

Initiative AID 013354/01/0 entitled
“Support for the Odessa Oblast paediatric hospital through the contribution of the Defence Industries Agency – Military Pharmaceutical Chemical Plant”

SPECIAL TENDER SPECIFICATIONS – TECHNICAL

SUBJECT

Supply of healthcare technologies and consumables, including installation, commissioning, maintenance and technical-practical training of staff for the paediatric hospital in the Odessa Oblast (Ukraine)

Lot 1: Electromedical devices for neonatal intensive care – CIG. BD7A6151AD

Lot 2: Devices for non-invasive respiratory support for newborns – CIG. BD7A616280

Lot 3: Electromedical devices for advanced clinical monitoring and controlled drug administration for newborns – CIG. BD7A617353

Lot 4: Electromedical devices for maternal diagnostics – CIG. BD7A618426

Procedure Manager: Col. Arcangelo Moro

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CHAPTER I - GENERAL PROVISIONS

Article 1 - DEFINITIONS

In these Special Tender Specifications, the following terms shall have the following meanings:

- a) *“Contractor/Supplier”*: the natural or legal person, in whatever form constituted, including associated entities, with whom the Buyer enters into a contract for the supply of goods, as governed by the Contract itself.
- b) *“Beneficiary”*: Municipal Non-Profit Enterprise “Odesa Regional Children’s Clinical Hospital” – 3 Vitaliya Nesterenka Street, Peresyp District, Odesa, Odesa Region, 65000, Ukraine.
- c) *“Special Tender Specifications”*: this document, containing the technical requirements, conditions and procedures for the performance of the supply and related ancillary services.
- d) *“Code”*: Legislative Decree No. 36 of 31 March 2023, containing the *“Public Contracts Code”* and its annexes.
- e) *“Buyer/Contracting Authority”*: Defence Industries Agency – Military Pharmaceutical Chemical Plant of Florence (MPCP).
- f) *“Contract”*: the written agreement between the Buyer and the Contractor for the performance of the supplies and services described in the Special Tender Specifications and in the technical documentation hereto annexed, containing details of the subject matter of the supplies and services, the agreed remuneration and the performance timescales. The Contract, unless otherwise specified, comprises the following documents which, even if not physically attached, form an integral and substantial part thereof:
 - the Special Tender Specifications, which set out the subject matter of the Contract, the amount and the duration; the terms for payment of the contractual fees; any further specific clauses governing the relationship between the parties;
 - the technical documentation referred to in Article 8 of these Special Tender Specifications, the declarations, documentation and financial offer submitted by the Contractor during the tender procedure;
 - any other document attached to and/or referred to in the foregoing.
- g) *“DUVRI”*: (where applicable) single document for the assessment of interference risks, i.e. the document drawn up by the Buyer containing the measures adopted to eliminate or, where this is not possible, minimise the risks of interference between activities connected with the performance of the Contract.
- h) *“Supply Order”*: the individual order issued by the Project Manager, specifying the quantities, times and methods of delivery of the goods to be supplied and/or the performance of the additional services provided for in the Contract.
- i) *“Party or Parties”*: the Buyer or the Contractor, or both, when referred to in the plural.

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- j) *“Technical Specifications”*: the document referred to in Annex 1 to these Specifications containing the technical and regulatory requirements, the terms, conditions and procedures for the performance of the supply.

Article 2 – DOCUMENTS GOVERNING THE CONTRACT

1. The supply and services must be carried out in accordance with the provisions of the following documents:

- a) the Special Tender Specifications;
- b) the Contract;
- c) the declarations, documentation and financial offer submitted by the Contractor during the tender procedure;
- d) the guarantee policies;
- e) the applicable safety regulations and technical standards referred to in Article 3 of these Special Tender Specifications;
- f) any other document attached to and/or referred to in the foregoing.

2. In the event of any conflict between the provisions contained in the documents listed above, precedence shall be given to the provision most favourable to the Buyer or, alternatively, where there is no provision most favourable to the Buyer, precedence shall be determined according to the order in which the documents are listed in paragraph 1 above.

Article 3 - COMPLIANCE WITH LAWS AND TECHNICAL REGULATIONS

1. The supply of the materials/devices specified in Annex 1 must comply with European and national regulations, in particular:

- **EU Regulation 2017/745 (MDR)**: governs the manufacture, marketing and conformity of medical devices. It is essential that medical equipment is certified in accordance with CE standards and complies with safety and performance requirements;
- **Legislative Decree 137/2022**: provisions for the alignment of national legislation with the provisions of Regulation (EU) 2017/745;
- **CEI EN 60601 (applicable parts)**: European standard for the safety of electro-medical equipment;
- **Current legislation** on medical devices and electrical equipment in Ukraine.

2. The supply of the equipment must also comply with current safety regulations. Economic operators participating in this tender must, when drawing up their tender, comply with all the requirements of the laws, regulations and standards in force concerning safety, construction, operation and installation, applicable to the supply covered by the Contract, even where these are not explicitly mentioned in the tender documents.

CHAPTER II – CONTRACTUAL PROVISIONS

Article 4 – SUBJECT MATTER AND PLACE OF PERFORMANCE OF THE CONTRACT

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1. The main scope of the contract is the supply, free to destination, of the devices and consumables specified in Annex 1 to these Special Tender Specifications, and, only in an ancillary way, the provision of the following services: (a) installation and testing of the medical devices supplied, and technical-practical training for medical and technical staff; (b) sustainable management of consumables associated with the medical devices supplied; and (c) support for routine and non-routine maintenance of the medical devices supplied.

The contract is divided into 4 Lots, as indicated below:

- **Lot 1** – CIG BD7A6151AD: Electromedical devices for neonatal intensive care;
- **Lot 2** – CIG BD7A616280: Devices for non-invasive respiratory support for newborns;
- **Lot 3** – CIG BD7A617353: Electromedical devices for advanced clinical monitoring and controlled drug administration for newborns;
- **Lot 4** – CIG BD7A618426: Electromedical devices for maternal diagnostics.

2. The devices covered by this supply must be suitable for use within the neonatal ward of the paediatric hospital of Odessa Oblast (Ukraine), where it is to be delivered and installed.

The details of the paediatric hospital of Odessa Oblast (Ukraine) are the following:

Name: Municipal Non-Profit Enterprise "Odesa Regional Children's Clinical Hospital".

Address: 3 Vitaliya Nesterenka Street, Peresyp District, Odesa, Odesa Region, 65000, Ukraine.

Contact person: Ms Nataliia SIVOLAP, tel: +380 95 312 6694, email: panisivolap@ukr.net.

At the same location, ancillary services must be carried out, including installation, testing and training of healthcare staff, sustainable management of consumables, and routine and non-routine maintenance of the devices supplied.

Article 5 – CONTRACT VALUE AND DURATION

1. The maximum total amount of all purchases under this call for tender, as set out in the tender documents and estimated *as a lump sum*, amounts to **€1.299.352,00** VAT included if due (as specified in point 3.2 of the Instructions for Tenderers).

This amount is broken down as follows for each individual Lot covered by the tender:

- for **Lot 1**, the total amount set out in the tender documents and estimated as a lump sum amounts to € 871.128,40, VAT included if due;
- for **Lot 2**, the total amount set as the tender basis and estimated as a lump-sum *basis* amounts to € 19.835,70, VAT included if due;
- for **Lot 3**, the total tender base amount, estimated as a lump sum, amounts to € 190.662,80, VAT included if due;
- for **Lot 4**, the total amount forming the basis of the tender and estimated as a lump sum amounts to € 217.725,10, VAT included if due

2. The cost of ancillary services (installation, testing, training, sustainable management of consumables and maintenance) is included in the amounts indicated; likewise, the tender

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base amounts include transport costs to the paediatric hospital in the Odessa Oblast (Ukraine), which are borne in full by the Contractor, as this is a ‘free-to-destination’ supply.

3. Safety charges not subject to a discount are equal to zero, in accordance with the provisions of the Authority for the Supervision of Public Contracts for Works, Services and Supplies (now ANAC) in its Decision No. 3 of 5 March 2008.

4. For each Lot, the ‘lump sum’ contract amount corresponds to the total amount offered by the Contractor in their financial offer. During the accounting phase, the prices indicated by the Contractor in the financial offer shall be applied in accordance with the provisions of these Special Tender Specifications and the individual Supply Orders issued by the Project Manager.

5. The tender lots are as follows:

Lot number and description	Equipment to be supplied	Number of units to be supplied
Lot No. 1 – Electromedical devices for neonatal intensive care	Neonatal ventilator	6
	Neonatal ventilator with HFOV (high-frequency oscillatory ventilation)	4
	Convertible neonatal incubator with radiant heating system	4
	Neonatal resuscitation bed with servo control	5
	Neonatal resuscitator	5
	Neonatal incubator	4
	Multi-parameter neonatal monitor	2
Lot No. 2 – Devices for non-invasive respiratory support for newborns	Non-invasive respiratory support device	1
Lot No. 3 – Electromedical devices for advanced clinical monitoring and controlled drug administration for newborns	Pulse oximeter for newborns	10
	Portable electric suction unit	15
	Dual-channel syringe pump	20
	Compressor	10
Lot 4: Electromedical devices for maternal diagnostics	Doppler ultrasound system – Stationary	2
	Doppler ultrasound system– Portable	2

Each Lot includes the supply of an adequate quantity of consumables to accompany the devices supplied, in order to ensure its proper use for a period of 10 (ten) months for the treatment of:

- 300 patients for the devices identified in Lots 1 and 2;
- 150 patients for the devices identified in Lots 3 and 4.

6. The duration of the Contract is set at a potential 12 months, commencing from the date of

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its signing by both parties. During the 12-month period, Supply Orders will therefore be issued by the Project Manager, specifying the services required from the Contractor.

7. The amount offered by the Contractor is understood to include, amongst other things: overheads, profit, transport and unloading, as well as any other costs arising from the performance of the Contract, as further detailed in these Special Tender Specifications. The price is also deemed to cover the costs and expenses arising both from the necessary adoption of exceptional or unforeseen measures for the performance of the supply and from the administrative management of the contract.

8. The amount quoted by the Contractor must also include the ancillary services to be provided, such as: the installation and commissioning of the devices at the Beneficiary's premises; training for 40 staff members, including doctors, nurses and technical staff of the Beneficiary; as well as routine and non-routine maintenance of the devices supplied; and the supply and sustainable management of consumables in accordance with paragraph 5 above.

Article 6 – SUBCONTRACTING

1. The Contractor shall perform the services covered by the Contract itself. Without prejudice to the provisions of Article 120, paragraph 1, letter d), of Legislative Decree No. 36/2023, the assignment of the Contract shall be null and void. Any agreement whereby the full performance of the contracted services is entrusted to third parties shall also be null and void.

2. Subcontracting is permitted in accordance with the provisions of Article 119 of Legislative Decree No. 36/2023.

Article 7 – SUPPLY TERMS

1. The technical and functional specifications described in Annex 1, which forms an integral part of these Special Tender Specifications, are considered by the Contracting Authority to be the minimum requirements for the products to be supplied by the Contractor and have been defined and accepted by the Beneficiary. When preparing their tender, economic operators must refer to the provisions of Annex 1 to this document, which sets out the characteristics of the products and the related accessories required, as well as the corresponding quantities.

2. Each product supplied must be brand new, not used or reconditioned, and must be accompanied by the manufacturer's official warranty.

3. Economic operators participating in the tender may propose, in their tender, products and related accessories equivalent to those indicated in Annex 1, provided that such products possess technical, functional and performance characteristics equivalent to or superior to those required. The assessment of equivalence shall be carried out on the tenderer ranked first in the provisional ranking, in accordance with the procedures set out in the tender specifications, based on the following minimum parameters:

- compliance with the specified functional performance;
- compliance with the technical standards cited;
- compliance with dimensional and weight requirements, if declared binding;
- the existence of quality or conformity certificates issued by accredited bodies.

In any case, the equivalent products offered must guarantee full technical, operational and logistical interoperability with the devices covered by the same Lot.

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4. Delivery must be made for each Lot in a single consignment to the final destination, the paediatric hospital of the Odessa Oblast, subject to approval by the Project Manager and, where deemed necessary by the Contracting Authority, a site visit to the Contractor's premises prior to transport.
5. The Project Manager shall issue supply orders in accordance with the timing and procedures deemed appropriate, without the Contractor being entitled to claim any compensation or special remuneration.
6. Delivery of the devices must in any event be made within 120 days from the date of signature of the Contract.
7. In the event of failure to deliver within the time limits set out in the individual Supply Order issued by the Project Manager, the Buyer shall be entitled to have the supply carried out by another economic operator (performance at the Contractor's expense); in such a case, in addition to the application of the penalty as provided for in Article 18 of these Special Tender Specifications, the additional costs incurred shall be borne entirely by the Contractor.
8. For each delivery of materials, the Contractor must submit a specific Transport Document (DDT) in duplicate. Upon delivery, the Project Manager or their delegate responsible for accepting the materials, having carried out the checks referred to in Article 20 below, shall countersign the DDT and retain a copy.

Article 8 - TECHNICAL DOCUMENTATION AND CERTIFICATIONS

1. The Contractor shall provide, together with the supply and for each device supplied, the documentation necessary to demonstrate compliance with the regulations in force regarding medical devices and electrical equipment in the European Union and in Ukraine. Specifically, the following documents must be made available:
 - a) CE Certificate issued in accordance with Regulation (EU) 2017/745, indicating the Notified Body for Class IIa, IIb or III devices, or a Manufacturer's Declaration for Class I devices;
 - b) Declaration of Conformity issued by the manufacturer for each device supplied in accordance with Regulation (EU) 2017/745;
 - c) A copy of the Instructions for Use, the Safety Data Sheet and the Technical Data Sheet for each device supplied in English and Ukrainian, with certified translations;
 - d) CE Certificate and Declaration of Conformity in accordance with Regulation (EU) 2017/745, Technical Data Sheet relating to the accessories supplied with the equipment and any consumables for use as indicated in Annex 1;
 - e) ISO 9001 and/or ISO 13485 certification, if held;
 - f) Certification of compliance with current European standards for electrical equipment, IEC 60601 (relevant parts);
 - g) Compliance with ISO 14971:2019 "Risk management for medical devices";
 - h) Compliance with DSTU 4388:2005 "Medical devices. Classification according to potential risk of use. General requirements";

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- i) *(where equivalent products have been offered)* a comparative table between the specifications set out in Annex 1 and the proposed devices, highlighting functional compliance with the minimum requirements specified and full equivalence;
- j) *(where equivalent products have been offered)* a declaration of compatibility and interoperability signed by the legal representative;
- k) *(if the Contractor is not based in Ukraine)* a copy of the Power of Attorney agreement entered into with an official representative appointed in Ukraine to carry out the certification and importation of goods into Ukrainian territory, including customs clearance, as well as installation, commissioning and routine and non-routine maintenance.

As an alternative to the documents listed above under points (a) to (h), the Contractor may provide proof of registration in the Ukrainian State Register of Medical Equipment and Devices or declare compliance with the requirements of the relevant Ukrainian technical standards, attaching a document of conformity as proof.

2. Following the award and in view of the signing of the Contract, the Contractor is therefore required to submit the above documentation, which will be assessed by the Contracting Authority, with the possibility of requesting additional information or clarifications, constituting an essential condition for the signing of the Contract. Should the documentation submitted not be compliant, the Contracting Authority will proceed to declare the award void, with the tender ranking list moving down accordingly.

3. The Contractor or its authorised representative on site must also prepare the following documentation to be provided to the Beneficiary's staff for each item of equipment supplied:

- Technical passport including the equipment's serial number, the device's risk class, the details of the CE Certificate and the equipment's specifications;
- Instructions for use in Ukrainian;
- Maintenance manual in Ukrainian;
- Warranty certificate;
- List of spare parts and consumables;
- Contact details for the technical support centre.

Article 9 - TECHNICAL SPECIFICATIONS – SPECIFIC OBLIGATIONS OF THE CONTRACTOR

A. Technical specifications

1. The technical requirements for the devices to be supplied, as well as their performance and quality characteristics, are set out in Annex 1 to these Special Tender Specifications, organised by Lot and by individual item of equipment.

B. Special obligations of the Contractor

The Contractor is required to bear, at no additional cost to the Contracting Authority and with

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costs included in the financial offer submitted, all specific costs associated with the performance of the supply covered by these Special Tender Specifications and the related ancillary services. In addition to those already provided for in this document, the specific costs also include:

- the installation of the equipment at the designated premises indicated in this document, carried out by qualified personnel (clinical engineer) of the Contractor or of the authorised representative in Ukraine referred to in Article 8, paragraph 1, and in compliance with current technical and safety standards. The Contractor shall be responsible for providing the aforementioned personnel with adequate knowledge of the Ukrainian language or an interpreter to assist them. Installation must be carried out in accordance with the Installation Qualification (IQ) protocol or an equivalent document provided by the Contractor in order to verify proper operation and full compliance with the technical specifications set out in these specifications and the relevant annexes. A copy of the aforementioned document certifying the correct installation of each device supplied must be delivered to the Project Manager or their delegate and to the Beneficiary. The documentation must be provided in English and Ukrainian with a certified translation;
- the performance of functional testing activities following installation (*i.e.* commissioning), carried out by qualified personnel (clinical engineer) from the Contractor or the authorised representative in Ukraine referred to in Article 1, paragraph 8, in compliance with current technical and safety standards. The Contractor shall be responsible for providing the aforementioned personnel with adequate knowledge of the Ukrainian language or an interpreter to assist them. The activities must be carried out in accordance with the provisions of the Operational Qualification (OQ) protocol or an equivalent document provided by the manufacturer in order to verify correct operation and full compliance with the technical specifications set out in these specifications and the relevant annexes. A copy of the aforementioned document certifying the correct operation of each piece of equipment supplied must be delivered to the Project Manager or their delegate and to the Beneficiary. The documentation must be provided in English and Ukrainian with a certified translation;
- all necessary cabling of any type (e.g. network, power, HDMI, etc.) to complete the installation, plus the supply and use of consumables and welding materials and any supports required for the correct positioning of the devices;
- the use of consumables and devices within the scope of the activities provided for in these Specifications, the costs of which shall be borne entirely by the Contractor.

Article 10 - PACKAGING

1. The packaging must ensure effective protection against the natural deterioration of the goods to be delivered, both during loading, unloading and transport operations, and during any storage in the Beneficiary's premises, warehouses or facilities.
2. The costs and responsibility for packaging shall be borne entirely by the Supplier.
3. The packaging must comply with current legislation on packaging, transport and

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environmental protection in the countries of the Buyer and of destination.

Article 11 - TRANSPORT

- 1.** Delivery of the equipment must be made on a DDP (*Delivered Duty Paid*) basis to the destination specified in Article 4, paragraph 2, unless otherwise indicated by the Contracting Authority. The Contractor is therefore responsible for all transport, insurance, export and import customs clearance operations, which are included in the lump sum amounts offered.
- 2.** The Contractor or its authorised representative must give the Beneficiary or its representative sufficient advance notice of the shipment of the equipment.
- 3.** The Contractor must ensure that each device is transported in the manufacturer's original packaging, in suitable conditions and securely fastened. The Contractor must ensure that transport is carried out using appropriate technical packaging for sensitive equipment.
- 4.** In the event that the supply involves a hazardous substance or one that requires transport by means of vehicles with specific authorisations, the Contractor undertakes, assuming all responsibility and costs, to use suitable means of transport, in accordance with the provisions of these Technical Specifications and the contract.
- 5.** The Contractor undertakes to transport each device accompanied by the following documentation, bearing an apostille where required, as a minimum:
 - Commercial invoice
 - Packing list
 - CMR or Air Waybill
 - Certificate of origin
 - CE certificate or manufacturer's declaration
 - Certificate of Free Sale
- 6.** The Contractor or its authorised representative on site must provide the necessary support to carry out the unloading and transport of the heavy equipment within the destination facility.
- 7.** The Contractor must arrange for multimodal transport (air, sea or land), including cargo insurance, shipment tracking and accompanying technical and customs documentation.
- 8.** The Contractor must manage customs clearance operations by preparing and submitting customs documentation, as well as coordinating with local freight forwarders and Ukrainian customs authorities, and provide adequate assistance with the receipt and compliance checks during customs clearance. The costs associated with carrying out customs clearance activities shall be borne by the Contractor.

Article 12 – TRAINING

- 1.** Each supply must be accompanied by a training programme designed to provide operational staff with the basic skills required for the correct use of the devices, as well as basic maintenance and cleaning procedures. The training programme must be divided into thematic modules covering, in particular, (a) the specific clinical use of the equipment; (b) safety regulations and risk prevention during use; (c) routine maintenance and operational checklists; and (d) the development of a fault reporting protocol and internal technical management.

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For the purposes of delivering the training, the Contractor is required to develop training materials (such as, for example, simplified user manuals and quick reference guides to be displayed in wards) in the Ukrainian language.

2. All training activities must be delivered in Ukrainian. The Contractor is responsible for providing a translator if it does not have specialist staff with knowledge of the Ukrainian language.

3. Training activities aimed at achieving the objectives set out in paragraph 1 must be set out in a specific training plan to be submitted for approval to the Project Manager and the Beneficiary.

4. Training sessions must be structured into technical-practical modules, clinical simulations and periods of technical mentoring. Sessions may be conducted in person, remotely or in a blended format, and upon completion, final effectiveness assessments must be carried out to certify the acquisition of the skills referred to in paragraph 1.

5. The training activities carried out must be recorded in specific registers, indicating for each session the start and end dates and times, as well as the pass or fail result following the final effectiveness assessment referred to in paragraph 4. Copies of these registers must be sent to the Project Manager and the Beneficiary.

6. The training must be provided to 40 or more staff members, including professionals such as doctors, nurses, biomedical technicians and maintenance staff. The list of staff undergoing training must be submitted to the Project Manager and the Beneficiary.

7. The Contractor must appoint qualified trainers with proven experience in the relevant sector, ensure compliance with safety and quality regulations during training sessions, and provide post-training technical support for clarifications and further guidance, including through additional training to be delivered in person or online.

8. Periodic training activities following those referred to in paragraph 1 must be listed in a specific training plan to be submitted to the Project Manager and the Beneficiary for approval. Should such periodic training activities include an assessment of participants' proficiency, these must be recorded in specific registers in accordance with the provisions of paragraph 5 of this article.

9. The training activities must commence following the delivery of the equipment to the destination referred to in Article 4, paragraph 2, and in any event no later than 30 days from the date of completion of the commissioning of the supplied equipment.

Article 13 - SUSTAINABLE MANAGEMENT OF CONSUMABLES RELATED TO THE SUPPLIED EQUIPMENT

1. The Contractor undertakes to supply the Beneficiary with adequate quantities of consumables to enable the use of the supplied equipment for a period of 10 months, based on an estimated user base as indicated in Article 5, paragraph 5, of these Specifications.

2. The Contractor undertakes to collaborate with the Beneficiary in order to carry out, during the term of the Contract, the mapping of critical consumables, in particular:

- Identification of consumables essential for the day-to-day operation of the equipment;
- Quantification of average consumption by type of equipment and department,

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based on intended use;

- Estimation of the annual requirements for the Beneficiary.

3. The Contractor undertakes to cooperate with the Beneficiary in order to define the consumables management system during the term of the Contract, in particular:

- Creation of a centralised register of consumables, either digital or paper-based;
- Defining procedures for internal requests (from department to warehouse), external reordering and monitoring of minimum stock levels;
- Production of technical data sheets and reference price lists.

4. The Contractor undertakes to collaborate with the Beneficiary to establish a robust management system for consumables through the preparation of operating procedures, request and reordering workflows, and the definition of responsibilities. The Contractor further undertakes to provide training to appropriately identified staff of the Beneficiary in order to ensure the effective management of the above.

5. The Contractor must provide technical, commercial and operational support to the Beneficiary in order to enter into supply agreements for the identified materials, based on the quantities specified in paragraph 2.

6. The Contractor undertakes to provide the Beneficiary with a list of materials to be procured and the relevant contact details of the supplier companies in order to ensure continuity of supply beyond the expiry of the Contract, as well as to provide adequate technical, commercial and operational support for the conclusion of supply agreements with the aforementioned companies.

7. The consumables supplied with the devices covered by each Lot must ensure the proper functioning and clinical use of the healthcare technologies from a technical, functional, and operational standpoint, guaranteeing the continuous use of the equipment in relation to the care needs and the activity/patient volumes estimated in these Special Tender Specifications. This includes disposable materials, consumable accessories, materials necessary for routine cleaning and sanitizing, as well as component subject to normal wear and tear associated with the regular functioning of the devices. The list of macro-categories indicated for each Lot in Annex 1 to these Special Tender Specifications is intended to be indicative and is not exhaustive of the materials necessary for the proper use of the devices offered.

Article 14 – ROUTINE AND NON-ROUTINE MAINTENANCE

1. The Contractor must ensure that routine maintenance operations are carried out on the equipment supplied, following installation and the activities referred to in Article 9, point B. To this end, the Contractor must draw up an appropriate routine maintenance plan based on the technical specifications of each device. Furthermore, the Contractor must cooperate with the Beneficiary in order to consolidate the planning of routine maintenance activities even beyond the expiry of the Contract.

2. The maintenance plan referred to in paragraph 1 must specify the frequency of interventions, the need to carry out functional checks, calibrations and replacements of parts subject to wear and tear, and the relevant procedures.

3. The Contractor must provide the Beneficiary with a list and quantity of spare parts that

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must be procured periodically for each device supplied.

4. The Contractor must provide the Beneficiary with specific corrective maintenance procedures setting out fault reporting procedures, response times and responsibilities both within and outside the Beneficiary's organisation. If necessary, the Contractor undertakes to provide specific training modules for the personnel involved in the aforementioned procedures in accordance with the procedures set out in Article 12.
5. The Contractor must ensure that non-routine maintenance work is carried out in accordance with the warranty terms provided by the Supplier.
6. Should defects in the equipment arise that cannot be resolved through maintenance work, the Contractor is obliged to ensure the replacement of defective accessories and parts. The costs of transport and/or any necessary spare parts shall be borne by the Contractor.
7. The Contractor must prepare a specific maintenance log for each device supplied in order to record the routine and non-routine maintenance activities carried out. Furthermore, the Contractor must include sessions on the correct management of these logs in the training activities to be provided to the Beneficiary's staff.
8. The Contractor undertakes to cooperate with the Beneficiary in order to establish a robust management system for spare parts by drawing up operating procedures, request and reorder workflows, and defining responsibilities. The Contractor further undertakes to provide training to the Beneficiary's designated staff in order to ensure the effective management of the above.

Article 15 – CONTRACTOR'S LIABILITY

1. The Contractor undertakes to comply with, and to ensure that its employees, agents or collaborators comply with, all legal provisions as well as any additional regulations in force at the paediatric hospital of the Odessa Oblast and those issued by the management thereof. In any event, the Buyer shall be held harmless from any liability for accidents or damage that the Supplier, its employees, agents or collaborators may, for any reason, suffer. The Supplier shall be liable for all damage that it, its employees, agents or collaborators may cause to the Buyer, its facilities or the premises and employees of the Beneficiary, or to third parties.
2. It shall be the Contractor's obligation to take, at its own expense, the necessary measures and precautions during the performance of the Contract, both to ensure the safety of the personnel involved in the Contract implementation and of third parties, and to prevent any damage to public or private property.
3. It is therefore agreed and confirmed that the Contractor shall assume – with discharging effect for the Buyer – the fullest possible civil and criminal liability in the event of accidents that may occur for any reason to persons or property, even if unrelated to the subject matter of the contract, during the performance of the Contract and in connection therewith.
4. The Buyer and its staff are hereby exempt from the aforementioned liability.

Article 16 – OBLIGATIONS OF THE CONTRACTOR

1. The Contractor must:
 - a) put in place all the tools and methodologies, as well as the relevant documentation, aimed

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at ensuring high levels of service and safety, and at enabling the Contracting Authority to monitor the compliance of the supplies and services with the standards set out in the Contract and, in particular, with the established quality parameters;

b) promptly notify the Contracting Authority of any changes to its organisational structure occurring during the performance of the Contract, providing a detailed breakdown of the changes made and the names of the new managers;

c) ensure the continuity of the performance of the activities provided for in these Special Tender Specifications until their completion within the prescribed time limits;

d) comply, throughout the performance of the Contract, with all regulations currently in force or which may be enacted during the term of the Contract, with any local regulations, and meet the minimum requirements set out in the Special Tender Specifications.

CHAPTER III - FINANCIAL PROVISIONS

Article 17 - PAYMENTS AND ACCOUNTING

1. The supplies and services covered by the Contract shall be calculated *on a “lump sum”* basis, based on the supplies and services actually performed by the Contractor.

In particular, with regard to the supply of the equipment and consumables specified in Annex 1 to these Special Tender Specifications, following each delivery, the Buyer, having verified the quantity and technical characteristics of the material supplied, shall authorise the Contractor to issue the relevant invoice, which shall be settled 30 (thirty) days after the end of the month in which the invoice was issued.

In the case of acceptance ‘on delivery’, where no further checks or tests are required, the countersigning of the delivery note shall replace the authorisation to issue the invoice.

All supplies and services specified in the Contract shall be invoiced on the basis of the prices offered by the Contractor in the financial offer, subject to the production of the relevant progress report based on the delivery of the goods to the agreed place and time and/or the performance of ancillary services as defined in these Special Tender Specifications.

Following the issue of the invoice by the Contractor, payment shall be made thirty days after the end of the month in which the invoice was issued.

2. An advance payment is provided for pursuant to Article 125 of Legislative Decree No. 36/2023.

3. The Buyer, in order to ensure strict compliance with the contractual clauses, may suspend payments to the Contractor against whom breaches in the performance of the supply/services covered by the Contract have been raised, without prejudice to the application of any penalties, until such time as the Contractor has complied with its contractual obligations.

4. Invoices issued by the Contractor must relate exclusively to the specific Contract and **must include the processing code, the CIG, the AID Initiative Code relating to this contract**, and the payment terms. The invoice must be made out to the Military Chemical Pharmaceutical Plant with the unique office code: C8XPAI. Invoices must therefore expressly state the subject of the initiative and the relevant code assigned to it, namely: **AID Initiative 013354/01/0**

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entitled “Support for the paediatric hospital of the Odessa Oblast through the contribution of the Defence Industries Agency – Military Chemical Pharmaceutical Plant”.

5. In the event of failure to comply with the invoicing procedures set out in the preceding paragraph, the Buyer reserves the right not to process the invoice and, consequently, not to pay it.

6. Authorisation for payment of the final instalment and the release of the performance guarantee are subject to the issue of the certificate of conformity referred to in Article 21 below.

Article 18 – PENALTIES

1. In the event of failure to comply with the delivery, installation and functional testing deadlines for the devices, as specified in detail in the Supply Orders issued by the Project Manager, a penalty equal to 0.5‰ of the contract amount shall apply for each calendar day of delay. Should the delay exceed 30 days, the Contracting Authority reserves the right to terminate the Contract on the grounds of material breach.

2. Throughout the warranty and/or maintenance period, the Supplier is required to ensure the restoration of full functionality of the equipment within 5 (five) business days of the fault being reported by the Beneficiary. Should this deadline be exceeded, for each subsequent period of 5 (five) business days, or any fraction thereof, during which the equipment remains inoperative, a penalty equal to 0.5‰ of the contract amount shall be applied, unless otherwise provided in paragraph 3 below.

3. If the fault has not been fully repaired or the equipment has not been restored to full functionality within 15 (fifteen) business days of the fault being reported by the Beneficiary, the Supplier is required to provide the Beneficiary, at no additional cost, with replacement equipment having technical and functional characteristics equal to or superior to those of the faulty equipment. Should this deadline be exceeded, an additional penalty equal to 0.1‰ of the contract amount shall be applied, effective as of the expiration of the 15 (fifteen) business days and for each subsequent period of 5 (five) business days, or any fraction thereof.

4. In the event of an objective and documented inability to promptly resolve the malfunction: (a) the time limit referred to in paragraph 2 above shall be extended to 30 (thirty) days; (b) the time limit referred to in paragraph 3 above shall be extended to 40 (forty) days.

5. Should any technical non-conformities be identified during the acceptance testing phase, the Contractor is obliged to replace the equipment within 15 calendar days and to carry out all the acceptance testing procedures on the new equipment as provided for in Article 9, point B. Should this deadline be exceeded, a penalty equal to 0.5‰ of the contract value shall be applied for each calendar day of delay.

6. Should the equipment not be correctly integrated with the hospital's IT systems, the Supplier shall have 10 working days to adapt the software. Upon expiry of this deadline, a penalty of 0.5‰ shall be applied for each day of non-interoperability. For the purposes of meeting the interoperability requirement referred to above, it is sufficient to ensure integration through an interface that complies with the HL7 standard. Any additional interoperability needs or requirements not expressly specified as minimum conditions in the tender documentation may be further examined, verified, and, if necessary, agreed upon on-

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site between the parties, in collaboration with the Beneficiary and in accordance with the principles of mutual good faith, based on specific operational needs and the operational context.

7. In the event of the supply of consumables which, upon use, prove to be incompatible or cause malfunctions/failures in the supplied equipment, the Supplier shall be required to immediately replace the non-compliant batch and restore the device to full working order free of charge. The continued supply of materials that are incompatible or of a quality below the declared standards shall constitute a serious breach of contract.

8. Any customs delays resulting from the failure to produce or the incorrect production of the necessary documentation shall be borne entirely by the Contractor. In the event of sudden regulatory changes due to a state of emergency, the parties undertake to cooperate in good faith to finalise the delivery as quickly as possible.

9. The procedures for applying penalties are also governed by the Contract.

CHAPTER IV – INSPECTIONS, CHECKS AND TESTS

Article 19 – INSPECTIONS, TESTS AND AUDITS

1. The purpose of the verifications and tests is to verify that the supply complies with the requirements set out in the technical specifications specified in these Special Tender Specifications, the relevant standards, and the characteristics declared and offered by the Contractor during the tender procedure.

2. The Contracting Authority reserves the right to carry out site visits at the Contractor's premises for the visual and documentary inspection of the equipment intended for delivery to the destination specified in Article 4, paragraph 2, in order to verify that it complies with the provisions of these Special Tender Specifications. The inspection shall be carried out by the Project Manager or their delegate.

3. The Project Manager shall have the right to select delivered products to be sent to a third-party certification body for appropriate testing. The costs incurred for laboratory testing, in addition to any penalties as set out in Article 18 of these Special Tender Specifications, shall be charged to the Contractor should the materials prove non-compliant with the contractual requirements.

4. The Buyer is also entitled to monitor and verify, at every stage of the production process, that the Supplier, or any subcontractors, are complying with all contractual requirements, as well as carrying out all activities necessary for the performance of the Contract. To this end, the Buyer is entitled to access, through its own employees or agents, the premises of the Supplier or of the subcontractors. The Buyer is also entitled to check at any time the suitability of the procedures, means and equipment used by the Supplier or subcontractors for the performance of the contractual activities. The Buyer shall at all times be entitled to repeat any tests and analyses deemed necessary in its own laboratories or in laboratories of its choice. The performance of the tests and checks referred to in this paragraph shall not suspend the performance of the Contract, and the Supplier shall be required to comply with the results of such checks.

5. The Buyer may carry out the checks and inspections itself or commission them, by means

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of a specific written order, to the Supplier. The Supplier is obliged to carry out all checks requested by the Buyer.

6. The costs of the inspections and tests shall be borne by the Supplier.

7. The Contractor hereby authorises the Buyer to exercise the right of audit, or permits any person, provided they are appointed and/or delegated by the Buyer, to visit the Contractor's premises to inspect the documentation and to verify the compliance of the performance and/or corporate organisation with the contractual requirements and/or sector regulations, including anti-corruption legislation.

Article 20 – INSPECTIONS AND CHECKS ON DELIVERY

1. Upon delivery of the products, before countersigning the delivery note, the Project Manager or their delegate shall carry out the following checks:

- a) that the packaging is intact and complies with the provisions of these Technical Specifications;
- b) that the quantities and types of products delivered, as well as the packaging systems, comply with the Buyer's supply order;
- c) that the goods delivered to the destination correspond to those inspected in accordance with the provisions of Article 19 of these Specifications.

2. Following delivery of the products, the Project Manager shall carry out the following checks:

- a. that the products comply with the technical and regulatory requirements set out in the technical specifications;
- b. that the Contractor has carried out the appropriate checks in accordance with the provisions of Article 19 of these Special Tender Specifications.

3. Should the checks not prove satisfactory, the provisions of the Contract shall apply.

4. The checks and verifications referred to in this Article may be replaced, where possible depending on the type of activity, by specific quality certificates submitted by the Contractor or by any other document suitable for the purpose.

Article 21 - CERTIFICATE OF CONFORMITY

1. Upon completion of the works, the Project Manager, having verified that the works carried out comply with and are in accordance with the contractual specifications, shall issue a certificate of conformity. The verification may also consist of acknowledging the correctness of the work carried out, as evidenced by the checks carried out during execution referred to in Articles 19 and 20 above. Otherwise, the verification shall take place in the presence of the Contractor. The certificate of conformity shall be sent to the Supplier, who shall sign it to indicate acceptance within 20 (twenty) days and forward it to the Buyer. Failure to forward it within the specified time limit shall be deemed acceptance. Upon a positive outcome of the conformity verification, the Procedure Manager shall issue the payment certificate for the purpose of the invoice issuance from the Contractor.

CHAPTER V - WARRANTIES

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Article 22 - WARRANTY FOR SUPPLIED DEVICES

- 1.** The Contractor must supply the devices with an appropriate warranty valid for at least 12 months.
- 2.** During the warranty period, the Supplier must ensure that maintenance work is carried out in a timely manner – within a maximum of 5 business days from the notice by the Beneficiary – in order to restore the devices to proper working order in the event of a malfunction or fault.
- 3.** During the warranty period, the Supplier must replace any accessories or parts within 15 business days in the event of a fault caused by defects in the supplied products that cannot be resolved solely through routine and/or non-routine maintenance.
- 4.** The costs of the parts and accessories referred to in the previous paragraph and their transport shall be borne by the Supplier.

CHAPTER VI - SAFETY AND ENVIRONMENTAL REGULATIONS

Article 23 – GENERAL SAFETY REGULATIONS

The Contractor must ensure compliance with current workplace safety regulations in accordance with European legislation and the regulations of the destination of the supply for all activities carried out from the signing of the Contract until its expiry.

Article 24 – ENVIRONMENT AND WASTE

- 1.** The Contractor must ensure compliance with current regulations on waste management and disposal in accordance with European regulations and those of the destination of the supply.
- 2.** Compliance with the provisions of the preceding point must be ensured for both the equipment supplied and its packaging.
- 3.** The Contractor must provide the beneficiary with comprehensive information to enable them to carry out the correct disposal of all packaging, consumables and the equipment itself.

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ANNEX 1 – TECHNICAL SPECIFICATIONS

Lot No. 1 – Electromedical devices for neonatal intensive care		
Type	Quantity	Minimum technical specifications
Neonatal ventilator	6	<ol style="list-style-type: none">1. Minimum patient weight: from 500 g2. Volume-controlled ventilation (with guaranteed volume option) and pressure-controlled ventilation.3. Supported modes: PCV+, PSIMV+, (S)CMV+, CPAP, VS, nIPPV, nCPAP, HiFlow oxygen therapy.4. Proximal flow sensor with minimal dead space.5. Tidal volume delivery from 2 ml.6. Graphical monitoring of patient data.7. Integrated monitoring: FiO₂, flow, pressure, volume.8. Touchscreen display no smaller than 8" or 15".9. Integrated battery providing at least 4 hours of operation.10. Turbine.11. Neonatal breathing circuits available, compatible with both disposable and reusable neonatal circuits.12. Mobile trolley included.13. Interface for connection to the hospital information system.

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ANNEX 1 – TECHNICAL SPECIFICATIONS

Lot No. 1 – Electromedical devices for neonatal intensive care		
Type	Quantity	Minimum technical specifications
Neonatal ventilator with HFOV (high-frequency oscillatory ventilation)	4	<ol style="list-style-type: none"> 1. Minimum patient weight: from 500 g. 2. Volume-controlled (with guaranteed volume option) with pressure-controlled ventilation. 3. HFOV mode with active inspiration and expiration; oscillation frequency 5–20 Hz. 4. Supported modes: IPPV/IMV, SIMV, CPAP, nCPAP, PCV, SIMV+VTG, nIPPV. 5. Proximal flow sensor with minimal dead space. 6. Tidal volume delivery from 2 ml. 7. Graphical monitoring of patient data. 8. Integrated monitoring: flow, pressure, volume, O₂. 9. 12.1" to 15" touchscreen display. 10. Integrated battery providing at least 1 hour 30 minutes or 270 minutes of operation. 11. Neonatal breathing circuits available, compatible with both disposable and reusable neonatal circuits. 12. Compressor. 13. Mobile trolley included.

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ANNEX 1 – TECHNICAL SPECIFICATIONS

Lot No. 1 – Electromedical devices for neonatal intensive care		
Type	Quantity	Minimum technical specifications
Convertible neonatal incubator with radiant heating system	4	<ol style="list-style-type: none">1. Can operate as a closed system.2. Servo-controlled body and air temperature, relative humidity in the incubation chamber.3. Manual control of the heating level.4. Central and peripheral body temperature sensors.5. Pull-out patient bed, electric Trendelenburg/Anti-Trendelenburg positioning6. Electric height adjustment.7. Anti-condensation system.8. Air curtain to maintain temperature whilst the door is open.9. Work and night lighting.10. Up to 10 ports on different sides for cables, hoses and tubing.

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ANNEX 1 – TECHNICAL SPECIFICATIONS

Lot No. 1 – Electromedical devices for neonatal intensive care		
Type	Quantity	Minimum technical specifications
Neonatal resuscitation table with servo control	5	<ol style="list-style-type: none"> 1. Heating system: infrared heater. 2. Control modes: manual, automatic (servo). 3. Heated platform and mattress with temperature sensor. 4. Procedure timer. 5. Procedure lighting. 6. Integrated suction and oxygen supply.
Neonatal resuscitator	5	<ol style="list-style-type: none"> 1. PIP and PEEP delivery with precise adjustment 2. Pressure support: PIP 0–60 cm H₂O, PEEP 0–20 cm H₂O 3. Display with digital pressure gauge 4. Overpressure protection 5. Humidification during resuscitation 6. Two flowmeters 7. Can be integrated into the resuscitation table

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ANNEX 1 – TECHNICAL SPECIFICATIONS

Lot No. 1 – Electromedical devices for neonatal intensive care		
Type	Quantity	Minimum technical specifications
Neonatal incubator	4	<ol style="list-style-type: none"> 1. Servo-assisted control of temperature, humidity and oxygen. 2. Continuous monitoring of the internal environment. 3. Access via side door and top lid. 4. Adjustable bed angle. 5. Humidification system with antibacterial filter. 6. Quiet ventilation.
Multi-parameter neonatal monitor	2	<ol style="list-style-type: none"> 1. Parameters: ECG, SpO2, NIBP, temperature, RR, HR 2. Neonatal sensors (cuffs, electrodes, temperature probes) 3. Touchscreen display of at least 10 inches 4. Trend and data storage for 96 hours 5. Battery: at least 2 hours' runtime 6. Port for connection to the medical information system

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ANNEX 1 – TECHNICAL SPECIFICATIONS

Lot No. 2 – Devices for non-invasive respiratory support for newborns		
Type	Quantity	Minimum technical specifications
Non-invasive respiratory support device	1	<ol style="list-style-type: none"> 1. Modes: CPAP, SiPAP. 2. For patients weighing 500 g or more. 3. Low noise level (<35 dB). 4. Integrated oxygen mixer. 5. Can be integrated with an SpO₂ monitor. 6. Compatible with disposable and reusable neonatal circuits.

Lot No. 3 – Electromedical devices for advanced clinical monitoring and controlled drug administration for newborns		
Type	Quantity	Minimum technical specifications
Paediatric pulse oximeter	10	<ol style="list-style-type: none"> 1. Measurement technology: Signal Extraction Technology (SET). 2. Parameters: SpO₂, PR, PI, PVI. 3. Portable design, touchscreen. 4. Trend memory for at least 72 hours. 5. Sensors: reusable or single-use for newborns.
Portable electric suction unit	15	<ol style="list-style-type: none"> 1. Suction power: up to 500 mmHg. 2. Flow rate: up to 30 L/min. 3. Continuously adjustable vacuum.

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ANNEX 1 – TECHNICAL SPECIFICATIONS

Lot No. 3 – Electromedical devices for advanced clinical monitoring and controlled drug administration for newborns		
		<ul style="list-style-type: none"> 4. Dual-chamber system (collection + pump protection). 5. Adjustable suction power. 6. Collection container: from at least 0.5 L to 2 L, autoclavable. 7. Operates on mains power and battery. 8. Supplied with catheters, filters and stand. 9. Option for active drainage or suction kit.
Dual-channel syringe pump	20	<ul style="list-style-type: none"> 1. Two independent channels 2. Compatible with 10–50 ml syringes from any manufacturer 3. Infusion rate: 0.1–500 ml/h 4. Accuracy $\pm 2\%$ 5. Volume control, occlusion detection, end-of-infusion alarm 6. Battery: 8–10 hours' runtime
Compressor	10	<ul style="list-style-type: none"> 1. Capacity: at least 40 L/min at 3–3.5 bar. 2. Tank capacity at least 2 L. 3. Soundproofed cabin. 4. Noise level ≤ 50 dB.

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ANNEX 1 – TECHNICAL SPECIFICATIONS

Lot No. 4 - Electromedical devices for maternal diagnostics		
Type	Quantity	Minimum technical specifications
Ultrasound system with Doppler – Stationary	2	<ol style="list-style-type: none">1. Continuous-wave Doppler.2. Pulsed and colour Doppler mapping.3. Probes: linear, small, micro-convex, large convex, paediatric cardiac, sectoral, vector.4. Printer.
Ultrasound system with Doppler – Portable	2	<ol style="list-style-type: none">1. Continuous-wave Doppler.2. Pulsed and colour Doppler mapping.3. Neonatal cardiac programme.4. Probes: linear and micro-convex for newborns, linear, small, large convex, paediatric cardiac, sectoral.5. Printer.

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ANNEX 1 – TECHNICAL SPECIFICATIONS

CONSUMABLES

Lot 1 – Electromedical devices for neonatal intensive care

- Consumables for ventilation and respiratory support;
- Consumables for patient monitoring;
- Consumables for thermoregulation and incubation;
- Consumables for suction and resuscitation;
- Single-use materials in contact with the patient;
- Materials for cleaning, disinfecting and sanitizing the machine;
- Technical materials and connection accessories;
- Materials subject to wear and tear and routine maintenance.

Lot 2 – Devices for non-invasive respiratory support for newborns

- Consumables for non-invasive ventilation;
- Patient interfaces and securing systems;
- Consumables for humidification and gas mixing;
- Single-use materials in contact with the patient;
- Materials for integrated monitoring;
- Materials for cleaning and sanitizing the machine;
- Technical materials and components subject to wear and tear.

Lot 3 – Electromedical devices for advanced clinical monitoring and controlled drug administration for newborns

- Consumables for clinical monitoring;
- Consumables for medical suction;
- Consumables for infusion and drug administration;
- Single-use materials in contact with the patient;
- Technical materials and operational accessories;
- Materials for cleaning, disinfecting and sanitizing the machine;
- Materials subject to wear and tear and routine maintenance.

Lot 4 - Electromedical devices for maternal diagnostics

- Consumables for ultrasound diagnostics;
- Consumables for probes and transducers;
- Single-use materials in contact with the patient;
- Materials for printing, archiving and image-management;
- Materials for cleaning, disinfecting and sanitizing the machine;
- Technical materials and operational accessories;
- Materials subject to wear and tear and routine maintenance.