EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate for Public Health, Country Knowledge, Crisis Management
Crisis Management and Preparedness in Health Unit

SENSITIVE*
RELEASABLE TO: Need to know basis

European Commission

Call for tenders SANTE/C3/2020/018 -

for the supply of medical equipment to support the breathing of patients with suspected or confirmed novel coronavirus (COVID-19)

Negotiated procedure[1]

TENDER SPECIFICATIONS

Part 2: Technical specifications

---

* Not for distribution. Do not read or carry openly in public places. Must be stored securely and encrypted in storage and transmission. Destroy copies by shredding or secure deletion. Full handling instructions: https://europa.eu/!db43PX

[1] Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193 of 30.07.2018, p.1).

TABLE OF CONTENTS

1. DETAILED CHARACTERISTICS OF THE PURCHASE

The subject of this contract is the supply of the supply of medical equipment to support the breathing of patients with suspected or confirmed novel coronavirus (COVID-19).

Common signs of COVID-19 infection include respiratory symptoms, fever, cough, shortness of breath and breathing difficulties. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure and even death.

According to the WHO, although the majority of people with COVID-19 have uncomplicated or mild illness, some will develop severe illness requiring oxygen therapy and approximately 5% will require intensive care unit treatment. Of those critically ill, most will require mechanical ventilation. The most common diagnosis in severe COVID-19 patients is severe pneumonia.

Providing medical support to patients breathing is therefore essential to minimize the impact of the pandemic.

The contract is divided into four lots:

Lot number	Lot title
1	Ventilators I – non-invasive
2	Ventilators II – invasive
3	Ventilators III – non-invasive (without CE certification)
4	Ventilators IV – invasive (without CE certification)

All products subject to this contract must comply with the requirements of applicable EU legislation (harmonisation Directives and Regulations on health and safety of products in the internal market, as well as any other applicable EU and/or national legislation) to be validly placed and made available on the market. European and international standards are also indicated in these technical specifications, as non-compulsory and non-exhaustive references for compliance with the applicable legal requirements.

The requirements of these technical specifications are minimum requirements. During the performance of the contract, the Contractor is responsible for providing any additional elements it has offered in its tender in order to exceed the minimum requirements.

1.1. Products

1.1.1. Lot 1 – Ventilators I – non-invasive

Ventilators under this lot comply with the following minimum quality requirements:

No	Type	Minimum requirements

		Description/Features	EU legislation	Reference standards[2] (non-obligatory)
1	Ventilators I – non-invasive	Pressure and volumetric ventilation, of latest generation, controlled by microprocessor Wide availability of ventilation methods, such as CPAP, PSV, PCV, PAV, BILEVEL (PAP + EPAP), and at least CPAP, PCV and BILEVEL) particularly oriented for non-invasive ventilation (but may in addition be suitable for invasive ventilation) Integrated turbine with good performance for compensation of possible (potentially large) leaks in the mask-circuit/patient interface -maintenance of high capacity fluxes (preferably up to 200 l/min) Backup ventilation for apnea • Mixing with oxygen from 21% to 100% • Wide availability of adjustable alarms – at least the following alarms must be present: o patient disconnection o high and low respiratory frequency o min and max pressure o min volume minutes o battery • Visualization of volumes in real time • Power supply and with rechargeable battery with good autonomy (at least 30 minutes) • Easy to use, ergonomic, with first level maintenance and easy to perform checks by the operator • Easy to disinfect contaminated parts • With flexible tubes, accessories and junctures to connect with plugs with AFNOR terminal • Trolley with wheels Documentation and languages • User manual, describing also maintenance needs (at least description of the activity and frequency) • Documents (e.g.: Instructions for Use, User Manual) at least in English • Serigraphs in English • Possibility to set the software language (English shall be the standard setting)	• Directive 93/42/EEC on medical devices	EN 60601-1-1:2001 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems

[2] Non obligatory

1.1.2. Lot 2 – Ventilators II – invasive

Ventilators under this lot comply with the following minimum quality requirements:

No	Type	Minimum requirements		
		Description/Features	EU legislation	Reference standards[3]
1	Ventilators II – invasive	• Tidal volume up to 1,000 mL • Pressure (inspiratory) up to 80 cm H20 • Volume (inspiratory) up to 120 L/min • Respiratory rate: up to 60 breaths per minute. • SIMV Respiratory Rate: up to 40 breaths per minute. • CPAP/PEEP up to 20 cm H2O. • Pressure support up to 45 cm H2O. • FiO2 between 21 to 100 % • Inspiratory and expiratory times up to at least 2 sec and 8 sec respectively • I:E Ratio at least from 1:1 to 1:3. Additional elements • Lung ventilator suitable for adult and paediatric ventilation (without the need to modify the machine's circuit) • Monitoring of respiratory parameters such as: static and dynamic compliance, resistance, P01, EtCO2, FiO2 • Presence of expiratory trigger and inspiratory trigger at pressure and flux with high sensitivity , at least 0.3 l/min Modes of ventilation: • Volume controlled (VC). • Pressure controlled (PC). • Biphasic pressure support (PS). • Synchronized intermittent mandatory ventilation (SIMV) with pressure support. • Assist / control mode • Continuous Positive Airway Pressure (CPAP) / Positive End Expiratory Pressure (PEEP) Alarms	• Directive 93/42/EEC on medical devices[4]	• EN 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance • EN 60601-1-1:2001 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems • EN 60601-2-12:2006 Medical electrical equipment - Part 2-12: Particular requirements for the safety of lung ventilators - Critical care ventilators

[3] Non obligatory
[4] OJ L 169, 12.7.1993, p. 1.

No	Type	Minimum requirements		
		Description/Features	EU legislation	Reference standards[3]
		• Alarms required: FiO2, minute volume, pressure, PEEP, apnoea, occlusion, high respiration rate, disconnection • System alarms required: power failure, gas disconnection, low battery, vent inoperative, self-diagnostics • If alarm silencing feature is incorporated, it must be temporary and clearly displayed when activated General requirements: • Air and externally supplied oxygen mixture ratios fully controllable • Inlet gas supply (O2) pressure range at least 35 to 65 psi • Medical air compressor integral to unit, with inlet filter • Power supply 220 – 240 V AC, 50 – 60 Hz • Rechargeable battery (back up time at least 30 minutes) • Complete with connection to oxygen distribution, compressed air: junctions with medical gas distribution system, compatible with existing distribution equipment, should be provided and installed by the chosen supplier Documentation and languages • User manual, describing also maintenance needs (at least description of the activity and frequency) • Documents (e.g.: Instructions for Use, User Manual) at least in English • Serigraphs in English • Possibility to set the software language (English shall be the standard setting)		

1.1.3. Lot 3 – Ventilators III – non-invasive (without CE certification)

Ventilators under this lot comply with the following minimum quality requirements:

No	Type	Minimum requirements

		Description/Features	EU legislation	Reference standards[5] (non-obligatory)
1	Ventilators III – non-invasive (without CE certification)	Pressure and volumetric ventilation, of latest generation, controlled by microprocessor Wide availability of ventilation methods, such as CPAP, PSV, PCV, PAV, BILEVEL (PAP + EPAP), and at least CPAP, PCV and BILEVEL) particularly oriented for non-invasive ventilation (but may in addition be suitable for invasive ventilation) Integrated turbine with good performance for compensation of possible (potentially large) leaks in the mask-circuit/patient interface -maintenance of high capacity fluxes (preferably up to 200 l/min) Backup ventilation for apnea • Mixing with oxygen from 21% to 100% • Wide availability of adjustable alarms – at least the following alarms must be present: o patient disconnection o high and low respiratory frequency o min and max pressure o min volume minutes o battery • Visualization of volumes in real time • Power supply and with rechargeable battery with good autonomy (at least 30 minutes) • Easy to use, ergonomic, with first level maintenance and easy to perform checks by the operator • Easy to disinfect contaminated parts • With flexible tubes, accessories and junctures to connect with plugs with AFNOR terminal • Trolley with wheels Documentation and languages • User manual, describing also maintenance needs (at least description of the activity and frequency) • Documents (e.g.: Instructions for Use, User Manual) at least in English • Serigraphs in English • Possibility to set the software language (English shall be the standard setting)	See * below	EN 60601-1-1:2001 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems

[5] Non obligatory

* In duly justified cases, the competent authorities of Member States may decide, within their territory, to authorise the placing on the market and putting into service of devices for which the relevant EU conformity assessment procedure(s) laid down in Directive 93/42/EEC on medical devices have not been carried out and the use of which is in the interest of protection of health.

Tenderers are therefore invited to submit separate tender bids for such devices, in particular where they can demonstrate, at the time of submission, that the concerned devices have been authorised in accordance with the conformity assessment procedures established under the national laws of at least one country.

Tenderers should note that it is the prerogative of each Member State to decide whether the placing on the market and putting into service of devices referred to above may be authorised on duly justified grounds.

1.1.4. Lot 4 – Ventilators IV – invasive (without CE certification)

Ventilators under this lot comply with the following minimum quality requirements:

No	Type	Minimum requirements		
		Description/Features	EU legislation	Reference standards[6]
1	Ventilators IV – invasive (without CE certification)	• Tidal volume up to 1,000 mL • Pressure (inspiratory) up to 80 cm H20 • Volume (inspiratory) up to 120 L/min • Respiratory rate: up to 60 breaths per minute. • SIMV Respiratory Rate: up to 40 breaths per minute. • CPAP/PEEP up to 20 cm H2O. • Pressure support up to 45 cm H2O. • FiO2 between 21 to 100 % • Inspiratory and expiratory times up to at least 2 sec and 8 sec respectively • I:E Ratio at least from 1:1 to 1:3. Additional elements • Lung ventilator suitable for adult and paediatric ventilation (without the need to modify the machine's circuit) • Monitoring of respiratory parameters such as: static and dynamic compliance, resistance, P01, EtCO2, FiO2 • Presence of expiratory trigger and inspiratory trigger at pressure and flux with high sensitivity	• See * below	•EN 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance • EN 60601-1-1:2001 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems • EN 60601-2-12:2006 Medical electrical equipment - Part 2-12: Particular requirements for the safety of lung

[6] Non obligatory

No	Type	Minimum requirements		
		Description/Features	EU legislation	Reference standards[6]
		, at least 0.3 l/min Modes of ventilation: • Volume controlled (VC). • Pressure controlled (PC). • Biphasic pressure support (PS). • Synchronized intermittent mandatory ventilation (SIMV) with pressure support. • Assist / control mode • Continuous Positive Airway Pressure (CPAP) / Positive End Expiratory Pressure (PEEP) Alarms • Alarms required: FiO2, minute volume, pressure, PEEP, apnoea, occlusion, high respiration rate, disconnection • System alarms required: power failure, gas disconnection, low battery, vent inoperative, self-diagnostics • If alarm silencing feature is incorporated, it must be temporary and clearly displayed when activated General requirements: • Air and externally supplied oxygen mixture ratios fully controllable • Inlet gas supply (O2) pressure range at least 35 to 65 psi • Medical air compressor integral to unit, with inlet filter • Power supply 220 – 240 V AC, 50 – 60 Hz • Rechargeable battery (back up time at least 30 minutes) • Complete with connection to oxygen distribution, compressed air: junctions with medical gas distribution system, compatible with existing distribution equipment, should be provided and installed by the chosen supplier Documentation and languages • User manual, describing also maintenance needs (at least description of the activity and frequency) • Documents (e.g.: Instructions for Use, User Manual) at least in English • Serigraphs in English • Possibility to set the software language (English shall be the standard setting)		ventilators - Critical care ventilators

No	Type	Minimum requirements		
		Description/Features	EU legislation	Reference standards[6]

* In duly justified cases, the competent authorities of Member States may decide, within their territory, to authorise the placing on the market and putting into service of devices for which the relevant EU conformity assessment procedure(s) laid down in Directive 93/42/EEC on medical devices have not been carried out and the use of which is in the interest of protection of health.

Tenderers may therefore consider the submission of separate tender bids for such devices, in particular where they can demonstrate, at the time of submission, that the concerned devices have been authorised in accordance with the conformity assessment procedures established under the national laws of at least one other third country.

Tenderers should note that it is the prerogative of each Member State to decide whether the placing on the market and putting into service of devices referred to above may be authorised on duly justified grounds.

1.2. Packaging

When possible, the packaging is made of recycled materials or of materials of plant origin. Preferably, the packaging can be reused, recycled or combusted.

Each packaging and labelling bears the following information:

1. Name of the product
2. Date of expiry (when applicable)
3. Manufacturer's name
4. CE marking.*
5. (Special) storage conditions, warning instructions (if applicable).

All labelling is at least in English and, according to the applicable EU legislation*, in additional official EU languages[7] of the locations of delivery.

Each packaging contains:

1. The EC or EU declaration of conformity drawn up by the manufacturer*.
2. Descriptions and/or certificates drawn up by official quality control institutes, conformity assessment bodies (if applicable) or agencies of recognised competence attesting the conformity of the products clearly identified by references to technical specifications or standards.
3. Usage and fitting instructions at least in English and, according to the applicable EU legislation*, in additional official EU languages[8] of the places of delivery.

[7] https://europa.eu/european-union/about-eu/figures/administration_en
[8] https://europa.eu/european-union/about-eu/figures/administration_en

* May not apply for lots 3 and 4.

1.3. Storage, transportation and delivery

The products are delivered in the original packaging under Incoterms DAP[9] to the address indicated in the specific contract or order form within the time limit set in the specific contract(s) or order form(s). The *Contractor* should notify the *Contracting authority* of the date of delivery at least 5 calendar days in advance.

1.3.1. Delivery documentation

Prior to each shipment, the *Contractor* sends by e-mail to the *Contracting authority* the delivery- and product- specific documentation.

The *Contractor* delivers a pack-out instruction for correctly unpacking the products.

Each delivery is accompanied by a consignment note in duplicate, duly signed and dated by the *Contractor* or its carrier, giving the specific contract number and particulars of the supplies delivered. One copy of the consignment note must be countersigned by the *Contracting authority* and returned to the *Contractor* or to its carrier.

2. ORDER MANAGEMENT

2.1 Optional preliminary inquiry prior to placement of orders

This point complements Article I.4.3 of the framework contract.

Whenever the *Contracting authority* wishes to order supplies, it may send the first *Contractor* in the cascade a preliminary inquiry e-mail with the required quantities of PPE as well as the requested delay of delivery. Within 3 calendar days from the reception of the e-mail, the *Contractor* replies to the *Contracting authority* whether it can entirely or partially satisfy the request within the requested delay or proposing an alternative delivery delay if applicable, or whether it cannot satisfy the request.

If the *Contractor* can entirely satisfy the request of the *Contracting authority* within the requested delay, *the Contracting authority* sends *the Contractor* a specific contract or order form according to Article I.4.3 of the framework contract. The specific contract indicates, among other things, the description, quantity and price of supplies, as well as the place of delivery. If additional modalities regarding placement of orders are necessary, they can be mutually agreed upon by the concerned contracting parties in writing.

If the *Contractor* can partially satisfy the request of the *Contracting authority*, the latter can decide if to place an order with the given *Contractor* for the available supplies or to approach the next *Contractor* in the cascade.

---

[9] Delivered At Place; Incoterms® 2020. These terms are for sale on the website https://iccwbo.org/resources-for-business/incoterms-rules/incoterms-2020/

If the *Contractor* cannot satisfy the request of the *Contracting authority*, the latter contacts the next *Contractor* in the cascade.

2.2 Change of orders

After an order has been placed in conformity with Article I.4.3 of the framework contract, any necessary change of that order can be mutually agreed upon by the concerned contracting parties in writing.

3. QUALITY CONTROL AND PRODUCT RECALL

The *Contractor* has a comprehensively designed and implemented system for the investigation and documentation of any quality issue.

Any quality issue detected by, reported to and/or recorded by the *Contractor* that might eventually affect the quality and/or supply of the product, shall be reported to the *Contracting authority* within 7 calendar days. To follow-up, the *Contractor* shall communicate to the *Contracting authority* a documented proof that the reported quality issues have been processed and completed.

Following quality checks of the product, the *Contractor* might decide to recall the shipped or delivered products. The *Contracting authority* will return the products following the instructions provided by the *Contractor*. The latter shall bear all the related costs and shall replace the products within the reasonable delays mutually agreed by both parties.

Following quality checks of the delivered products, the *Contracting authority* might decide to recall the products due to the fact that they do not comply with the contract or for any other sound reason and shall notify the *Contractor* in writing immediately. Upon receipt of such notice, the *Contractor* shall provide the instructions on how to proceed with the return of products and shall replace the defective products within reasonable delays mutually agreed by both parties. The *Contractor* shall bear all the costs related to the return and replacement of the defective products.

4. OTHER PROVISIONS RELATIVE TO PERFORMANCE OF THE CONTRACT

4.1. Document and change management

The *Contractor* has a document management process and procedures related to this contract. Records are retained according to regulatory requirements, including release, reference samples, and shipping documentation. The Contracting authority retains shipping documentation at the disposal of the competent authorities.

The *Contractor* has a management system for follow-up, review, implementation and evaluation of changes related to this contract.

The *Contractor* shall inform the *Contracting authority* in writing of any changes that may affect product quality, especially with regards to the minimum quality requirements, or administrative aspect (e.g. a reference or catalogue number, etc.).

4.2. Inspections and audits

During the duration of the contract, the *Contracting authority* reserves a right to carry out inspections, audits or to request the *Contractor* any document demonstrating that the latter meets any contractual requirement.

The *Contractor* shall provide full cooperation during these inspections as long as the inspections are related to this contract. All costs related to the inspection will be borne by the *Contracting authority*, unless the inspection shall result in proof of default. In the latter case, all the inspection-related costs shall be borne by the *Contractor*.

The *Contractor* shall respond to all critical and major observations reported during the audit within 15 calendar days. Actions may be reviewed on site by the *Contracting authority* or any competent body designated by the latter.

4.3. Working languages

All the communication and documents related to carrying out this contract are in English, unless mutually agreed differently by the parties.