Request for Quotation (RFQ) for Procurement and Supply of Cylinders and Cylinder Accessories for Medical Use

1 Summary of Key Information

Release of Request for Quotes, RFQ:	Friday, April 30th, 2021
Quotations Due:	~~Monday, May 17th, 2021~~ Tuesday, May 18th, 2021
Contact Information:	oxygenRFQ@clintonhealthaccess.org
Version No:	3.0

2 Summary of Documents Required

1. Cover Letter
2. Completed Proposal Template in Excel format including tabs for:
    a. Quantities and Key Technical Specifications (See ANNEX A – QUANTITIES AND KEY TECHNICAL SPECIFICATIONS BY COUNTRY)
    b. Budget (See 5.2 BUDGET)
    c. Vendor Details (See 5.3 VENDOR DETAILS)
    d. Technical Specification (See ANNEX D – TECHNICAL REQUIREMENTS BY EQUIPMENT TYPE)
    e. Regulatory Requirements (See ANNEX C – REGULATORY REQUIREMENTS BY COUNTRY for checklist of regulatory requirements by country)
3. Supporting Documentation shared in folders as follows, clearly labeled in English, as described in 5.1 TECHNICAL SPECIFICATIONS
    a. **Technical Information**
    b. **Proof of Quality**
    c. **Warranties**
    d. **Repair and Maintenance**
    e. **Regulatory** (See ANNEX C – REGULATORY REQUIREMENTS BY COUNTRY for checklist of regulatory requirements by country)
    f. **Product Recall**

A template is available here to assist with Section 2 of the proposal submission:

CHAI & PATH Request for Quotation (RFQ) for Procurement (Cylinders and Cylinder Accessories for Medical Use)

3 Overall Purpose

The Clinton Health Access Initiative (CHAI) and PATH, supported by funding from Unitaid, are pleased to invite interested and capable vendors to submit quotes for the procurement and delivery of cylinders and cylinder accessories used for the transportation, storage, and dispensation of medical oxygen to 5 countries (Liberia, Malawi, Nigeria, Uganda and Zambia). Interested organizations should make their submissions to oxygenRFQ@clintonhealthaccess.org by ~~Monday, May 17th, 2021~~ Tuesday, May 18th, 2021.

3.1 Background

The main objective of this project is to facilitate the purchase of respiratory care equipment prioritized by the Ministries of Health in Liberia, Malawi, Nigeria, Uganda and Zambia. CHAI and PATH will work with the appropriate government agencies in each of the countries to fund prioritized equipment for respiratory care used in the management of severe and critical COVID-19 patients.

Recipient countries of this specific procurement – Liberia, Malawi, Nigeria, Uganda and Zambia – face significant shortages cylinders and ancillary devices. These shortages have been exacerbated by oxygen demand surges resulting from COVID-19. Rapid procurement of these prioritized items will strengthen the emergency response in recipient countries, as well as strengthen the long-term ability to provide safe oxygen therapy.

This procurement will be conducted with consideration given to efficiency, cost-effectiveness, and long-term sustainability. The specific procurement requests were developed by the respective Ministries of Health in focus geographies, each corresponding to the national COVID-19 task force plans.

3.2 Owners and end users

The ultimate owners of the goods to be procured will be the Ministries of Health in targeted countries. The main users of the products procured will be clinicians delivering oxygen in public health facilities in targeted countries.

4 Procurement Requirements

4.1 Objectives and Scope

CHAI and PATH are seeking quotes which include the procurement and delivery of five orders to five countries, preferably under DAP INCOTERMS (CIP minimum) of 8,427 cylinders, 2,155 pressure regulators with manometer 2,155 flowmeters, and 2,155 bubble humidifier bottles with specified connections to ensure compatibility for oxygen delivery to the patient.

For detailed quantities and key specification country, please refer to **9.**

ANNEX A – QUANTITIES AND KEY TECHNICAL SPECIFICATIONS by Country.

4.2 Vendor Selection Criteria

Submitted quotes will be reviewed and evaluated by the review committee based on criteria which include the following:

- Specifications
- Performance criteria
- Operational criteria (including warranty)
- Quality requirements (including regulatory and standards and proof thereof)
- After sales service support at site(s) including costs of spare parts, service and maintenance - where applicable
- Manufacturing and Delivery Lead Times

Once specifications have been met and terms of after sales (if applicable) have been deemed acceptable, the financial offer will be considered.

Cost in Dollars ($USD) inclusive of delivery, preferably DAP INCOTERMS (CIP minimum).

5 Response Format

5.1 Technical Specifications

The following information must be included for each commodity, where it is applicable.

- **Technical Information:** Device/equipment classification and name which should be accompanied by technical information in English, such as leaflets, brochures, or catalogue pages.
- **Proof of Quality:** Proof of quality e.g., requisite standards and/or Stringent Regulatory Authority (SRA) approval/marking.
- **Warranties:** Warranty for device and warranty on labor, including information on how any issues are managed should they arise under the warranty period. Warranties should be managed directly via the consignee of each product, (i.e., country governments). Please clearly indicate otherwise if this is not the case.
- **Repair and Maintenance:** Availability of repair and maintenance service contract.
- **Regulatory:** Proof of approval from local Regulatory Authorities in target countries where available and applicable and import permits. (See ANNEX C – REGULATORY REQUIREMENTS BY COUNTRY for checklist of regulatory requirements by country
- **Product Recall:** Standard Operating Procedure for product recall where applicable
- **Technical Specifications:** In addition, a detailed checklist of technical specifications should be filled out for each product type and model. One checklist can be used for multiple sizes of cylinders, provided they are of the same model and specifications other than those noted in table (size, valve-stem, color) remain the same.
- Please see ANNEX D – TECHNICAL REQUIREMENTS BY EQUIPMENT TYPE for a full list of specifications
- If the proposed items do not comply exactly with the technical specifications and descriptions provided in the RFQ, the nearest functional equivalent or closest standard should be offered as an alternative.

5.2 Budget

Interested parties are asked to prepare a budget detailing cost for procurement and delivery. Value for money will be a key criterion in selection and the final budget will be agreed with the successful party.

Provide the following information in the template provided in **2. SUMMARY OF DOCUMENTS REQUIRED**.to cost items, inclusive of packaging, with a separate table for each country. All costs should be in Dollars ($USD)

S/No	Item	Name/Type	Model	Quantity	Unit Cost ($USD)	Total Cost ($USD)
1	Cylinder					
2	Flowmeter					
3	Pressure Regulator (incl. gauge)					
4	Bubble Humidifier					
	TOTAL COSTS					

Please use the format below to cost delivery, in the same tab for each country. All costs should be in Dollars ($USD)

S/No	Item	Delivery Service (Company/Service)	Expected Delivery Time (Days)	Total Cost ($USD)
1	Cylinder			
2	Flowmeter			
3	Pressure Regulator (incl. gauge)			
4	Bubble Humidifier			

5.3 Vendor Details

Provide the following information in the template provided in **2. SUMMARY OF DOCUMENTS REQUIRED**.

5.3.1 Basic Details

	Company Name	
	Local Address (HQ)	
	Phone	
	Contact name	
	Contact information	
	Years in Business	

	Any quality certifications (type e.g., QMS & date); Please attach copies of each certificate to RFQ submission	
	Previous export experience to target countries (please describe and list any relevant registrations, qualifications, licenses, attaching copies of each to RFQ)	
	Client portfolio	
	Tax Identification Number	

5.3.2 Services

If services are managed by a partner (3rd party), please fill out separately for each partner and describe nature of partnership. Please also fill in any basic details for any partners, if applicable, and clearly describe any additional costs are incurred for any after care services in the budget. If variance exists for each product, please note.

	Company Name	
	Contact information	
	HQ Location	
	After care services provided as a part of the warranty	
	Offers hydrostatic/pressure testing?	
	Nature of Partnership	
	Products Covered	
	Additional Costs	

6 RFQ Terms and Conditions

Distribution of this document does not mean there is any commitment on the part of CHAI and PATH to engage an applicant. CHAI and PATH will not reimburse or otherwise bear any costs associated with this RFQ regardless of whether applicant is selected to implement the project. Please note that no fee is required in submission of these quotes. All RFQs, along with any responses thereto, are considered the property of CHAI and PATH and the proposals will not be returned to the originator.

6.1 Confidentiality

All information provided by CHAI and PATH as part of this solicitation must be treated as confidential. In the event that any information is inappropriately released, CHAI and PATH will seek appropriate remedies as allowed. Proposals, discussions, and all information received in response to this solicitation will be held as strictly confidential, except as otherwise noted.

6.2 Conflict of interest disclosure

Suppliers bidding on CHAI and PATH business must disclose, to the procurement contact listed in the RFQ, any actual or potential conflicts of interest. Conflicts of interest could be present if; there is a personal relationship with a CHAI or PATH staff member that constitutes a significant financial interest, board memberships, other

employment, and ownership or rights in intellectual property that may be in conflict with the supplier's obligations to CHAI and PATH. Suppliers, CHAI, and PATH are protected when actual or perceived conflicts of interest are disclosed. When necessary, CHAI and PATH will create a management plan that provides mitigation of potential risks presented by the disclosed conflict of interest.

6.3 Communication

All communications regarding this solicitation shall be directed to appropriate parties at CHAI and PATH via the contact information provided in 1. SUMMARY OF KEY INFORMATION. Contacting third parties involved in the project, the review panel, or any other party may be considered a conflict of interest and could result in disqualification of the proposal.

6.4 Acceptance

Acceptance of a proposal does not imply acceptance of its terms and conditions. CHAI and PATH reserve the option to negotiate on the final terms and conditions. We additionally reserve the right to negotiate the substance of the finalists' proposals, as well as the option of accepting partial components of a proposal if appropriate.

6.5 Right to final negotiations

CHAI and PATH reserve the option to negotiate on the final costs and final scope of work and reserves the option to limit or include third parties at CHAI and PATH's sole and full discretion in such negotiations.

6.6 Third-party limitations

CHAI and PATH do not represent, warrant, or act as an agent for any third party as a result of this solicitation. This solicitation does not authorize any third party to bind or commit CHAI or PATH in any way without our express written consent.

6.7 Proposal Validity

Proposals submitted under this request shall be valid for 90 days from the date the proposal is due. The validity period shall be stated in the proposal submitted to CHAI and PATH.

7 Timetable and Milestones

CHAI and PATH request interested parties to adhere to the following timeframes:

#	Dates	Milestone
1	Friday, April 30th, 2021	RFQ Published
2	~~Friday, May 7th, 2021~~ Monday, May 10th, 2021	Deadline for Submission of Questions
3	~~Tuesday, May 11th, 2021~~ Wednesday, May 12th, 2021	Deadline for Addressing Questions
4	~~Monday, May 17th, 2021~~ Tuesday, May 18th, 2021	Deadline for Receiving Bids
5	~~Tuesday, May 25th, 2021~~ Tuesday, May 26th, 2021	Bid Evaluation and Issue of Award
6	Monday, June 7th – Friday, June 11th , 2021	Negotiation and Signing of Contracts

7	Monday, July 12th, 2021	Anticipated Delivery of Products

Note that CHAI and PATH reserve the right to modify this schedule as needed. All parties will be notified simultaneously by email of any changes.

8 RFQ Related Questions, Clarifications and Submissions

All questions and submissions related to this RFQ should be directed to the following:

Email Address: oxygenRFQ@clintonhealthaccess.org

9 Annex A – Quantities and Key Technical Specifications by Country

This section details the quantities of each equipment type required, disaggregated by country. Connection specifications, particularly those which vary by country are indicated in each table. Further detailed technical requirements which do not vary by country are available in **ANNEX D – TECHNICAL REQUIREMENTS BY EQUIPMENT TYPE**. A successful proposal must meet both specifications and requirements for each country.

A template is included to indicate specifications which your products meet is provided for submission in **2. SUMMARY OF DOCUMENTS REQUIRED**.

Table 1 - Cylinder Requirements by Destination

Destination	Quantity	Size	Colour Coding System	Valve Type	Comments
Liberia	80	"D" - 2.32 L water (340 L @ 137 bar)	ANSI	Bullnose (5/8 inch BSP (F) / BS 341 valve)	
Liberia	80	"E" - 4.68 L water (680 L @ 137 bar)	ANSI	Bullnose (5/8 inch BSP (F) / BS 341 valve)	
Liberia	50	"F" - 9.43 L water (1,360 L @ 137 bar)	ANSI	Bullnose (5/8 inch BSP (F) / BS 341 valve)	
Liberia	15	"G" - 23.6 L water (3,400 L @ 137 bar)	ANSI	Bullnose (5/8 inch BSP (F) / BS 341 valve)	
Liberia	10	"J" - 47.2 L water (6,800 L @ 137 bar)	ANSI	Bullnose (5/8 inch BSP (F) / BS 341 valve)	
Malawi	2,250	"J" - 47.2 L water (6,800 L @ 137 bar)	ISO	Bullnose (5/8 inch BSP (F) / BS 341 valve)	
Nigeria	1142	"J" - 47.2 L water (6,800 L @ 137 bar)	ISO	· Bullnose (5/8 inch BSP (F) / BS 341 valve)	Color: a black body and white shoulders will be ISO
Uganda	1,600	"J" - 47.2 L water (6,800 L @ 137 bar)	ISO	Bullnose (5/8 inch BSP (F) / BS 341 valve)	Color: a black body and white shoulders will be ISO
Zambia	3200	"J" - 47.2 L water (6,800 L @ 137 bar)	ISO	Bullnose (5/8 inch BSP (F) / BS 341 valve)	Valve guard included for safety, painted as per British

Table 2 - Pressure Regulator and Gauge Requirements by Destination

Destination	Quantity Required	Inlet Connection	Outlet Connection	Comments
Liberia	235	Bullnose	DISS, male	
Malawi	450	Bullnose	DISS, male	
Nigeria	380	Bullnose	DISS, male	
Uganda	450	Bullnose	DISS, male	
Zambia	640	Bullnose	DISS, male	Preset 345 kPA outlet pressure

Table 3 - Flowmeter Requirements by Destination

Destination	Quantity Required	Flow Range	Inlet Connection	Outlet Connection
Liberia	235	0-15 L/min, accuracy 10%, dual taper graduations 0.5 L/min (0-5 L/min)	DISS, female	DISS, male
Malawi	450	0-15 L/min, accuracy 10%, dual taper graduations 0.5 L/min (0-5 L/min)	DISS, female	DISS, male with 'Christmas tree' tubing adapter
Nigeria	380	0-15 L/min, accuracy 10%, dual taper graduations 0.5 L/min (0–5 L/min range) and 1 L/min (5 L/min – maximum range)	DISS, female	DISS, male
Uganda	315	0-15 L/min, accuracy 10%, dual taper graduations 0.5 L/min (0-5 L/min)	DISS, female	DISS, male
Uganda	135	0-70 L/min, accuracy 10%, single taper graduations 5 L/min full range	DISS, female	DISS, male
Zambia	640	0-15 L/min, accuracy 10%, dual taper graduations 0.5 L/min (0-5 L/min)	DISS, female	DISS, male with 'Christmas tree' tubing adapter

Table 4 - Bubble Humidifier Requirement by Destination

Destination	Quantity Required	Inlet Connection	Outlet Connection

Liberia	235	DISS, female (nut)	6mm barbed connector
Malawi	450	DISS, female (nut)	6mm barbed connector
Nigeria	380	DISS, female (nut)	6mm barbed connector
Uganda	450	DISS, female (nut)	6mm barbed connector
Zambia	640	DISS, female (nut)	6mm barbed connector

10 Annex B – Consignee and Delivery Information by Country

This section details the consignee information and delivery address for each product, disaggregated by country. Please note, in some cases, original copies of required to be delivered to a separate address in order for those documents to be available for important clearance.

All finalized consignee information will be provided prior to contract negotiation and is subject to change at the discretion of CHAI and PATH.

Country	Consignee	Delivery Address	Notes
Liberia	The Ministry of Health of Liberia	Ministry of Health, 2nd Floor, Rm 242 Oldest Congo Town Road, Congo Town Monrovia, Liberia	Clearing agent will arrange for delivery from airport to ministry of health
Malawi	TBD	TBD	TBD
Nigeria	TBD	TBD	TBD
Uganda	Ministry of Health Uganda Attention: Ministry of Health Clinical Health Services Department	Delivery address: Ministry of Health Ugand c/o National Medical Stores Plot 4-12 Nsamazi Road. P.O.BOX 16, Entebbe. Attention: Mr. Moses Kambare +256 772 933926 Document delivery address: CHAI Uganda Moyo Close Plot 8 Kololo, P.O.Box 33252 Kampala Uganda Contact Person: Andrew Musoke Mobile: +256 781 492186 Office telephone number: +256 312219 700	None
Zambia	TBD	TBD	TBD

11 Annex C – Regulatory Requirements by Country

This section details the regulatory requirements, disaggregated by country.

Import Requirements detail any requirement of product, supplier or consignee which is required by the governing bodies of each country in order for successful importation of the product.
Requirements for the Supplier is any information or action which the consignee requires the supplier to provide or take in order for successful importation.
Requirements of Consignee should be indicated so supplier understands capacity & role of consignee in import process.

All finalized regulatory requirements will be provided prior to contract negotiation and are subject to change at the discretion of CHAI and PATH.

Country	Import Requirements	Requirements for Supplier	Requirements of Consignee
Liberia	• Original copy of packaging list. • Original copy of invoice. • Certificate of origin"	Provide all listed documents to clearing agent	Provide contact information and address of clearing agent to supplier
Malwai	TBD	TBD	TBD
Nigeria	TBD	TBD	TBD
Uganda	One-time Import Approval (Pre-Import permit)	Copies, in triplicate hard copy sent to Document Delivery Address seperately from products and in soft copy as soon as available: • Signed commercial invoice. • Signed detailed packing list. • Full set of original clean shipped on board AWB made out to: • Two copies of the certificate of origin • Any applicable CE/FDA inspection document	Since goods are procured/imported currently for donation, there is no need for registration in the county. CHAI team will prepare and get one-time import approval (pre-import permit) from EFDA at the time when we get the soft copies of the documents from the supplier. The team has an experienced procurement officer who is able to manage the import process. . Additional documents required are: -Donation letter to the Ministry of

			Health,-MOH acknowledgement letter, - Commercial Invoice
Zambia	TBD	TBD	TBD

12 Annex D – Technical Requirements by Equipment Type

All technical specifications have been adapted from WHO-UNICEF's technical specifications and guidelines for oxygen therapy devices (2019).

A template is included to indicate specifications which your products meet is provided for submission in **2. SUMMARY OF DOCUMENTS REQUIRED**.

• Cylinders

Product	Category	Specifications
Cylinder	Description	A container designed as a refillable cylinder used to hold compressed medical oxygen (O2) under safe conditions at high pressure (e.g., 50–200 bar). It is typically filled with oxygen when delivered from the gas supplier and includes a valve stem, an opening/closing valve, and will be graded according to size (capacity) and colour-coded to denote oxygen content. The cylinder may be made of steel, aluminium (Al) or other ferrous or non-ferrous materials and must be used together with a pressure regulator in order to release the oxygen at the correct working pressure. (SOURCE: GMDN 47225)
	Technical	Refillable cylinders for compressed oxygen gas for medical use.
		Sizes, either ISO/US standard - specify (indicated in addendum table):
		· "J" - 47.2 L water (6,800 L @ 137 bar)
		· "G" - 23.6 L water (3,400L @ 137 bar)
		· "F" - 9.43 L water (1,360L @ 137 bar)
		· "E" - 4.68 L water (680L @ 137 bar)
		· "D" - 2.32 L water (340 L @ 137 bar)
		Nominal / working pressure: 137-150 bar
		Fitted with a primary valve stem, specify standard (indicated in addendum table):
		· Pin-index (ISO 407/BS 850/CGA 870 valve)
		· Bullnose (5/8 inch BSP (F) / BS 341 valve)
		Valve assembly material: brass
		Valve handle/key operated, supplied with tools.
		Material: seamless steel
		Colour coding: according to ISO/ANSI/CGA/NFPA (indicated in addendum table)
		Supplied with valve stem cap / safety cap
		Stamped onto shoulder:
		· Nominal and test pressures
		· Cylinder capacity (water litres)
		· Weight (kg)
		· Date of manufacture
		· Serial number
		· Company and country of origin
		Environmental:
		· Suitable for continuous operation in ambient temperature of at least 5–45 °C, relative humidity of at least 15–90% non-condensing
		· Capable of being stored in ambient temperature of at least 5–50 °C, relative humidity of at least 15–95% non-condensing
	Warranty	5 years recommended
	After sales	Availability of repair and/or service level agreements
	Standards	ISO 9001 (General QMS)
	Regulatory	CE

	Product performance standards	ISO 10297: Gas cylinders – Cylinder valves – Specification and type testing
		ISO 14246: Gas cylinders – Cylinder valves – Manufacturing tests and examinations
		ISO 7866: Gas cylinders – Refillable seamless aluminium alloy gas cylinders – Design, construction and testing
		ISO 9809: Gas cylinders – Refillable seamless steel gas cylinders – Design, construction and testing
		ISO 13341: Gas cylinders – Fitting of valves to gas cylinders
		ISO 15996: Gas cylinders – Residual pressure valves – Specification and type testing of cylinder valves incorporating residual pressure devices
		ISO 15001: Anaesthetic and respiratory equipment – Compatibility with oxygen
	Regional/local standards	Country-specific and regional colour gas coding and other standards apply and must be listed (indicated in addendum table).
	Packaging	Name and/or trade mark and address of the manufacturer.
		Product name.
		Product reference.
		Type of product and main characteristics.
		Performance testing information against the mentioned standards.
		Lot number prefixed by the word "LOT" (or equivalent harmonised symbol).
		Expiry date by year and month, prefixed by the word "EXP" (or equivalent harmonised symbol).
		Information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonised symbol), if applicable.
		Information for handling, if applicable (or equivalent harmonised symbol).
		If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging.
		Gross Weight.
		Cubic Measurement.
		All indicated at least in English.
		Standard units of packaging

- **Regulator with Manometer**

Product	Category	Specifications
Pressure regulator	**DESCRIPTION**	A reduction valve designed to be attached through a gas-tight connector (e.g., a pin-index or bull-nosed screw thread connection) to the valve stem of an oxygen (O2) cylinder to lower high, variable gas pressure (e.g., 50–250 bar) to a lower, constant working pressure, typically 3–5 bar. It can be a single- or a dual-stage regulator, usually of a piston or diaphragm design. It will have a safety relief valve to avoid excessive pressure due to increased ambient temperatures, and it may have associated devices, usually a manometer or manometers, to display the available gas reserve of a gas cylinder and the working pressure. (SOURCE: GMDN 43438) High-pressure gas regulators are placed between the output port of the high-pressure gas container at one end and the patient breathing circuit at the other end.
	Technical	Pressure regulator assembly to have inlet connections compatible with the following valve(s) (indicated in addendum table):
		·Pin index
		·Bullnose
		Outlet connection standard DISS, male
		Steel/plated brass/aluminium casing, brass valve.
		Nominal inlet pressure 13 700 kPa (137 bar, 1987 psi), maximum 20 000 kPa (200 bar, 2901 psi).
		Outlet pressure 345 kPa (3.5 bar, 50 psi).
		Integrated manometer, 0–20 000 kPa (0–200 bar, 0–2901 psi).
		Safety over-pressure release valve.
		Pressure regulator supplied with flowmeter, if required (see specifications)
		Rated for use with medical oxygen (clearly indicated on manometer)
	Warranty	5 years (min. 2)
	After sales	Availability of repair and/or service level agreements
	Standards	ISO 13485 (medical device QMS)
		ISO 14971 (application of risk management)
	Regulatory	CE
		FDA-registered
	Product performance standards	ISO 10524 Pressure regulators for use with medical gases.
		ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen.
	Packaging	Name and/or trademark and address of the manufacturer.
		Product name.
		Product reference.
		Type of product and main characteristics.
		Performance testing information against the mentioned standards.
		Lot number prefixed by the word "LOT" (or equivalent harmonised symbol).

		Information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonised symbol), if applicable.
		Information for handling, if applicable (or equivalent harmonised symbol).
		If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging.
		Gross Weight.
		Cubic Measurement.
		All indicated at least in English.

- ## Flowmeter

Product	Category	Specifications
Flowmeter, Thorpe tube, pressure compensated	**Description**	A device intended to measure and regulate the flow of a medical gas [e.g., oxygen (O2), carbon dioxide (CO2), nitrous oxide (N2O), helium/oxygen gas mixture (heliox), medical air] during various procedures (e.g., therapeutic administration, anesthesia, insufflation during surgery). It consists of an upright tube containing a float, which rises and falls in relation to gas flow, and a distal valve (compensated flowmeter) to control gas flow rate. It will be calibrated to a specific medical gas and have a dedicated flow rate range; therefore, some types may be dedicated to a specific patient group (e.g., neonate, infant, adult) or clinical use. (SOURCE: GMDN) Oxygen respiration flowmeters are intended for use with a variety of oxygen-supply systems such as central piped systems, cylinders valves, or concentrators and are connected to various delivery modalities or interfaces such as to a patient circuit or a medical device that uses or delivers the gas, including nasal cannulae or various types of mask-patient interfaces.
	Technical	Device suitable for use with medical oxygen
		Thorpe tube flowmeter type, contains inlet and outlet port, a flow regulator, a valve and a clear measuring tube
		Flowmeters to measure and regulate flow from an already pressure-reduced and regulated oxygen source to the patient or other medical device
		Pressure compensated flowmeters, calibrated at 345–380 kPa (3.4–3.8 bar, 50–55 psi) inlet gauge pressure.
		Max gauge inlet pressure 690 kPa (6.9 bar, 100 psi).
		Flow adjustment knobs to have rough surface to prevent slipping.
		Flowmeters calibrated to the following flow range, all metric (indicated in addendum table):
		0–200 mL/min, accuracy 10%, single taper, graduations 25 mL/min
		0–1,000 mL/min, accuracy 10%, single taper, graduations 100 mL/min
		0-3.5 L/min, accuracy 10%, *dual taper graduations 0.25 L/min (0–1 L/min range) and 0.5 L/min (1 L/min – maximum range), or single taper graduations 0.25 L/min full range*
		0-8 L/min, accuracy 10%, *dual taper graduations 0.5 L/min (0–5 L/min range) and 1 L/min (5 L/min – maximum range)*
		0-15 L/min, accuracy 10%, *dual taper graduations 0.5 L/min (0–5 L/min range) and 1 L/min (5 L/min – maximum range)*
		0-70 L/min, accuracy 10%, single taper graduations 5 L/min full range
		All minimum flowrates to be zero when fully closed
		All graduations to be clearly visible for 270 degrees (most breadth for provider vantage points)

		Inlet and outlet ports to be clearly specified and will in part be determined by use case (suitable for connection to centralized system, cylinders, concentrators or compressors) (indicated in addendum table):
		Cylinder source inlet: Connection to a pressure regulator
		Confirm inlet connection of flowmeter to be DISS, female (specify otherwise)
		Outlets: Specify outlet adapter, e.g., "Christmas tree" tubing adapter, DISS female to barbed 1/4 inch ID (male) hose connector or DISS, male (indicated in addendum table)
		Flowmeter material:
		Column to be transparent, clear, shatter-resistant, medical-grade polymer (polypropylene, polycarbonate)
		Hardware/valves: Brass/steel/aluminum
		All materials in contact with oxygen certified for medical use.
		Internal parts (e.g., valve, inlet filter if present), replaceable by user.
		Environmental
		Capable of being stored in ambient temperature of at least 5–50 °C, relative humidity of at least 15–95% non-condensing.
		Suitable for continuous operation in ambient temperature of at least 5–45 °C, relative humidity of at least 15–90% non-condensing.
		Specific requirements for altitude may be required, depending on the installation site.
		Disinfectable with hospital grade detergents.
	Warranty	5 years (min. 2)
	After sales	Availability of repair and/or service level agreements
	Regulatory	CE
		FDA-registered
	Product performance standards	ISO 32 Gas cylinders for medical use — Marking for identification of content (or ANSI equivalent)
		ISO 5359 Low-pressure hose assemblies for use with medical gases.
		ISO 15001 Anesthetic and respiratory equipment – Compatibility with oxygen.
		ISO 15002 Flow-metering devices for connection to terminal units of medical gas pipeline systems.
		ISO 18082 Anesthetic and respiratory equipment – Dimensions of non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases.
		ISO 18562 Biocompatibility evaluation of breathing gas pathways in healthcare applications.
	Packaging	Name and/or trade mark and address of the manufacturer.

		Product name.
		Product reference.
		Type of product and main characteristics.
		Performance testing information against the mentioned standards.
		Lot number prefixed by the word "LOT" (or equivalent harmonized symbol).
		Information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonized symbol), if applicable.
		Information for handling, if applicable (or equivalent harmonized symbol).
		If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging.
		Gross Weight.
		Cubic Measurement.
		All indicated at least in English.

- ## Humidifier

Product	Category	Specifications
Bubble Humidifier	**Description**	A device designed to prevent the drying of airway passages associated with the inhalation of oxygen (O2) by adding water vapor to the dry gas as it is passed through, or more seldom, over water. It typically consists of a graduated container (reservoir) for the water, a top piece that functions as a detachable lid (typically a screw lid with a gastight seal), and a tube that protrudes into the water to divert the gas below the water level. This device, commonly known as a bubble humidifier, does not heat the water. It has connectors: 1) one (e.g., a winged nut) that connects to an oxygen therapy flowmeter; and 2) one to which the patient tubing is connected. This is a reusable device. (SOURCE: GMDN 35113)
	Technical	Reusable humidifier for oxygen therapy and ventilation/anesthesia inspiratory lines.
		Non-heated humidifier - ambient temperature functionality.
		Bubble-through humidification system.
		Unbreakable or shatter resistant.
		Transparent humidification bottle
		Graduated, graduation shall show minimum and maximum water level.
		Humidification chamber working volume at least 150 mL, not greater than 500 mL.
		Detachable metal or rigid durable polymer cap with gas connectors.
		Pressure relief safety valve, ≥ 14 kPa (0.1 bar, 2 psi) pressure rating.
		DISS, female (nut) connectors for inlet.
		6 mm barbed connector for outlet.
		Flow rate capacity up to 15 L/min.
		Must be capable of disinfection.
		Materials, all to be certified for medical use:
		Cap and connectors made of brass/steel/other biocompatible metal or polymer
		Bottle and tubes made of polypropylene, polycarbonate or equivalent biocompatible plastic/polymer
		Pressure valve made of brass chromium plated or equivalent metal
		Supplier must define decontamination procedure.
	Warranty	Min. 1 year (ideal 2)
	After sales	Availability of repair and/or service level agreements
	Standards	ISO 13485 (medical device QMS)
		ISO 18562-1: Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process.
	Regulatory	CE
		FDA

	Product performance standards	ISO 8185 Respiratory tract humidifiers for medical use – Particular requirements for respiratory humidification systems.
		ISO 15001 Anesthetic and respiratory equipment – Compatibility with oxygen.
		ISO 18562 Biocompatibility evaluation of breathing gas pathways in healthcare applications.
		ISO 18190 Anesthetic and respiratory equipment – General requirements for airways and related equipment
		ISO 18562-1 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process.
	Packaging	Name and/or trade mark and address of the manufacturer.
		Product name.
		Product reference.
		Type of product and main characteristics.
		Performance testing information against the mentioned standards.
		Lot number prefixed by the word "LOT" (or equivalent harmonized symbol).
		Expiry date by year and month, prefixed by the word "EXP" (or equivalent harmonized symbol).
		Information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonized symbol), if applicable.
		Information for handling, if applicable (or equivalent harmonized symbol).
		If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging.
		Gross Weight.
		Cubic Measurement.
		All indicated at least in English.