defects on their behalf.

In the event of a positive outcome of the aforementioned tests, the date of the relevant report drawn up by the Contract Execution Director will be considered as the "date of certification of regular execution". The application of the penalties referred to in the art. 8, if the test report shows the need for any repair, replacement or completion work, in the absence of which the certification of regular execution of the Supply cannot be issued, the contracting authority will formally request in writing the completion of the execution.

In this case, the Director of Execution will issue the certificate of regular execution within 30 days from the date of completion of the Supply, after joint verification with the Supplier's technicians.

From the date of the report certifying the regular execution of the Supply, the guarantee referred to in the following article "Warranty and maintenance" begins.

Shape subject to conformity verification, pursuant to art. 116 of Legislative Decree no. 36/2023, the verification that all contractual services have been carried out in a workmanlike manner from a technical and functional point of view, in accordance with and in compliance with the conditions, methods, terms and provisions of the contract, as well as the applicable legislation in force.

The verification activities also have the aim of ascertaining that the data resulting from the accounting and supporting documents correspond to each other and with the findings of fact, as well as including the technical checks required by sector laws.

The person in charge of verifying conformity issues the certificate of verification of conformity at the end of the contract, when it appears that the Supplier has completely and regularly performed the contractual services.

The conformity verification certificate is sent to the Supplier for acceptance, who must sign it within fifteen days of receiving it. Upon signing, the Supplier may add any objections it deems appropriate exclusively relating to conformity verification operations.

Following the issue of the conformity verification certificate, payment is made within 30 days for the services performed and the definitive deposit given by the Supplier to guarantee the failure or incorrect fulfillment of the contractual obligations is released.

The conformity verification does not exempt the Supplier from contractual and legal guarantees and responsibilities.

Art. 7 – Warranty and Support

The supply guarantee must last 24 months (twenty-four) months from the date of the report certifying the regular execution of the supply.

During the warranty period the Supplier must undertake to:

- guarantee timely interventions, no later than 15 natural and consecutive days from the report, aimed at restoring the correct functioning of the Supply in the event of malfunctions/anomalies;
- replace, within 15 days, the accessories or parts of the equipment supplied with new ones, if the fault is caused by defects in the product supplied and cannot be resolved with simple maintenance interventions.
- transport costs and/or costs of spare parts possibly necessary for non-functioning repairs will be borne by the Supplier.

If the successful tenderer of the Supply is a distributor, the latter must issue a declaration on how it intends to carry out the operations indicated above, if it does not have its own structures.

Art. 8 - Specific obligations of the Supplier

The Supplier undertakes, in addition to what is provided in other parts of the Contract, also to:

- perform the services covered by the Contract under the conditions and methods established in the Special Specifications;

- indemnify and hold harmless the contracting authority from claims that third parties may make in relation to damages deriving from services rendered in ways other than those provided for in the Contract and in the tender documents, or in relation to property rights claimed by third parties;
- prepare all the tools and methodologies, including the relevant documentation, aimed at guaranteeing high levels of service, including those relating to security and confidentiality, as well as allowing the contracting authority to monitor the compliance of the services with the standards set out in the Contract and, in particular, with the quality parameters established;
- promptly communicate any changes to its organizational structure involved in the execution of the Contract, analytically indicating the changes that have occurred and the names of the new managers;
- guarantee the continuity of the execution of contractual services.

The Supplier undertakes, in all cases, to provide all the services described in the Special Specifications even if not expressly stated in the Contract.

The Supplier, during the execution of the services, must comply with all regulations in force or which may be issued during the duration of the Contract, comply with any local regulations as well as comply with the minimum requirements set out in the Special Specifications.

Art. 9 – Start of the invoicing period

The supplier may issue the invoice only after the successful completion of the conformity check referred to in Article 6.

Art. 10 - Industrial patents and copyrights

The Supplier assumes all responsibility resulting from the use of devices or the adoption of technical or other solutions that infringe patent, copyright and general property rights of others.

If legal action is brought against the contracting authority by third parties for violation of patent, copyright or industrial property rights in relation to the activities performed under this Supply, the Supplier undertakes to indemnify and hold harmless the contracting authority, assuming all consequent costs, including damages towards third parties, judicial and legal costs to be borne by the contracting authority itself.

The contracting authority undertakes to promptly inform the Supplier of the legal initiatives referred to in the previous paragraph; in the case of joint defence, the Supplier recognizes the contracting authority's right to appoint its own trusted lawyer to assist the defender chosen by the Supplier.

In the event of legal action for the violations referred to in the previous paragraphs attempted against the contracting authority, the latter, without prejudice to the right to compensation for damages in the event that the claim brought is well-founded, has the right to declare the termination of the contract by law, to the extent of respective reasons, recovering and/or repeating the amount paid, less fair compensation for the services provided.

Art. 11 – Training

All supplies shall include basic training activities for the beneficiary, ensuring the transfer of the necessary skills for the effective and safe use of the provided product/service.

Training sessions may be delivered in person, remotely, or in a blended format, and shall include theoretical lessons, practical exercises, and final assessments. The supplying company shall also provide manuals, handouts, and multimedia materials suitable for facilitating the understanding of the training contents. The

training shall be addressed to the future operators of the supplied equipment, ensuring that each participant acquires the minimum skills required for the operational use of the product/service.

The supplying company shall commit to appointing qualified trainers with proven experience in the relevant field, ensuring compliance with safety and quality regulations during the training sessions, and providing post-training technical support for clarifications and further guidance.

The beneficiary, in turn, shall ensure the participation of the designated trainees, make available the necessary infrastructure for conducting in-person sessions (if applicable), and cooperate with the supplier to optimise the training programme.

Upon completion of the basic training activities, the supplier shall issue a certificate attesting to the completion of the training for the personnel involved.

Training activities shall be delivered after the delivery of the goods to the beneficiary and in any case no later than 30 September 2026.

The Project Manager (RUP): Gen.D. Giorgio RAINO'