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Ministry of Health

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MEDICAL OXYGEN & OXYGEN THERAPY

TECHNICAL SPECIFICATIONS FOR DEVICES AND EQUIPMENTS

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FOREWORD

The Kenyan health sector is guided by the Kenya Health Policy, 2014-2030's whose goal is the attainment of the highest possible health standards in a manner responsive to the population needs as enshrined in The Constitution of Kenya, 2010.

Ensuring that effective, safe, and affordable health products and technologies are available and rationally used, is pivotal to a functioning health care system that supports the Universal Health Coverage (UHC) agenda. Medical Oxygen is an essential medicine, and lack of access to it results in serious consequences. Oxygen requires a whole system approach to safely reach patients.

The Ministry of Health envisions a sustainable, resilient and responsive health system that effectively responds to health emergencies requiring Medical Oxygen for therapy or breathing support. This will be achieved through providing quality Medical Oxygen; investing in relevant generation, storage and distribution infrastructure; as well as using appropriate administration devices and equipment.

The purpose of these technical specifications is to provide harmonized specifications for a wide range of products for delivering Medical Oxygen for therapy, and to provide guidance on the selection, procurement, use and maintenance of these equipment and devices.

The technical specifications are intended to guide policy and decision makers at all levels, health facility managers, administrators, procurement officers, planning officers, biomedical engineers, and infrastructure engineers to properly select, procure, use and maintain Medical Oxygen systems, infrastructure and equipment.

Dr. Patrick Amoth, EBS
Ag. Director General of Health
Ministry of Health

ACKNOWLEDGEMENTS

Reaching Impact, Saturation, and Epidemic Control (RISE) is a multi-year cooperative agreement that helps meet or exceed PEPFAR targets for reaching adults, key, and priority populations by finding those who have not yet been identified as positive, linking HIV-positive clients to treatment, and keeping those on treatment virally suppressed. RISE has partnered with ministries of health, nongovernmental organizations, and other local stakeholders in more than 20 countries globally to advance HIV and COVID-19 response efforts. With funding from the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), RISE works across the HIV prevention, care, and treatment cascade to assist efforts by countries to reach the UNAIDS 95-95-95 goals. RISE works with a range of stakeholders to ensure that host government health systems and host countries in general are able to maintain program gains with appropriately decreasing dependence on PEPFAR/USAID. Beyond PEPFAR, RISE supports emergency health response, strengthening global health security in affected countries, health systems support, and the COVID-19 response. RISE is a multi-year project led by Jhpiego and implemented by a consortium, which includes ICAP at Columbia University, Management Sciences for Health, Anova Health Institute, BAO Systems, the Johns Hopkins University Center for Public Health and Human Rights, and Mann Global Health.

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SECTION 1: TECHNICAL SPECIFICATION FOR PSA (PRESSURE SWING ADOPTION) PLANT

INTRODUCTION TO PRESSURE SWING ADSORPTION

Pressure swing adsorption (PSA) is the process by which ambient air passes through an internal filtration system (e.g., a molecular sieve [zeolite granules or membranes]), which has a large enough total surface area to separate nitrogen (N2) from the air, concentrating the remaining oxygen (O2) to a known purity. It typically consists of an air compressor, dryer, filters, dual separation chambers, a reservoir, and controls.

PRESSURE SWING ADSORPTION (PSA) PLANT		
i.	Version number	1
ii.	Date of initial version	November 2023
iii.	Date of last modification	November 2023
iv.	Date of publication	November 2023
v.	Developed by	MINISTRY OF HEALTH
FUNCTIONAL REQUIREMENTS		
	Overview of functional requirements	• Uses pressure swing adsorption (PSA) technology to produce medical oxygen 93%±3 from ambient air • Easy to install: preassembled and skid-mounted, or containerized • Oxygen production monitoring • Control panel/user interface, with numerical and graphical values, as applicable • On-site training for installation, use, and maintenance preferable • Remote support for installation, use and maintenance • Plant life-span of a minimum of 10 years; guaranteed by a letter from the manufacturer • Alarm for low oxygen concentration and System malfunction • Alarm when automatic back-up engaged, as configured (e.g., secondary plant in duplexed parallel system or reserve cylinders from ancillary manifold) **Optional:** • Remote monitoring feature • Cylinder refilling capabilities
	Detailed requirements	• Oxygen concentration monitor with +/- 1% accuracy • Continuous display of the oxygen concentration and pressure • Alarm when an oxygen concentration is lower than 90% • Function of purge of low concentration of oxygen • Continuous output flow to cover 100% of the oxygen demand • Continuous output pressure of 400-600 kPa / 4 – 6 bars / 58-87 psi. A gauge or sensor located between the source and the line pressure control to monitor the output pressure • Alarm when the output pressure is < 3.5 bar / 50.7 psi • Feed air compressor, either oil-free or filtered oil-injected or oil-lubricated: minimum 750 kPa / 7.5 bars / 108 psi • External air dryer with capacity sized to manage compressor output
	Control panel and user interface	**Digital display, clearly visible in English, for at least:** • Oxygen concentration [%] • Oxygen production trending [Nm3/hour and LPM] • Output pressure [PSI, kPa and Bars] • System status, including current maintenance need • Cumulative hours of operation (digital or analogue meter) • Cumulative Oxygen production [Nm3, L) **Audible & visual alarms and automatic shutdown for:** • High temperature • Low/high pressure • Low oxygen concentration (<90%) • Power failure • System failure • Second/reserve source active (optional) • Air dryer pressure dew point (>3°C)
	Components	• Air compressor with air dryer and pre-filters with automatic drains • Air receiver/buffer tank • Filter assembly to include: pre-filter; coalescing filter; and, coal filter (coal tower, alternatively activated carbon filter), as applicable • Oxygen generator unit (PSA) • Oxygen analyzer for medical application • Oxygen tank with bacterial outlet filter • Oxygen filling station (optional)
	Spare parts and consumables	• 3-year spare parts kit as per recommended preventive maintenance program clearly defined in a disaggregated list comprising part numbers, descriptions, and unit cost, as well as indicating brand/model specifics by the manufacturer • Set of inlet filters and outlet bacteria filter for 3-years operation (estimated from the usage)

	Power supply	• Three-Phase, 415 VAC 50Hz • Single-phase, 240 VAC 50 Hz • UPS for PSA control unit • Control unit with protective switchgear

1.2 SPECIFICATIONS FOR PSA PLANT COMPONENTS

Feed-Air Compressor, Air Dryer, Filters, Oxygen Generator, Control Panel, Air Receiver Tank, Oxygen Receiver Tank.

1.2.1 FEED-AIR COMPRESSOR WITH AIR DRYER AND FILTERS		
i.	Version number	1
ii.	Date of initial version	November 2023
iii.	Date of last modification	November 2023
iv.	Date of publication	November 2023
v.	Developed by	MINISTRY OF HEALTH
NAME, CATEGORY AND CODING		
	Generic name	Feed Compressor for PSA and filter module
	Specific type or variation	Feed air compressor, either oil-free or filtered oil-injected or oil-lubricated rotary screw type
	Alternative name/s	Medical Compressor, dryer and filters
	Keywords	Feed air compressor, oil free, filtered oil injected, oil lubricated, medical compressor, rotary screw compressor, dryer, filter, carbon filter
PURPOSE OR USE		
	Level of use	Sub-county hospital (Level 4) County referral (Level 5)
	Clinical Department / Ward	All departments where oxygen and/or respiratory support/therapy is delivered, including, but not limited to, intensive care units, inpatient ward, emergency, operating theatre, recovery room, observation, etc.
TECHNICAL SPECIFICATIONS		
	Detailed requirements	**FEED-AIR COMPRESSOR** The compressor draws atmospheric air and compresses it to 5 to 10 bar to feed the PSA unit. The compressed air should be processed through oil separation, dryer system and filtration. The compressor must comply with **ISO 8573-1:2010 - Compressed air — Part 1:** Contaminants and purity classes; Requirements for purity of compressed air with respect to particles, water and oil independent of the location in the compressed air system at which the air is specified or measured; Ready to run, fully automatic, super silenced, vibration damped all panels powder coated. Built-in oil separator.
		Suitable for use in ambient temperatures up to +45°C. User interface, automatic controls. Fluid and air flow cooling; Sound level 65-75dB. Sound insulated. • Easy to install: preassembled and skid-mounted, or containerized • Production monitoring in terms of service hours, running hours, error codes monitoring of dew point, hydrocarbons, aerosol mist • Control panel/user interface, with numerical and graphical values, as applicable • On-site training for installation, use, and maintenance • Remote support for installation, use and maintenance (optional) • Lifespan of a minimum of 10 years; guaranteed by a letter from the manufacturer • Alarm for low pressure and machine error codes • Variable speed drive (VSD) compressor • Oil/Water separator where applicable • Electronic drain • Sequential soft start-stop (star/delta starter for larger motors) • High energy efficiency rating not less than 5-star as per KS 2449-1:2013 or equivalent internationally recognized standard • Noise reduction canopy. Sound pressure levels less than 74 dB(A) at one meter **Optional** — Remote monitoring feature **PRE-FILTER** • Air intake side: Filtration assembly, comprising: Replaceable particulate filter (<10 micron) **AIR DRYER** • External air dryer with capacity sized to manage compressor output. Able to operate at 7.5 bar. Three-Phase 415VAC 50Hz Integrated design, energy saving, compressed air drying for stable PDP +3 °C, maximum working pressure: 16 bar flow rate 0.35 to 106.18 m³/min, refrigerating drier. • Provide air treatment to meet the quality required for the PSA Compliant with the following European Pharmacopoeia monograph: — O_2 20.4% < x < 21.4% — CO_2 <500 ppm — CO <5 ppm — SO_2 <1 ppm — NO_x <2 ppm — Water vapor ADP -45ºC (-49ºF) / PDP -31ºC (-23ºF) — Oil vapor <0.1 mg/m3 — Taste and odor: taste and odor-free

- Designed and manufactured in accordance with **ISO 9001 - Quality management, ISO 14001- Environmental management and ISO 13485 - Medical devices — Quality management systems — Requirements for regulatory purpose; complies to ISO 7396-1:2016 - Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum, ISO 14971 - Medical devices — Application of risk management to medical devices, and conform to Medical Device Directive MDD 93/42/EEC, HTM 02-01 and HTM 2022;** which means dependable, sustained pressure dew point performance of +3°C even at high ambient temperatures up to +43°C
- Refrigeration Circuit
  - Refrigerant (CFC free)
  - Refrigerant separator
  - Refrigerant compressor with fan (optional)
  - Control pressure switches
  - Condenser fan
  - Condenser
  - Capillary filter
  - Capillary tube
  - Thermostatic Expansion Valve (TEV)
- Air Circuit
  - Air inlet
  - Air to refrigerant heat exchanger
  - Air/heat exchanger
  - Water separator
  - Automatic electronic drain
  - Air outlet
- Dew point
  - Constant dew point ≤3°C
  - Device for continuous measurement of Dew point
  - Dew point display unit

AIR RECEIVER TANK

- Air receiver tank shall be designed and constructed in accordance with ASME section VIII standards
- Interior shall be constructed from stainless steel while exterior shall be constructed from mild steel primer painted.
- The tank shall be sized to match the air demand of the PSA/hospital and also enable a steady air pressure supply at all times including during peak demands.
- It shall be vertical mounting complete with the following fittings
  - Pressure indicator
  - Pressure relief Valve
  - Electronic Drain
  - Pressure control valve
- In general, the tank shall be sized to at least 5000 litres for PSA of capacity 250 lpm to 1000 lpm
- The working pressure of the tank shall be at least 1.5 times the working pressure of the air compressor
- The tank shall be cleaned according to ISO 15001, ASTM G93 or equivalent
- The tank shall be Inspected, tested and certified in accordance with ASME VIII or equal and equivalent recognized international standards and a certificate issued.

FILTERS

- Filter types:
  - Coalescing filter (≤0.01 micron) - conforms to ISO 12500-1:2007 Filters for compressed air — Test methods — Part 1: Oil aerosols
  - Carbon absorption filter (Coal tower, if applicable) - Oil indicator fitted as standard
  - Bacterial/viral filters (medical sterile filters)
  - Must comply to ISO 12500:2007 - Filters for Compressed Air
- Manufactured according to ISO 9001 and ISO 13485 quality management systems, and should be Oxygen safe and tested as per ISO 12500:2007 Filters for compressed air
- Quality of air to meet to meet ISO 8573-1:2010 - Compressed air — Part 1: Contaminants and purity classes; and detailed below:
  - Particles (maximum number per m3)
    i. 0.01μm<d≤0.5μm (≤ 20,000)
    ii. 0.5μm<d≤ 1.0μm (≤400)
    iii. 1.0μm<d≤ 5.0μm (≤10)
  - Water (vapor dew point) ≤-70°C
  - Oil (liquid, aerosol & vapor) ≤0.01
- Air cleaning must comply with ***ASTM G93/ G93M Standard Guide for Cleanliness Levels and Cleaning Methods for Materials and Equipment Used in Oxygen-Rich Environments***

OXYGEN RECEIVER TANK

- Oxygen receiver tank shall be designed and constructed in accordance with ASME section VIII standards
- Interior shall be constructed from stainless steel while exterior shall be constructed from mild steel primer painted.

		• The tank shall be sized to match the oxygen demand of the hospital in such a manner as to enable a steady oxygen pressure supply at all times including during peak demands. • It shall be vertical mounting complete with the following fittings — Pressure indicator — Pressure relief Valve — Electronic Drain — Pressure control valve • In general, the tank shall be sized to at least 5000 liters for PSA of capacity 250 lpm to 1000 lpm • The working pressure of the tank shall be at least 10 bars. • The tank shall be cleaned according to ISO 15001, ASTM G93 or equivalent • The tank shall be Inspected, tested and certified in accordance with ASME VIII or equal and equivalent recognized international standards and a certificate issued.
	Configurations/options	Skid mounted, containerized or free standing
	Displayed parameters	Measured flow rate, pressure
	User adjustable settings	Flow rate
PHYSICAL/CHEMICAL CHARACTERISTICS		
	Components	Feed air compressor, either oil-free or filtered oil-injected or oil-lubricated: minimum 750 kPa / 7.5 bars / 108 psi; Oil separators; Dryer system; Filters
	Mobility, portability	Skid mounted or Free standing
	Raw materials	N/A
UTILITY REQUIREMENTS		
	Electrical, water and/or gas supply	3-phase (415 VAC) electrical connection, well-ventilated building setting, Drainage for effluent water
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
	Accessories	O-rings and seals, filters
	Sterilization/disinfection process for accessories	Suitable for cleaning and disinfection.
	Spare parts	Filters, seals
PACKAGING		
	Transportation and storage	Capable of being transported and stored at ambient temperature of at least 5–50 °C, relative humidity of at least 15–95% non-condensing. Specific requirements for altitude may be required, depending on the installation site.
	Labeling	**Labeling on the primary packaging:** Name and/or trademark of the manufacturer; serial number; manufacturer's product reference; type of product and main characteristics; lot number prefixed by the word "LOT" (or equivalent harmonized symbol) (if applicable); information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonized symbol); information for handling, if applicable (or equivalent harmonized symbol); power consumption; power requirement
ENVIRONMENTAL REQUIREMENTS		
	Context-dependent requirements	• Capable of being stored at 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
TRAINING, INSTALLATION AND UTILIZATION		
	Pre-installation requirements	Verification of fittings on oxygen sources (concentrator, cylinders, wall outlet/central supply, etc.) and on the medical devices/equipment working with the flowmeter
	Requirements for commissioning	Local clinical and technical staff to affirm completion of installation, proper operation, free from leaks
	Training	Training of users in operation and basic maintenance is recommended, depending on the case, and shall be provided upon request. Training on preventive maintenance i.e., daily, weekly, monthly, quarterly and annual
	User and technical care	• Pre-use checks • Proper connection • Cleaning with compatible products • Periodic functionality checks
WARRANTY AND MAINTENANCE		
	Warranty	Warranty - 2 years. The product shall be fully supported for a period of 10 years.
	Maintenance tasks	Regular cleaning and functionality checks, oil checks, filter replacement, O-ring replacement. Manufacturers to submit maintenance manuals
	Service-Level Agreements (SLA)	The manufacturer or local authorized agent is to provide comprehensive maintenance services during the warranty period, including spares
	Spare parts availability post-warranty	At least 10 years, starting from the date of installation.
DOCUMENTATION		
	Documentation requirements	• User and maintenance manuals, hard and soft copies, to be supplied in English and other agreed languages. • Certificates of calibration and inspection to be provided.

		• List to be provided of equipment and procedures. required for local calibration and routine maintenance. • List to be provided of common spare parts and accessories (with part numbers). • Service Level Agreement, post-warranty, including pricing of common parts and spares. Contact details of manufacturer, supplier and local service agent to be provided.
DECOMMISSIONING		
	Estimated life span	10 years
SAFETY AND STANDARDS		
	Risk classification	Class A (GHTF), Class I (USA), Class IIa (Europe, Australia), Class II (Canada, Japan). Electrical dangers, fumes, flying particles, high pressures and high noise levels, oil leaks, fire hazard
	Regulatory approval / Certification	Proof of regulatory compliance (e.g., registration, clearance, approval) by PPB or as required
	International standards	Standards applicable to the manufacturer and the manufacturing process (compliance to the last available version is required, proof of compliance must be provided): — ISO 7396-1:2016 Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gasses and vacuum — ISO 2151:2014 - Acoustics — Noise test code for compressors and vacuum pumps — Engineering method (Grade 2) — ISO 9614-2 - Acoustics — Determination of sound power levels of noise sources using sound intensity — Part 2: Measurement by scanning — ISO 8573-1:2010 class 1.4.1 - Compressed air — Part 1: Contaminants and purity classes — ISO 12500-1:2007— Filters for Compressed Air — Part 1: Oil Aerosols — ISO 12500-2:2007— Filters for compressed air — Part 2: Oil Vapors — ISO 7183:2007 - Compressed-air dryers — Specifications and testing — Flow rate complete system as per ISO 1217:2009 Standards applicable to the product (where applicable, compliance to the last available version is required, proof of compliance must be provided): **Electrical Standards** — IEC 61800 (part 1 to 5, as applicable) - Adjustable speed electrical power drive systems — EN 60034 (Part 1 to 30, as applicable) - Rotating Electrical Machines – Rating and Performance

		— EN 60204-1:2009, Safety of Machinery – Electrical Equipment of Machines – Part 1: General Requirements — EN 60439-1:2004, Low-voltage and control gear assemblies – Part 1: Type tested and partially type tested assemblies
	Regional / Local standards	Country-specific and regional standards apply and must be listed
	Regulations	Country-specific and regional regulations apply and must be listed. Compliance to (where applicable, but not limited to, and last available version)

1.2.2 OXYGEN GENERATOR UNIT/PSA MODULE/PSA GENERATOR UNIT		
i.	Version number	1
ii.	Date of initial version	November 2023
iii.	Date of last modification	November 2023
iv.	Date of publication	November 2023
v.	Developed by	MINISTRY OF HEALTH
NAME, CATEGORY AND CODING		
	Generic name	Oxygen generator, PSA generator unit/module
	Keywords	Pressure Swing Adsorption (PSA), Oxygen generator
	GMDN definition	N/A
PURPOSE OR USE		
	Clinical or other purpose	The Oxygen generator (PSA module) passes ambient air through an internal filtration system (e.g., a molecular sieve [zeolite granules or membranes]), which has a large enough total surface area to separate Nitrogen (N) from the air, concentrating the remaining Oxygen (O2) to a known purity (93±3%)
	Level of use	Sub-county hospital (Level 4) County referral (Level 5) National referral hospital (Level 6)
	Clinical department / Ward	All departments where oxygen and/or respiratory support/therapy is delivered, including, but not limited to, intensive care units, inpatient ward, emergency, operating theatre, recovery room, observation, etc
	Overview of functional requirements	• Pressure Swing Adsorption (PSA) unit consisting of a molecular sieve (zeolite granules or membranes) • A filter assembly before the adsorber vessels • A particulate filter to remove condensed water, oil, dirt, scale, etc. from the feed air • A separate coalescing filter to remove additional oil and water vapor

<table>
<tr><th colspan="3">TECHNICAL CHARACTERISTICS</th></tr>
<tr><td></td><td>Detailed requirements</td><td>
PSA Generator Unit
PSA standard purity module. Fully automatic, with digital controls.
Supply of compressed air at intake of the PSA required, as per KS 2170-2:2008 - Medical gases - Specification - Part 2: Medical air or equivalent standard
— Minimum supply pressure: to match the PSA requirement
— Vapor Pressure Dewpoint: ≤-40°C ambient
— Oil-Content: 0.1 mg/m3
— Particles: ≤6000 (0.5-1.0 microns)
The Oxygen produced shall be medical grade with purity of 93±3% (as defined in Monograph ‘Oxygen, 93 per cent’ 04/2011:2455 European Pharmacopoeia 7.1)
<table>
<tr><th colspan="2">Impurity limits (at STP)</th></tr>
<tr><td>Carbon monoxide ppm v/v</td><td>≤ 5</td></tr>
<tr><td>Carbon dioxide ppm v/v</td><td>≤ 300</td></tr>
<tr><td>Water ppm v/v</td><td>≤67</td></tr>
<tr><td>Oil mg/m3</td><td>≤ 0.1</td></tr>
<tr><td>Nitrogen Monoxide & Nitrogen dioxide ppm v/v</td><td>≤ 2</td></tr>
<tr><td>Sulphur dioxide ppm v/v</td><td>≤ 1</td></tr>
</table>
</td></tr>
<tr><td></td><td></td><td>
All interconnecting pipelines including pressure regulators and valves shall be designed in compliance with ISO 7396-1:2016 - Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum.
Base frame shall be a complete unit covered with plates made from steel material.
Pressure gauges shall be made of stainless steel with stainless steel needle valves.
Control panel
Digital control - The control panel on the oxygen generator shall contain the controls needed to operate the oxygen generator and monitor its operation.
The system shall incorporate a microprocessor programmable unit (PLC) with an LCD/LED display and touch buttons.
It shall be capable of controlling the medical oxygen gas pressure in the hospital pipeline to acceptable design values.
Typical measurement and control parameters:
• Oxygen concentration
• Carbon Monoxide
• Oxygen flow rate
• Cumulative volume of oxygen produced
• Data logging
• Remote monitoring capability (optional)
• Multi-level secured access for supervisory control
• Multi-language option
• Process parameter and fault notifications (alarms, on-screen display, SMS, email, and automatic shutdown for critical faults)
• Air receiver pressure
• Dew point monitoring
• Visual recommended service maintenance reminders
• Parameters displayed in metric units
• Real time trends of process parameters
• General maintenance guidelines
• Interface facilities- GSM module, TCP/IP port, USB port
</td></tr>
<tr><td></td><td>Configurations/options</td><td>Skid mounted, containerized or free standing</td></tr>
<tr><td></td><td>Displayed parameters</td><td>Measured flow rate, air and oxygen pressures, run time, process, faults, graphs, volume, purity and impurity</td></tr>
<tr><td></td><td>User adjustable settings</td><td>Flow rate, run time, and pressures</td></tr>
<tr><th colspan="3">PHYSICAL/CHEMICAL CHARACTERISTICS</th></tr>
<tr><td></td><td>Components</td><td>The PSA generator unit, control panel, piping, pressure valves/regulators, solenoid valves, filters, transducers, non-return valves, power supply and UPS</td></tr>
<tr><th colspan="3">UTILITY REQUIREMENTS</th></tr>
<tr><td></td><td>Electrical, water and/or gas supply</td><td>
• Single-phase (240 VAC) electrical connection/ trunking with UPS.
• Well-ventilated building setting.
• Drainage for effluent water
</td></tr>
<tr><th colspan="3">ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS</th></tr>
<tr><td></td><td>Accessories</td><td>Air hoses, and Oxygen hoses</td></tr>
<tr><td></td><td>Sterilization/disinfection process for accessories</td><td>Suitable for cleaning and disinfection.</td></tr>
<tr><td></td><td>Spare parts</td><td>Filters, Solenoid valve, pressure valves and seals, fuses</td></tr>
<tr><th colspan="3">PACKAGING</th></tr>
<tr><td></td><td>Transportation and storage</td><td>Capable of being transported and stored at ambient temperature of at least 5–50 °C, relative humidity of at least 15–95% non-condensing. Specific requirements for altitude may be required, depending on the installation site.</td></tr>
<tr><td></td><td>Labeling</td><td>Labeling on the primary packaging:
Name and/or trademark of the manufacturer; serial number; manufacturer’s product reference; type of product and main characteristics; lot number prefixed by the word “LOT” (or equivalent harmonized symbol) (if applicable); information for particular storage</td></tr>
</table>

		conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonized symbol); information for handling, if applicable (or equivalent harmonized symbol); power consumption; power requirement
ENVIRONMENTAL REQUIREMENTS		
	Context-dependent requirements	• Capable of being stored at 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
TRAINING, INSTALLATION AND UTILIZATION		
	Pre-installation requirements	Verification of fittings on oxygen sources (concentrator, cylinders, wall outlet/central supply, etc.)
	Requirements for commissioning	Local clinical and technical staff to affirm completion of installation, proper operation, free from leaks
	Training	Training of users in operation and basic maintenance is recommended, depending on the case, and shall be provided upon request. Training on preventive maintenance i.e., daily, weekly, monthly, quarterly and annual
	User and technical care	• Pre-use checks • Proper connection • Cleaning with compatible products • Periodic functionality checks
WARRANTY AND MAINTENANCE		
	Warranty	2 years
	Maintenance tasks	Regular cleaning and functionality checks, oil checks, filter replacement, O-ring replacement. Manufacturers to submit maintenance manuals
	SLA	The manufacturer or local authorized agent is to provide comprehensive maintenance services during the warranty period, including spares
	Spare parts availability post-warranty	The manufacturer shall guarantee availability of spare parts for at least 10 years starting from the date of installation.
DOCUMENTATION		
	Documentation requirements	• User and maintenance manuals, hard and soft copies, to be supplied in English and other agreed languages. • Certificates of calibration and inspection to be provided. • List to be provided of equipment and procedures. required for local calibration and routine maintenance.
		• List to be provided of common spare parts and accessories (with part numbers). • Service Level Agreement, post-warranty, including pricing of common parts and spares. Contact details of manufacturer, supplier and local service agent to be provided
DECOMMISSIONING		
	Estimated life span	10 years
SAFETY AND STANDARDS		
	Risk classification	Class 1- (GHTF),
	Regulatory approval / Certification	Proof of regulatory compliance (e.g., registration, clearance, approval) by PPB/KEBS as required
	International standards	Standards applicable to the manufacturer and the manufacturing process (compliance to the last available version is required, proof of compliance must be provided): — ISO 9001:2015 - Quality management systems Standards applicable to the product (where applicable, compliance to the last available version is required, proof of compliance must be provided): — ISO 13485:2016 - Medical devices — Quality management systems — Requirements for regulatory purposes — ISO 7396-1 - Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gasses and vacuum — ISO 8573-1:2010 class 1.4.1 - Compressed air — Part 1: Contaminants and purity classes — ISO 12500:2007 - Filters for Compressed Air — ISO 7183:2007 - Compressed-air dryers — Specifications and testing — ISO 1217:2009 - Displacement compressors — Acceptance tests **Electrical Standards** — IEC 60601-1:2015 - Medical electrical equipment — General requirements for basic safety and essential performance
	Regional / Local standards	Country-specific and regional standards apply and must be listed
	Regulations	Country-specific and regional regulations apply and must be listed. Compliance to (where applicable, but not limited to, and last available version)

SECTION 2: SPECIFICATIONS FOR MEDICAL OXYGEN

INTRODUCTION

Liquid Medical Oxygen, Medical Oxygen, Medical Air

2.1 LIQUID MEDICAL OXYGEN		
i.	Version number	1
ii.	Date of initial version	November 2023
iii.	Date of last modification	November 2023
iv.	Date of publication	November 2023
v.	Developed by	MINISTRY OF HEALTH
NAME, CATEGORY AND CODING		
	Generic name	99.5 % Medical E.P. Grade Compressed Oxygen
	Chemical structure	O=O; O_2
	Specific type or variation	N/A
	CAS number	7782-44-7
	Alternative name/s	N/A
	Alternative code/s	ATC Code V03AN01
	Keywords	medical oxygen, liquid medical oxygen, medical EP grade compressed gas
PURPOSE OR USE		
	Clinical or other purpose	Liquid medical oxygen is widely used in clinical practice to provide a basis for most modern anesthetic techniques including pre and postoperative management. To restore the tissue oxygen tension towards normal by improving oxygen availability in a wide range of conditions. In all cases, the liquid medical oxygen is vaporized to a compressed gas at ambient conditions before being administered to the patient.
	Level of use	Sub-county (Level 4) County referral (level 5) National referral (Level 6) hospitals
	Clinical department / Ward	All sites where oxygen and/or medical air supply is needed, including, but not limited to, intensive care units, inpatient ward, emergency, operating theatre, recovery room, observation, etc.,
TECHNICAL CHARACTERISTICS		
	Detailed requirements	**Medical Oxygen:** Liquid medical oxygen shall be certified for medical use and complies with **KS 2170-1:2009 - Medical gases - Specification - Part 1: Medical oxygen.**
		After vaporization it shall: • Contain no less than 99.5% v/v of oxygen • Not more than 5 ppm v/v of carbon monoxide • Not more than 300 ppm v/v of carbon dioxide • Less than 0.1mg/m3 oil • Less than 67 ppm v/v of water It shall be free of halogens and oxidizing substances. The gas will pass through existing pipeline network in hospitals
PHYSICAL/CHEMICAL CHARACTERISTICS		
	Physical characteristics	• Appearance - Odorless, colorless gas • Molecular weight 32 • Boiling point -183.1°C (at 1 bar) • Density 1.335 kg/m3 (at 15°C) Markings and labels as per ***KS ISO 32:1977 - Gas cylinders for medical use - Marking for identification of content.*** Combustion characteristics - Non-flammable. Strongly supports combustion.
	Chemical Characteristics	Complies with current ***KS 2170-1:2009 - Medical gases - Specification - Part 1: Medical oxygen*** specifications:- • Purity not less than 99.5% v/v. • Carbon dioxide not more than 300 ppm v/v • Carbon monoxide not more than 5 ppm v/v • Water not more than 67 ppm v/v
PACKAGING		
	Shelf life	Liquid medical oxygen is not meant to be stored for prolonged periods **(NOT MORE THAN 3 MONTHS)**
	Packaging	The product shall be supplied as compressed/ liquified gas in appropriate steel cylinders/containers (**CGA approved** seamless steel/aluminium alloy/ composite body as per ***BS EN 13458-2 - Cryogenic vessels. Static vacuum insulated vessels design, fabrication, inspection and testing*** complying with relevant Kenya standards). Valves or taps shall not be lubricated with oil or grease.
	Transportation and storage	Compliance with regulations on hazardous goods, flammable, explosive, compressed gas, according with GHS and international standards is mandatory. Transportation in a sealed container. Capable of being transported and stored in ambient temperature of at least 5–50 °C, relative humidity of at least 15–95% non-condensing
	Labeling	• ***GHS (Global Harmonized System)*** hazard classification coding and regulations for hazardous goods, flammable, explosive and compressed gas labeling • ***KS ISO 7225:2005 - Gas cylinders - Precautionary labels***

		• Markings and color-coding as per ***KS ISO 32:1977 - Gas cylinders for medical use - Marking for identification of content***
SAFETY AND STANDARDS		
	Regulatory approval / Certification	Proof of regulatory compliance (e.g., registration, clearance, approval) must be provided as appropriate per the product's risk classification
	International standards	• Standards applicable to the manufacturer and the manufacturing process (compliance to the last available version is required, proof of compliance must be provided) • Applicable standards for quality management e.g., ***ISO 9001:2015 - Quality management systems*** and Good Manufacturing Practices (GMP) • Standards applicable to the product (where applicable, compliance to the last available version is required, proof of compliance must be provided): — Color coding ***KS ISO 32:1977 - Gas cylinders for medical use — Marking for identification of content*** for medical gases
	Regional / Local standards	Country-specific and regional color gas coding and other standards apply and must be listed i.e. ***KS 2170-1:2009 - Medical gases - Specification - Part 1: Medical oxygen***
	Regulations	Country-specific and regional regulations apply and must be listed. Compliance to (where applicable, but not limited to, and last available version)

2.2 MEDICAL OXYGEN		
i.	Version number	1
ii.	Date of initial version	November 2023
iii.	Date of last modification	November 2023
iv.	Date of publication	November 2023
v.	Developed by	MINISTRY OF HEALTH
NAME, CATEGORY AND CODING		
	Generic name	Oxygen 93% ± 3 (Ph. Eur., USP)
	Chemical structure	O=O; O_2
	Specific type or variation	N/A
	CAS number	7782-44-7
	Alternative name/s	Medical Oxygen, Medicinal Oxygen
	Alternative code/s	ATC Code V03AN01
	Keywords	medical oxygen, Medical E.P. grade compressed oxygen

PURPOSE OR USE		
	Clinical or other purpose	Medical oxygen is widely used in clinical practice to provide a basis for most modern anesthetic techniques including pre and postoperative management. To restore the tissue oxygen tension towards normal by improving oxygen availability in a wide range of conditions. In all cases, the medical oxygen is a compressed gas at ambient conditions before being administered to the patient.
	Level of use	Dispensary (Level 2) Health center (Level 3) Sub-County (Level 4) County referral (level 5) National referral (Level 6) hospitals
	Clinical department / Ward	All sites where oxygen and/or medical air supply is needed, including, but not limited to, intensive care units, inpatient ward, emergency, operating theatre, recovery room, observation, etc.,
TECHNICAL CHARACTERISTICS		
	Detailed requirements	**Medical Oxygen:** **Ph. Eur. 8: (Oxygen 93 percent) -** It contains 90.0% v/v to 96.0% v/v of 02, the remainder mainly consisting of argon and nitrogen.
		A colorless gas. It is normally used on the site where it is produced. It is fed directly into a medicinal gas pipeline or administration system. Where authorized, it may be stored in suitable containers. Oils and grease are not to be used unless oxygen-compatible.
PHYSICAL/CHEMICAL CHARACTERISTICS		
	Physical characteristics	• Appearance - odorless, colorless gas • Molecular weight 32 • Boiling point -183.1°C (at 1 bar) • Density 1.335 kg/m3 (at 15°C) Combustion characteristics - Non-flammable. Strongly supports combustion
	Chemical Characteristics	Complies with current ***European Pharmacopoeia (Ph.Eur)*** specifications; • Purity 93%±3 v/v

Impurity limits (at STP)	
Carbon monoxide *ppm v/v*	≤ 5
Carbon dioxide *ppm v/v*	≤ 300
Water *ppm v/v*	≤67
Oil *mg/m3*	≤ 0.1
Nitrogen Monoxide & Nitrogen dioxide *ppm v/v*	≤ 2
Sulphur dioxide *ppm v/v*	≤ 1

PACKAGING		
	Shelf life	Not applicable
	Packaging	The product shall be supplied as compressed gas in appropriate steel cylinders/containers complying with relevant standards; Valves or taps shall not be lubricated with oil or grease
	Transportation and storage	Compliance with regulations on hazardous goods, flammable, explosive, compressed gas, according to GHS and international standards is mandatory. Transportation in a sealed container. Capable of being transported and stored in ambient temperature of at least 5–50 °C, relative humidity of at least 15–95% non-condensing
	Labeling	• ***GHS (Global Harmonized System)*** hazard classification coding and regulations for hazardous goods, flammable, explosive and compressed gas labeling • ***KS ISO 7225:2005 - Gas cylinders - Precautionary labels*** • Markings and color-coding as per ***KS ISO 32:1977 - Gas cylinders for medical use - Marking for identification of content***
SAFETY AND STANDARDS		
	Regulatory approval / Certification	Proof of regulatory compliance (e.g., registration, clearance, approval) must be provided as appropriate per the product's risk classification
	International standards	• Standards applicable to the manufacturer and the manufacturing process (compliance to the last available version is required, proof of compliance must be provided) • Applicable standards for quality management e.g., ***ISO 9001:2015 - Quality management systems*** and Good Manufacturing Practices (GMP) • Standards applicable to the product (where applicable, compliance to the last available version is required, proof of compliance must be provided): — Color coding ***KS ISO 32:1977 - Gas cylinders for medical use — Marking for identification of content*** for medical gases
	Regional / Local standards	Country-specific and regional color gas coding and other standards apply and must be listed i.e. ***KS 2170-1:2009 - Medical gases - Specification - Part 1: Medical oxygen***
	Regulations	Country-specific and regional regulations apply and must be listed. Compliance to (where applicable, but not limited to, and last available version)

2.3 MEDICAL AIR		
i.	Version number	1
ii.	Date of initial version	November 2023
iii.	Date of last modification	November 2023
iv.	Date of publication	November 2023
v.	Developed by	MINISTRY OF HEALTH
NAME, CATEGORY AND CODING		
	Generic name	Medical Air
	Chemical structure	O_2 + N +CO_2 + inert gases
	Specific type or variation	N/A
	CAS number	N/A
	Alternative name/s	Medicinal Air
	Alternative code/s	N/A
	Keywords	medical air, medical compressed air
PURPOSE OR USE		
	Clinical or other purpose	The main uses of medical compressed air are: driving ventilators, where it provides uncontaminated and controlled air flows helping to reduce high concentration of oxygen exposure, as a carrier gas for anesthetic agents, as a power source for powering surgical tools in the operating room
	Level of use	Sub-county (Level 4) County referral (level 5) National referral (Level 6) hospitals
	Clinical department / Ward	All sites where medical air supply is needed, including, but not limited to, intensive care units, inpatient ward, accident and emergency, operating theatre, recovery room, observation, etc.,
TECHNICAL CHARACTERISTICS		
	Detailed requirements	**Medical Air:** **KS 2170-2:2008 - Medical gases - Specification - Part 2: Medical air** (Ph. Eur. 8, or equivalent) - It is compressed ambient air containing not less than 20.4% and not more than 21.4% of oxygen. A colorless, odorless gas. Soluble I in about 50 of water by volume at 20 degrees and at a pressure of 10 kPa. Store as a gas in suitable containers. Store in cylinders or in a low-pressure collecting tank.
PHYSICAL/CHEMICAL CHARACTERISTICS		
	Physical characteristics	• Appearance - odorless, colorless gas • Density 1.204 kg/m3 (at 20°C) Combustion characteristics - Non-flammable. Supports combustion

<table>
<tr><td></td><td>Chemical Characteristics</td><td>A natural or synthetic mixture of gases consisting largely of nitrogen and oxygen. It contains not less than 20.4 % and not more than 21.4 % of oxygen (KS 2170-2:2008 - Medical gases - Specification - Part 2: Medical air)

<table><tr><th colspan="2">Impurity limits (at STP)
(PhEur. 7.1, No. 04/2011: 2455)</th></tr><tr><td>Carbon monoxide ppm v/v</td><td>≤ 5</td></tr><tr><td>Carbon dioxide ppm v/v</td><td>≤ 300</td></tr><tr><td>Water ppm v/v</td><td>≤67</td></tr><tr><td>Oil mg/m3</td><td>≤ 0.1</td></tr><tr><td>Nitrogen Monoxide & Nitrogen dioxide ppm v/v</td><td>≤ 2</td></tr><tr><td>Sulphur dioxide ppm v/v</td><td>≤ 1</td></tr></table></td></tr>
<tr><td colspan="3">PACKAGING</td></tr>
<tr><td></td><td>Shelf life</td><td>Not applicable</td></tr>
<tr><td></td><td>Packaging</td><td>The product shall be supplied as compressed gas in appropriate steel cylinders/containers complying with relevant standards (international and local).
Can also be generated from a PSA plant/medical air plant
Valves or taps shall not be lubricated with oil or grease</td></tr>
<tr><td></td><td>Transportation and storage</td><td>Compliance with regulations on hazardous goods, flammable, explosive, compressed gas, according to GHS and international standards is mandatory. Transportation in a sealed container. Capable of being transported and stored in ambient temperature of 5–50 °C, relative humidity of at least 15–95% non-condensing</td></tr>
<tr><td></td><td>Labeling</td><td>• GHS (Global Harmonized System) hazard classification coding and regulations for hazardous goods, flammable, explosive and compressed gas labeling
• KS ISO 7225:2005 - Gas cylinders - Precautionary labels
• Markings and color-coding as per KS ISO 32:1977 - Gas cylinders for medical use - Marking for identification of content</td></tr>
<tr><td colspan="3">SAFETY AND STANDARDS</td></tr>
<tr><td></td><td>Regulatory approval / Certification</td><td>Proof of regulatory compliance (e.g., registration, clearance, approval) must be provided as appropriate per the product’s risk classification</td></tr>
<tr><td></td><td>International standards</td><td>• Standards applicable to the manufacturer and the manufacturing process (compliance to the last available version is required, proof of compliance must be provided):
• Applicable standards for quality management e.g., ISO 9001:2015 - Quality management systems and Good Manufacturing Practices (GMP)</td></tr>
<tr><td></td><td></td><td>• Standards applicable to the product (where applicable, compliance to the last available version is required, proof of compliance must be provided):
— Color coding KS ISO 32:1977 - Gas cylinders for medical use — Marking for identification of content for medical gases</td></tr>
<tr><td></td><td>Regional / Local standards</td><td>Country-specific and regional color gas coding and other standards apply and must be listed i.e.
KS 2170-1:2009 - Medical gases - Specification - Part 1: Medical oxygen</td></tr>
<tr><td></td><td>Regulations</td><td>Country-specific and regional regulations apply and must be listed. Compliance to (where applicable, but not limited to, and last available version)</td></tr>
</table>

SECTION 3: SPECIFICATIONS FOR LIQUID OXYGEN CYLINDERS AND TANKS

INTRODUCTION

Cylinder for Liquid Oxygen, Vacuum Insulated Evaporator (VIE)/Tank for Liquid Oxygen

3.1 CYLINDER FOR LIQUID OXYGEN		
i.	Version number	1
ii.	Date of initial version	November 2023
iii.	Date of last modification	November 2023
iv.	Date of publication	November 2023
v.	Developed by	MINISTRY OF HEALTH
NAME, CATEGORY AND CODING		
	Generic name	Medical gas cylinder, portable
	Specific type or variation	Liquid oxygen, with valves and regulators
	GMDN name	Oxygen cylinder, Oxygen cylinder with regulator
	GMDN code	47225 (Oxygen cylinder)
	UMDNS name	Medical gas cylinders
	UMDNS code	16501 (Medical gas cylinders)
	Alternative name/s	Portable liquid gas cylinder
	Alternative code/s	N/A
	Keywords	Cylinder, oxygen, tank, respiratory care, liquid gas, medical gas
PURPOSE OR USE		
	Clinical or other purpose	Liquid oxygen cylinders are dedicated refillable containers for holding such medical gases in liquid state. They are fitted with an internal vaporization coil in the interspace, to convert the liquid oxygen to gas, for use by the patient. The liquid gas cylinders have an operating pressure of up to 12.1 bar and a capability of supplying vaporized gas at a rate of up to 300 liters/min for each cylinder.
	Level of use	Dispensary (Level 2) Health center (Level 3) Sub-County (Level 4) County referral (level 5) National referral (Level 6) hospitals
	Clinical Department / Ward	All sites where oxygen and/or medical air are supplied, including but not limited to, intensive care units, inpatient ward, emergency, operating theatre, recovery room, observation, etc.
	Overview of functional requirements	• Liquid oxygen cylinders are refillable containers for medical oxygen in liquid form, available in international standard capacity/pressure and dimensions. • The cylinders can be made of steel, aluminium/ alloy, carbon fiber or other composite material. Each cylinder is fitted and supplied with a valve. The valves are constructed from either high tensile brass or stainless steel. The regulator diaphragm and relief valve components, used to control the flow and pressure of the gas, are made from oxygen compatible materials. All materials used in the construction of the tanks and valves are compatible with liquid oxygen in terms of reacting or suitability with respect to auto ignition. • Multiple options for pressure regulators, various fitting and outlets, and integral valves should be available separately. Specific ISO, ANSI and other international color coding for oxygen and medical air should be available. Accessories like holders, racks and trolleys should be available separately. • The supply system (s) for oxygen shall (each) comprise a centralized battery of cylinders, complete with support racks, headers, automatic manifold distribution panel (s) and shall have necessary controls, safety devices, alarms, pipework, valves and terminal units for distributing the gases to the required positions as listed on the schedule of terminal units.
TECHNICAL SPECIFICATIONS		
	Detailed requirements	**Oxygen cylinders:** Liquid oxygen cylinders are refillable containers for medical oxygen in liquid form, available in international standard capacity/pressure and dimensions. The cylinders are made of steel, aluminium/alloy, carbon fiber or other composite material. CGA approved seamless steel/aluminium alloy/composite body, color coding according to ISO/ ANSI/CGA/NFPA, sizes ISO/US standard. Cylinders supplied with optional pressure regulators, multiple fitting according to all the international standards. Safety over-pressure release valve (if not built-in in the integral valve fitted cylinders). **Primary valve and pressure regulator assemblies:** Pin Index or Bullnose primary valve and compatible pressure regulators, providing pressure regulated supply of oxygen (oil-free and compliant to ISO standards) or medical air (compliant to ISO standards). Steel/plated brass/aluminium casing, brass valve. Pin Index and Bullnose primary valve versions, handle/key operated, supplied with tools. 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).

Configurations / Options	Safety over-pressure release valve. Pressure regulator supplied with flowmeter, if required – see configurations/options for specifications. **Integral valves:** All-in-one cylinder valve for oxygen (oil-free and compliant to ISO standards) or medical air (compliant to ISO standards), providing direct attachment to the cylinder, pressure regulation and supply of medical gas with adjustable flow rate. Steel/plated brass/ aluminium casing, brass valve 6 mm barbed and BS 5682 Schrader (if applicable depending on the size of the cylinder) outlets. Integrated open/close valve, outlet nominal pressure 400 kPa (4 bar, 58 psi). Inlet pressure 23 000–30 000 kPa (230–300 bar, 3336–4351 psi), depending on the cylinder model. Integrated refill valve ISO 5145/CGA 540 compliant. Integrated manometer, covering the full nominal pressure range of the cylinder (standard 23 000–30 000 kPa (230–300 bar, 3336–4351 psi), for integral valve cylinders, or whatever applicable). Integrated flowmeter. Safety over-pressure release valve. **Oxygen cylinder configurations/versions/options:** Standard and MRI - compatible versions. Specific ISO/ANSI/CGA/NFPA color coding for oxygen and medical air. Seamless cylinders made of steel, aluminium/alloy, carbon fiber or other composite material (CGA approved and compliant to ISO applicable standards). Pin index/bullnose and integral valve options. OXYGEN and MEDICAL AIR cylinders with STANDARD VALVE available in all the ISO international standard sizes Regulator/integral valve configurations/versions: Standard and MRI-compatible versions. Oxygen and medical air versions. Pressure regulators and integral valves should be available with DISS 1240 (or equivalent) and 6 mm barbed outlet. Pressure regulators should be available in basic open/close model and fitted with integrated flowmeter, Thorpe tube or Bourdon gauge) **Sizes:**

Size (m^3)	Use	Water capacity (L)
1	Anesthetic machine and patient transport	1
1.36	Ambulance	9.4
3.84	Hospital, General	24
6.8	Hospital, General	50
8.5	Hospital, General	Refer to standards
9.5	Manifolds	Refer to standards
11.5	Manifolds	Refer to standards

	Displayed parameters	Pressure and flow (for integral valve cylinders only)
	User adjustable settings	Open/close control, pressure and flow (for integral valve cylinders)
PHYSICAL/CHEMICAL CHARACTERISTICS		
	Components	Cylinder body, integral valve assembly – Pin Index, 1x *Schrader, Fir Tree* therapy outlet, outlet connectors, safety pressure release valve, valve/regulator knob, manometer and flowmeter, flow rate indicator and selector)
	Mobility, portability	Portable
	Raw materials	Brass valve assemblies. Cylinders made of steel, aluminium/alloy, carbon fiber or compound material. Bronze/brass/synthetic sealings. All materials in contact with air certified for medical use.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
	Accessories	Cylinder holding, carts, trolleys. Supplied with keys and tools to operate valves and regulators. Complete set of tubing and adapters to use the pressure regulator and the integral valve with all common international standard fittings, for medical gas sources, patient circuits and other medical devices.
	Spare parts	Common and frequently used spare parts, sensors/ transducers/actuators, reusable probes/cables/patient connection accessories, periodic maintenance and calibration kits/materials. Sealing set, maintenance kit, regulating unit (knob), adapters and connectors, keys and tools to operate the valves.
PACKAGING		
	Sterility status on delivery	Not sterile, suitable for storage and supply of medical grade oxygen. Supplied with certificate of cleanliness.
	Shelf life	N/A
	Transportation and storage	**Applicable regulations on transport and storage of cylinders as required for the cylinders, either empty or partially/fully filled.** Compliant with regulations on hazardous goods, flammable, explosive, compressed gas, according with GHS and international standards is mandatory. Sealed container. Capable of being transported and stored in ambient temperature of at least 5–50 °C, relative humidity of at least 15–95% non-condensing.
	Labeling	**Labeling** ***GHS (Global Harmonized System)*** hazard classification coding and regulations for hazardous goods, flammable, explosive and compressed gas labelling. **1. GHS-US labelling:** • H270 – May cause or intensify fire; oxidizer

		• H280 – Contains gas under pressure; may explode if heated • P220 – Keep/Store away from combustible material, oxidizable materials, and incompatible materials. • P244 – Keep reduction valves/valves and fittings free from oil and grease • P370+P376 – In case of fire: Stop leak if safe to do so • P410+P403 – Protect from sunlight. Store in a well-ventilated place **2. Precautionary labels as may be prescribed by KS ISO 7225:2005** — Primary packaging Unit of use: one (1) cylinder with valve/ regulator in a box or case with manufacturer's instruction for use, spare parts and accessories (as applicable). Cylinder type and content in liters, tare weight (weight when empty), maximum cylinder pressure, cylinder size code. — Labelling on the primary packaging Name and/or trademark of the manufacturer; manufacturer's product reference; type of product and main characteristics; 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); information for handling, if applicable (or equivalent harmonized symbol).
ENVIRONMENTAL REQUIREMENTS		
	Context-dependent requirements	• 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 5–45 °C, relative humidity of at least 15–90% non-condensing. • Compliance with regulations on hazardous goods, flammable, explosive, compressed gas, according with KEBS, GHS and international standards is mandatory.
TRAINING, INSTALLATION AND UTILIZATION		
	User care	Common user care tasks, other device-specific procedures may apply, according to the use and the manufacturer's instructions. • Pre-use checks • Proper connection • Cleaning with compatible products, without oil and grease • Common maintenance tasks • Other device-specific procedures that may apply according to the use and the manufacturer's instructions • Periodic functionality checks, calibration
WARRANTY AND MAINTENANCE		
	Warranty	5 years recommended for the cylinders, 3 years for the pressure regulators and valves
	Maintenance tasks	Planned maintenance, with appropriate maintenance kit and materials, and regular cleaning and functionality checks, performed by a certified provider of service for compressed medical gases, or local technician if properly trained, certified and equipped. Valves and regulators may require periodic recalibration
	Service contract	• Refill • Periodic maintenance • Calibration
	Spare parts availability post-warranty	10 years starting from date of installation
DOCUMENTATION		
	Documentation requirements	• User and maintenance manuals, hard and soft copies, to be supplied in English. • Certificate of calibration and inspection to be provided. • List of equipment and procedures required for local calibration and routine maintenance. • List of common spares and accessories, with part numbers. • Contact details of manufacturer, supplier and local service agent to be provided.
DECOMMISSIONING		
	Estimated life span	20–25 years for the cylinders, 10 years for the valves, 7 years for the flowmeters.
SAFETY AND STANDARDS		
	Risk classification / Hazard identification	**1. GHS-US labelling** • H270 – May cause or intensify fire; oxidizer • H280 – Contains gas under pressure; may explode if heated • P220 - Keep/Store away from combustible material, oxidizable materials, and incompatible materials. • P244 – Keep reduction valves/valves and fittings free from oil and grease • P370+P376 – In case of fire: Stop leak if safe to do so • P410+P403 – Protect from sunlight. Store in a well-ventilated place **2. Precautionary labels** as may be prescribed by ***KS ISO 7225:2005 - Gas cylinders — Precautionary labels***

	Regulatory approval / Certification	Proof of regulatory compliance (e.g., registration, clearance, approval) must be provided as appropriate per the product's risk classification
	International standards	Standards applicable to the manufacturer and the manufacturing process (compliance to the last available version is required, proof of compliance must be provided): — ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes — ISO 9001:2015 – Quality Management Systems — ISO 14971:2019 - Medical devices – Application of risk management to medical devices — ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. Standards applicable to the product (where applicable, compliance to the last available version is required, proof of compliance must be provided): — Color-coding ISO or ANSI for medical gases — Conforms to ISO, NFPA and/or CGA standards, and/or UL or CSA approved — ISO 11114 Gas cylinders – Compatibility of cylinder and valve materials with gas contents — ISO 10524 Pressure regulators for use with medical gases — ISO 15002 Flow-metering devices for connection to terminal units of medical gas pipeline systems — ISO 15245 Gas cylinders – Parallel threads for connection of valves to gas cylinders — ISO 10297 Gas cylinders – Cylinder valves – Specification and type testing — ISO 17871 Gas cylinders – Quick-release cylinder valves – Specification and type testing — ISO 17879 Gas cylinders – Self-closing cylinder valves – Specification and type testing — ISO 407 Small medical gas cylinders – Pin-index yoke-type valve connections — ISO 5145 Cylinder valve outlets for gases and gas mixtures – Selection and dimensioning — ISO 11117 Gas cylinders – Valve protection caps and valve guards – Design, construction and tests — ISO 11363 Gas cylinders – 17E and 25E taper threads for connection of valves to gas cylinders — ISO 12209 Gas cylinders – Outlet connections for gas cylinder valves for compressed breathable air — ISO 14246 Gas cylinders – Cylinder valves – Manufacturing tests and examinations — ISO 22435 Gas cylinders – Cylinder valves with integrated pressure regulators — ISO 7866 Gas cylinders – Refillable seamless aluminium alloy gas cylinders – Design, construction and testing — ISO 20701 Gas cylinders – Refillable welded aluminium-alloy cylinders – Design, construction and testing — ISO 9809 Gas cylinders – Refillable seamless steel gas cylinders – Design, construction and testing — ISO 11119 Gas cylinders – Refillable composite gas cylinders and tubes – Design, construction and testing — ISO 13341 Gas cylinders – Fitting of valves to gas cylinders — ISO 32:1977 - Gas cylinders for medical use – Marking for identification of content — ISO 7225 Gas cylinders – Precautionary labels — ISO 10461 Gas cylinders – Seamless aluminium-alloy gas cylinders – Periodic inspection and testing — ISO 11623 Gas cylinders – Composite construction – Periodic inspection and testing — ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements — ISO 15996 Gas cylinders – Residual pressure valves – Specification and type testing of cylinder valves incorporating residual pressure devices — ISO 15001 Anesthetic and respiratory equipment – Compatibility with oxygen
	Regional / Local standards	Country-specific and regional color gas coding and other standards apply and must be listed. • ***KS ISO 7225:2005 - Gas cylinders — Precautionary labels*** • ***KS ISO 32:1977 - Gas cylinders for medical use – Marking for identification of content***
	Regulations	Country-specific and regional regulations apply and must be listed. Compliance to (where applicable, but not limited to, and last available version)

3.2 VACUUM INSULATED EVAPORATOR TANK (TANK FOR LIQUID OXYGEN)		
i.	Version number	1
ii.	Date of initial version	November 2023
iii.	Date of last modification	November 2023
iv.	Date of publication	November 2023
v.	Developed by	MINISTRY OF HEALTH
NAME, CATEGORY AND CODING		
	Generic name	Vacuum insulated Evaporator (VIE) tank
	Specific type or variation	Liquid oxygen, with valves and regulators
	GMDN name	Oxygen cylinder, Oxygen cylinder with regulator
	GMDN code	36271 (Medical gas supply systems)
	UMDNS name	Medical gas cylinders
	UMDNS code	N/A
	Alternative name/s	Oxygen tank with valves and regulators, Bulk storage vessel, Vacuum Insulated Evaporator - VIE, Vacuum Insulated Cryogenic Storage Tanks
	Alternative code/s	N/A
	Keywords	Bulk storage, vessel, VIE, cylinder, oxygen, tank, respiratory care, liquid gas, medical gas
PURPOSE OR USE		
	Clinical or other purpose	Bulk storage vessels are dedicated refillable containers for holding such medical gasses in liquid state. The bulk storage vessels have an external ambient heated vaporizer fitted to ensure that only gas is supplied down the pipeline to the ward outlet points. The outlet flow capability depends upon the size of the vessel and the type of vaporizer system.
	Level of use	Sub-County referral (level 4) - 10,000L County referral (level 5) - 20,000L National referral (Level 6) hospitals - 20,000L ***NB: Consideration of health facility Oxygen demand should be made in selection of tank capacity***
	Clinical department / Ward	N/A
	Overview of functional requirements	Cryogenic Oxygen tanks/bulk storage vessels are refillable containers for medical oxygen in liquid form, available in various capacity/pressure and dimensions. The cylinders can be made of steel, aluminium/alloy, carbon fiber or other composite material Each vessel is fitted and supplied with a valve. The valves are constructed from either high tensile brass or stainless steel. The regulator diaphragm and relief valve components, used to control the flow and pressure of the gas, are made from oxygen compatible materials. All materials used in the construction of the tanks and valves are compatible with liquid oxygen in terms of reacting or suitability with respect to auto ignition. Multiple options for pressure regulators, various fitting and outlets, and integral valves should be available separately Color coding: ***KS ISO 32 - Gas cylinders for medical use – Marking for identification of content***
TECHNICAL CHARACTERISTICS		
	Detailed requirements	**Bulk oxygen vessels** Cryogenic Liquid oxygen tanks are refillable containers for medical oxygen in liquid form, available in various capacity/pressure and dimensions. The cryogenic vessel shall typically consist of an inner and outer cylinder. The inner cylinder shall be constructed from high grade stainless steel while the outer cylinder shall be made from steel, aluminium/alloy, carbon fiber or other composite material. In between shall be filled with high performance insulating material under vacuum. The Cryogen tank shall be designed and fabricated in accordance with BS EN 13458-2 - Cryogenic vessels. Static vacuum insulated vessels Design, fabrication, inspection and testing. Color-coding shall be according to ***ISO 32:1977 - Gas cylinders for medical use — Marking for identification of content*** The cryogenic tank shall be supplied complete with:- — Vaporizer — Vent valves — Pressure regulators — Trycock valve — Bottom fill valve — Service fill valve — Safety valves — Gauges — Valves on liquid level gauges — Fill connection coupler and — Control system All interconnecting pipings shall be high grade stainless steel 304 degreased for medical oxygen and pneumatic tested The vessel should be maintained in such a way that to keep natural evaporation of less than 1% per day **Vaporizer** Ambient Air Vaporizer – should provide ambient air heat exchange which is able to vaporize adequate liquid oxygen to meet the hospital demand typically between 300-600 M3 per hour. A heated vaporizer may be considered depending on climate and location to prevent the evaporator from icing.

		— The vaporizer shall consist of aluminium finned tubes and interconnecting pipe between tank and vaporizer. — ***NB: Capacity to be calculated based on the maximum demand of Oxygen in the health facility*** **Duplex pressure reduction system** Shall be capable of ensuring steady supply of medical oxygen from the VIE to the hospital pipeline at all times at the design pressure, temperature and flow rates. — It shall consist of Duplex configuration (Standby and Duty) of Pressure regulators, switches, ball valves, check valves, sensors, gauges and relief valves designed to BS EN 737-3 — Inlet pressure to the control unit shall be typical 10 bars while outlet pressure to the hospital line shall be regulated to typical 4.2 bars (adjustable depending on the piping system requirement) — ***NB. The sizing of the pipes and pressure switches should match the hospital oxygen demand*** Three-way gauge valve for isolation of line pressure with manual control shall be installed **Control and monitoring system** The control system shall be capable of monitoring the following parameters:- — Oxygen stock levels in the vessel - Segregated as operation, risk assessed and unusable — System operations parameters — Report any malfunction. — Telemetry capabilities **Alarms** Audio and Visible alarms shall be installed for; — Low oxygen content level — System malfunction
	Configurations/options	**Oxygen tank configurations/versions/options:** **Materials** — Seamless cylinders made of steel, aluminium/ alloy, carbon fiber or other composite material; — CGA approved — International applicable standards e.g., BS EN 13458-2 - Cryogenic vessels. Static vacuum insulated vessels Design, fabrication, inspection and testing) **Sizes** — 10,000L for Level 4 — 20,000L for Level 5 and 6

	Displayed parameters	Pressure and flow
	User adjustable settings	Open/close control, pressure and flow
PHYSICAL/CHEMICAL CHARACTERISTICS		
	Components	Bulk cryogenic storage tank, outlet connectors, safety pressure release valve, valve/regulators, flow rate indicators and selectors
	Mobility, portability	Not moveable, fixed
	Raw materials	Brass valve assemblies. Cylinders made of steel, aluminum/alloy, carbon fiber or compound material. Bronze/brass/synthetic sealings. All materials in contact with air certified for medical use.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
	Accessories	Supplied with keys and tools to operate valves and regulators. Complete set of tubing and adapters with all common international standard fittings for refilling as per the country
	Spare parts	Common and frequently used spare parts, sensors/ transducers/actuators, periodic maintenance and calibration kits/materials. Sealing set, maintenance kit, regulating unit, adapters and connectors, keys and tools to operate the valves.
PACKAGING		
	Sterility status on delivery	Suitable for storage and supply of medical grade oxygen. Supplied with a certificate of cleanliness.
	Labeling and packaging	**Labeling** ***GHS (Global Harmonized System)*** hazard classification coding and regulations for hazardous goods, flammable, explosive and compressed gas labeling **1. 1. GHS-US labeling** • H270 – May cause or intensify fire; oxidizer • H280 – Contains gas under pressure; may explode if heated • P220 – Keep/Store away from combustible material, oxidizable materials, and incompatible materials. • P244 – Keep reduction valves/valves and fittings free from oil and grease • P370+P376 – In case of fire: Stop leak if safe to do so • P410+P403 – Protect from sunlight. Store in a well-ventilated place **2. Precautionary labels** as may be prescribed by ***KS ISO 7225:2005 - Gas cylinders - Precautionary labels*** **3. Certification** according to ***EC Directive PED 2014/68/EU (FDA approval or equivalent)*** **4. Specific *ISO 32:1977 - Gas cylinders for medical use — Marking for identification of content*** color coding for oxygen and medical air

ENVIRONMENTAL REQUIREMENTS		
	Context-dependent requirements	• Suitable for continuous operation in ambient temperature of 5–45 °C, relative humidity of at least 15–90% non-condensing. • Compliance with regulations on hazardous goods, flammable, explosive, compressed gas, according with KEBS, GHS and international standards is mandatory. • Installation of tanks should adhere to safe distances and location from other installations
TRAINING, INSTALLATION AND UTILIZATION		
	User care	Common user care tasks, other device-specific procedures may apply, according to the use and the manufacturer's instructions. • Pre-use checks • Proper connection • Cleaning with compatible products, without oil and grease • Common maintenance tasks • Other device-specific procedures that may apply according to the use and the manufacturer's instructions • Periodic functionality checks, calibration ***NB: Training on how to refill, fill and empty the liquid oxygen tank to be carried out by the liquid oxygen supplier***
WARRANTY AND MAINTENANCE		
	Warranty	5 years for the bulk storage tank, 3 years for the pressure regulators and valves
	Maintenance tasks	Periodic checkups and maintenance by a LOX technician, with appropriate maintenance kit and materials, and regular cleaning and functionality checks, performed by a certified provider of service for compressed medical gasses, or local technician if properly trained, certified and equipped. Valves and regulators may require periodic recalibration.
	Service contract	• Refill • Periodic maintenance • Calibration
	Spare parts availability post-warranty	10 years starting from date of installation
DOCUMENTATION		
	Documentation requirements	• User and maintenance manuals, hard and soft copies, to be supplied in English. • Certificate of testing, calibration and inspection (as per BS EN 13458-2) to be provided . • List of equipment and procedures required for local calibration and routine maintenance. • List of common spare parts and accessories, with part numbers. • Contact details of manufacturer, supplier and local service agent to be provided.

DECOMMISSIONING		
	Estimated life span	20–25 years for the bulk storage vessels, 10 years for the valves, 7 years for the pressure and flow indicators
SAFETY AND STANDARDS		
	Risk classification / Hazard identification	**GHS-US labeling** • H270 – May cause or intensify fire; oxidizer • H280 – Contains gas under pressure; may explode if heated • P220 – Keep/Store away from combustible material, oxidizable materials, and incompatible materials. • P244 – Keep reduction valves/valves and fittings free from oil and grease • P370+P376 – In case of fire: Stop leak if safe to do so • P410+P403 – Protect from sunlight. Store in a well-ventilated place
	Standards	**Applicable standards** **Product** • *BS EN 13458-2 - Cryogenic vessels.* Static vacuum insulated vessels Design, fabrication, inspection and testing) **Management** • *ISO 9001:2015 – Quality Management Systems* • *ISO 13485:2016 - Medical devices — Quality management systems* — Requirements for regulatory purposes • *ISO 14971:2019 - Medical devices* — Application of risk management to medical devices
	Regulatory approval / Certification	Proof of regulatory compliance (e.g., registration, clearance, approval) must be provided as appropriate per the product's risk classification — Certification according to ***EC Directive PED 2014/68/EU, or FDA Approval***, or equivalent from a stringent regulatory body

SECTION 4: SPECIFICATIONS FOR OXYGEN THERAPY DEVICES

INTRODUCTION

Pressure Regulator for Use with Medical Gases, Medical Gas Flowmeter, Flowmeter Stand, Humidifier, Oxygen Saturation Meter – Finger-tip, Oxygen Saturation Meter – Hand-held, Oxygen Saturation Meter – Table-top

4.1 PRESSURE REGULATOR FOR USE WITH MEDICAL GASES		
i.	Version number	1
ii.	Date of initial version	November 2023
iii.	Date of last modification	November 2023
iv.	Date of publication	November 2023
v.	Developed by	MINISTRY OF HEALTH
NAME, CATEGORY AND CODING		
	Generic name	Medical oxygen regulator
	Specific type or variation	Integral assemblies with inlet and outlet fittings, pressure gauge, therapy flow selector and indicator
	EC device classification	Class IIb (Rule 9)
	GMDN name	Non-fixed medical gas cylinder regulator, medical air cylinder regulator
	GMDN code	43438, 60944
	Keywords	Pressure regulator, Medical Oxygen
PURPOSE OR USE		
	Clinical or other purpose	Pressure regulator assemblies/units are used to provide oxygen to a device which requires an input at specific pressure (typically 4 bar). — Primarily, pneumatically powered medical devices such as a ventilator or Demand Valve. The pressure outlet is supplied in accordance with a national or international standard and there is the potential for a second pressure outlet for use with another item. — The second outlet may be to the same national or international standard as the first, or it may be different. Units fitted with a flow outlet are used to deliver variable flow rates of oxygen to a patient who requires oxygen therapy. — The patient will be breathing on their own but may have a need for support perhaps to supply oxygen enriched air to increase blood oxygen levels. — The flow outlet will be either a 'fir tree connector' or a threaded outlet. Flow outlets can be switched between different rate in the range of 0.5 lpm (liters per minute) to 15 lpm, with an optional 'MAX' setting of approximately 25 lpm used for system purging
	Level of use	Sub-county (Level 4) County referral (level 5) National referral (Level 6) hospitals
	Clinical department / Ward	All sites where oxygen and/or medical air is supplied
	Overview of functional requirements	Integral assemblies
TECHNICAL CHARACTERISTICS		
	Detailed requirements	**Regulator configurations/versions/options:** Standard and MRI - compatible versions. Specific ISO/ANSI/CGA/NFPA color coding for oxygen and medical air. Made of steel, aluminium/alloy, carbon fiber or other composite material (CGA approved and compliant to ISO applicable standards). *Pin index/ Bullnose* and integral valve options. STANDARD VALVE available in all the ISO international standard sizes, including size AZ, C, D, E, F, G, H, J, and also US sizes M2 to M 265 (not all sizes apply to both oxygen and medical air). The type of standard valve has to be compliant to international ISO and US standards, i.e. • **Pin Index,** ISO 407:2004/BS 850/CGA 870 valve, CGA 540 valve, 5/8-inch BSP (F) Bullnose BS 341 valve, also according to the size/pressure of the cylinder and to any applicable regulation. OXYGEN cylinders should be available also with INTEGRAL VALVE (with manometer and flow regulator, 400 kPa (4 bar) nominal outlet pressure, 6 mm barbed and, • **Schrader outlets,** BS 5682, in all the ISO international standard sizes, including size ZA, CD, ZD, HX and ZX, and also US sizes in M coding system
	Configuration options	**Regulator/integral valve configurations/versions:** Standard and MRI-compatible versions. Oxygen and medical air versions. Pressure regulators and integral valves should be available with DISS 1240 (or equivalent) and 6 mm barbed outlet. Pressure regulators should be available in basic open/close model and fitted with integrated flowmeter, Thorpe tube or Bourdon gauge. *Pressure regulators and integral valves with dial style flowmeter* should be available at least in the following flow ranges, for oxygen and medical air:

		— **Low flow** 0–3 or 4 L/min (only for oxygen), discrete (dial) flow setting (indicative steps 0, 0.03, 0.06, 0.12, 0.25, 0.50, 0.75, 1.0, 1.5, 2.0, 3.0, 4.0), accuracy 10%. — **Standard flow** 0–15 L/min, discrete (dial) flow setting (indicative steps 0, 0.25, 0.5, 1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 8.0, 10.0, 12.0, 15.0), accuracy 10%. — **High flow** 0–25 L/min minimum, discrete (dial) flow setting (indicative steps 0, 0.25, 0.50, 1.0, 2.0, 3.0, 4.0, 6.0, 8.0, 10.0, 15.0, 25.0), accuracy 10%. *Pressure regulators and integral valves with Thorpe or Bourdon flowmeter* should be available at least in the following flow ranges, for oxygen and medical air: — **Low flow** 0–3 or 4 L/min (only for oxygen), accuracy 10%, indicative graduation (L/min) 0.03, 0.06, 0.12, 0.25, 0.5, 0.75, 1.0, 1.5, 2.0, 3.0, 4.0. — **Standard flow** 0–7 or 8 and 0–15 or 16 L/min, accuracy 10%, graduation 0.5 L/min (0.5–3 range) and 1 L/min (3–max range). — **High flow** 0–25 L/min minimum, accuracy 10%, graduation 0.5 L/min first increment and 1 L/min full range
	Displayed parameters	Pressure, Flow rate
	User adjustable settings	Flow rate
PHYSICAL/CHEMICAL CHARACTERISTICS		
	Components	Cylinder body, integral valve assembly – Pin Index, 1x Schrader, Fir Tree Therapy Outlet, outlet connectors, safety pressure release valve, valve/regulator knob, manometer and flowmeter, flow rate indicator and selector)
	Mobility, portability	N/A
	Raw materials	Brass valve assemblies, aluminium/alloy, carbon fibre or compound material. Bronze/brass/synthetic sealings. All materials in contact with air certified for medical use.
WARRANTY AND MAINTENANCE		
	Warranty	5 years
	Service interval	5 years
	Intended life	10 years
	Maintenance tasks	Planned maintenance, with appropriate maintenance kit and materials, and regular cleaning and functionality checks, performed by a certified provider of service for compressed medical gases, or local technician if properly trained, certified and equipped. Valves and regulators may require periodic recalibration
	Service contract	• Periodic maintenance • Calibration

	Spare parts availability post-warranty	10 years starting from date of installation
SAFETY AND STANDARDS		
	International standards and certification	— EN ISO 10524-1:2006 Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow-metering devices for use with medical gases — EN ISO 15001:2011 - Anesthetic and respiratory equipment -Compatibility with oxygen — EC Directive 93/42/EEC; — ISO 13485:2016 – Medical devices — BS EN 1041:2008+A1:2013
	Regulatory approval / Certification	Proof of regulatory compliance (e.g., registration, clearance, approval) must be provided as appropriate per the product's risk classification

4.2 MEDICAL GAS FLOWMETER

i.	Version number	1
ii.	Date of initial version	November 2023
iii.	Date of last modification	November 2023
iv.	Date of publication	November 2023
v.	Developed by	MINISTRY OF HEALTH
NAME, CATEGORY AND CODING		
	Generic name	Medical gas flowmeter
	Specific type or variation	Thorpe tube, pressure-compensated
	GMDN name	Medical gas flowmeter, Thorpe tube
	GMDN code	61365
	UMDNS name	Flowmeters, Gas, Respiratory, Oxygen; Flowmeters, Gas, Respiratory, Medical air.
	UMDNS code	24782 (Oxygen) 25074 (Medical air)
	Alternative name/s	Oxygen flowmeter, medical air flowmeter.
	Keywords	Flow meter, flowmeter, Thorpe, oxygen, medical air, regulator, respiratory care.
	GMDN definition	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.

PURPOSE OR USE		
	Clinical or other purpose	Flowmeters are devices designed to measure and regulate the flow of a medical gas. They connect the low-pressure medical gas source (up to 345–380 kPa, 3.5–3.8 bar, 50–55 psi), such as central system, cylinders valves, concentrators or another medical device, to a patient circuit or a medical device that uses or delivers the gas. The purpose of the flowmeters included in this description is to regulate and measure the flow of oxygen or medical air. Dedicated flowmeters, calibrated to specific gas and flow ranges, pressure-compensated, are covered.
	Level of use	All levels: Dispensary (Level 2), Health center (Level 3), Sub-County (Level 4), County referral (level 5) and National referral (Level 6) hospitals.
	Clinical department / Ward	All departments where medical gas (including Oxygen) and/or respiratory support/therapy is delivered, including, but not limited to, intensive care units, inpatient ward, emergency, operating theatre, recovery room, observation, etc., and also emergency vehicles and home care
	Overview of functional requirements	The Thorpe tube flowmeter is composed of inlet and outlet ports, a regulator, a valve and a clear tapered measuring tube. It regulates and measures the flow of oxygen or medical air, depending on the model, from the source to the patient or to another medical device. It Is suitable for connection with various medical gas sources, such as centralized systems, cylinders, concentrators or compressors. Standard (absolute, non-compensated) and pressure-compensated flowmeter versions, suitable for specific flow ranges.
TECHNICAL CHARACTERISTICS		
	Detailed requirements	Thorpe tube flowmeter, to measure and regulate the flow of medical gas. Can be disinfected with hospital grade detergents. Transparent, clearly readable and graduated (metric system) column, shatter resistant polymer certified for medical use. Clearly visible graduation, 270 or more degrees of visibility. Needle valve and body constructed of brass or aluminium. Calibrated at 345–380 kPa (3.4–3.8 bar, 50–55 psi) inlet gauge pressure. Inlet gauge pressure (nominal) > 380–413 kPa (3.8–4.1 bar, 55–60 psi), peak gauge inlet pressure 690 kPa (6.9 bar, 100 psi). Pressure-compensated design to give specified accuracy for the whole range of input pressures. Built-in inlet filter, replaceable by user. Minimum flow rate to be zero, i.e., fully closed. Maximum flow rate when fully open to be stated. Anti-slip knob. ISO 32 color-coded for medical gases. DISS (Diameter-Index Safety system) style inlet and outlet.
	Configuration options	**Wall-mounted and cylinder-mounted versions** Must be fitted with appropriate and standard connectors/adapters suitable for connection with various medical gas sources, such as centralized system, cylinders, concentrators or compressors **Oxygen and medical air versions** Versions with absolute non-pressure compensated Thorpe tube (non-compensated) and with pressure-compensated column, calibrated within the range (gauge) 345–380 kPa (3.4–3.8 bar, 50–55 psi). Available in international ISO 32 color-coding systems for oxygen and medical air. Available in versions suitable for mounting on all the international standard fittings, like (but not limited to) 1/8-inch FNPT female, 3/8-inch BSP female, UNI EN 737, *DIN, DISS, AFNOR, Ohmeda, Chemtron, Puritan Bennet*, Schrader, etc. Mounting to be on panel, equipment or pressure regulator, as specified by the purchaser. Availability of various outlet adapters (tubing nipples/ Christmas trees), with ISO 32 color-coding and suitable for all international standard outlet fittings, including (but not limited to) threaded, non-threaded, 6 mm barbed and 9/16-inch UNF female thread for oxygen and medical air. — ***NOTE: Age specific versions to be used (adult, child, infants, neonates)***
	Displayed parameters	Measured flow rate
	User adjustable settings	Flow rate
PHYSICAL/CHEMICAL CHARACTERISTICS		
	Components	Reusable components suitable for disinfection including (but not limited to): sealing set, flowmeter body, Thorpe (measuring) tube, valve and regulating knob, inlet and outlet connectors (different types) and tubing, pressure safety valve, bacteria filter, float ball, etc.
	Mobility, portability	Portable
	Raw materials	Brass/steel/aluminium/polymers/hard plastic body and valve, certified for medical use (ISO 13485) Polypropylene, polycarbonate, acrylic or transparent equivalent biocompatible plastic/polymer certified for medical use, unbreakable or shatter resistant, for the column
UTILITY REQUIREMENTS		
	Electrical, water and/or gas supply	Oxygen, Medical air (up to 345–380 kPa, 3.5–3.8 bar, 50–55 psi)
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
	Accessories	T-bar double fitting, complete set of adapters to use the flowmeter (inlet and outlet) with all common international standard fittings, for medical gas sources, patient circuits and other medical devices.

	Sterilization/disinfection process for accessories	Suitable for cleaning and disinfection.
	Spare parts	Sealing set, regulating unit (knob), inlet filter, adapters and connectors. Needle valve, pressure safety valve, Thorpe column and float ball, flowmeter body.
PACKAGING		
	Transportation and storage	Sealed container. Capable of being transported and stored in ambient temperature of at least 5–50 °C, relative humidity of at least 15–95% non-condensing. Specific requirements for altitude may be required, depending on the installation site.
	Labelling	**Primary packaging:** Unit of use: one (1) Thorpe tube flowmeter in a box or case or bag with manufacturer's instruction for use, spare parts and accessories (when applicable). Gas type, calibration temperature and pressure should be specified on the label. **Labelling on the primary packaging:** Name and/or trademark of the manufacturer; manufacturer's product reference; type of product and main characteristics; lot number prefixed by the word "LOT" (or equivalent harmonized symbol) (if applicable); information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonized symbol); information for handling, if applicable (or equivalent harmonized symbol). **Over packaging:** Packaging unit. Labelling on the packaging unit: Labelling to be the same as primary packaging. **Extra information required:** number of units
ENVIRONMENTAL REQUIREMENTS		
	Context-dependent requirements	• Capable of being stored at 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.
TRAINING, INSTALLATION AND UTILIZATION		
	Pre-installation requirements	Verification of fittings on oxygen sources (concentrator, cylinders, wall outlet/central supply, etc.) and on the medical devices/equipment working with the flowmeter
	Requirements for commissioning	Local clinical and technical staff to affirm completion of installation, proper operation, free from leaks
	Training	• Training of users in operation and basic maintenance is recommended, depending on the case, and shall be provided upon request.
		• Training of technical staff in advanced maintenance tasks is recommended, depending on the case, and shall be provided upon request.
	User and technical care	• Pre-use checks • Proper connection • Cleaning with compatible products • Periodic functionality checks
WARRANTY AND MAINTENANCE		
	Warranty	2 years. The product shall be in production and fully supported when procured
	Maintenance tasks	Regular cleaning and functionality checks, calibration
	Spare parts availability post-warranty	5 years at least, starting from the installation
DOCUMENTATION		
	Documentation requirements	— User and maintenance manuals, hard and soft copies, to be supplied in English and any other agreed language. — Certificate of calibration and inspection to be provided. — List to be provided of equipment and procedures required for local calibration and routine maintenance. — List to be provided of common spares and accessories, with part numbers. — Contact details of manufacturer, supplier and local service agent to be provided.
DECOMMISSIONING		
	Estimated life span	5 years.
SAFETY AND STANDARDS		
	Risk classification	Class A (GHTF), Class I (USA), Class IIa (Europe, Australia), Class II (Canada, Japan).
	Regulatory approval / Certification	Proof of regulatory compliance (e.g., registration, clearance, approval) must be provided as appropriate per the product's risk classification (e.g., by a founding member of IMDRF - EU, USA, Canada, Australia, Japan).
	International standards and certification	Standards applicable to the manufacturer and the manufacturing process (compliance to the last available version is required, proof of compliance must be provided): — ISO 13485:2016 - Medical devices – Quality management systems – Requirements for regulatory purposes — ISO 9001:2015 – Quality Management Systems-Regulatory — ISO 14971:2019 - Medical devices – Application of risk management to medical devices Standards applicable to the product (where applicable, compliance to the last available version

		is required, proof of compliance must be provided): Conforms to ISO, NFPA, and/or CGA standards, and/ or UL or CSA approved. — ISO 15002:2008 - Flow-metering devices for connection to terminal units of medical gas pipeline systems — ISO 18562-4:2017 - Biocompatibility evaluation of breathing gas pathways in healthcare applications — ISO 10524 - Pressure regulators for use with medical gases
		— ISO 18082:2014 - Anesthetic and respiratory equipment – Dimensions of non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases — ISO 15223-1:2021 - Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements — ISO 5359:2014 - Low-pressure hose assemblies for use with medical gases — ISO 32:1977 - Gas cylinders for medical use — Marking for identification of content — ISO 9170-1:2008 - Terminal units for medical gas pipeline systems
	Regional / Local standards	Country-specific and regional color gas coding and other standards apply and must be listed.
	Regulations	Country-specific and regional regulations apply and must be listed. Compliance to (where applicable, but not limited to, and last available version): **1. US regulations:** — 21 CFR part 820 — 21CFR part 868.2320 – Uncompensated Thorpe tube flowmeter — 21CFR part 868.2340 – Compensated Thorpe tube flowmeter **2. EU regulations:** — Regulation (EU) 2017/745. **3. Japan regulations:** — MHLW Ordinance No. 169 — 37132000 Flowmeter, oxygen therapy

4.3 FLOW METER STAND		
i.	Version number	1
ii.	Date of initial version	November 2023
iii.	Date of last modification	November 2023
iv.	Date of publication	November 2023
v.	Developed by	MINISTRY OF HEALTH
NAME, CATEGORY AND CODING		
	Generic name	Flowmeter stand
	Alternative name/s	Flow splitter
	Keywords	Flowmeter stand, flow splitter, oxygen, flowmeter, concentrator, regulator, respiratory care.
PURPOSE OR USE		
	Clinical or other purpose	The oxygen flowmeter stand is a device intended to distribute medical oxygen from a source to multiple independent outlets. The flowmeter stand, depending on the design, can be connected to concentrators (typically 138 kPa (1.4 bar, 20 psig) inlet) or to any low-pressure oxygen source (345–380 kPa, 3.5–3.8 bar, 50–55 psi), including concentrators, cylinders and a centralized system, and has dedicated flowmeters, calibrated to specific flow ranges. The ability of the flowmeter stand to deliver rates indicated by the flow settings for the outlets, is limited by the flow and pressure provided by the oxygen source.
	Level of use	All levels: Dispensary (Level 2), Health center (Level 3), Sub-County (Level 4), County referral (level 5) and National referral (Level 6) hospitals.
	Clinical department / Ward (if relevant)	All departments where oxygen and/or respiratory support/therapy is delivered, including, but not limited to, intensive care units, inpatient ward, emergency, operating theater, recovery room, observation, etc.
	Overview of functional requirements	The flow splitter is a tabletop or wall-mounted device composed of an inlet valve that delivers oxygen to multiple independent flowmeters, each one providing an outlet. Up to five independent Thorpe tube pressure compensated flowmeters, that can be calibrated to multiple flow ranges, are installed in the flowmeter stand housing. It can be connected to concentrators or to any standard pressure oxygen source, like cylinders and central system, according to device version.
TECHNICAL CHARACTERISTICS		
	Detailed requirements	Device suitable to deliver oxygen from the source to multiple independent outlets. Tabletop device, suitable also for wall mounting. Equipped with four or five independent, pressure-compensated, Thorpe tube flowmeters, to measure and regulate the flow of medical gas. Can be disinfected with hospital grade detergents.

		Inlet port to be compatible with all the international standards for oxygen fittings, included DISS, threaded and non-threaded, 6 mm barbed – availability of different ports and/or adapters to be stated. 6 mm barbed outlet as standard – availability of adapters and outlet options to match all the international standards for oxygen fittings to be stated. 0–2 L/min, accuracy better than 10%, graduation 0.125 L/min or lower. Transparent, clearly readable and graduated (metric system) column, shatter resistant polymer certified for medical use (ISO 13485). Needle valve and body constructed of brass or aluminium. Inlet pressure up to at least 138 kPa (1.4 bar, 20 psi). Adjustment knobs to have a rough surface to prevent slipping. color-coded flowmeter preferable, e.g. to ISO 32. Internal parts (e.g. valve, inlet filter if present), replaceable by user
	Configuration options	N/A
	Displayed parameters	Measured flow rate (on each independent flowmeter)
	User adjustable settings	Flow rate (on each independent flowmeter)
PHYSICAL/CHEMICAL CHARACTERISTICS		
	Components	Reusable components suitable for disinfection with hospital grade detergents including (but not limited to): sealing set, flowmeter stand and flowmeter bodies, Thorpe (measuring) tube, valve and regulating knob, inlet and outlet connectors (different types) and tubing, pressure safety valve, bacteria filter, float ball, etc.
	Mobility, portability	Portable
	Raw materials	Flowmeter stand hard plastic or metal epoxy painted, suitable for cleaning and disinfection with hospital grade cleaning products. For the flowmeters:- — Brass/steel/aluminium/polymers/hard plastic body and valve, all materials in contact with oxygen certified for medical use. — Polypropylene, polycarbonate, acrylic or transparent equivalent biocompatible plastic/polymer certified for medical use, unbreakable or shatter resistant, for the column.
UTILITY REQUIREMENTS		
	Electrical, water and/or gas supply	Oxygen, envisaged for use with oxygen concentrators, cylinders and piped oxygen
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
	Accessories	Wall mount accessories, additional power take off, T-bar double fitting, complete set of adapters and tubing to use the flowmeter stand (inlet and outlet)

		with all common international standard fittings, for medical gas sources, patient circuits and other medical devices.
	Sterilization/disinfection process for accessories	Suitable for cleaning and disinfection with hospital grade cleaning products.
	Spare parts	• Sealing set, regulating unit (knob), inlet filters, adapters and connectors. • Needle valve, pressure safety valve, Thorpe column and float ball, flowmeter stand and flowmeter bodies.
	Other components	N/A
PACKAGING		
	Sterility status on delivery	Not sterile
	Shelf life	N/A
	Transportation and storage	Sealed container. Capable of being transported and stored in ambient temperature of at least 5–50 °C, relative humidity of at least 15–95% non-condensing. Specific requirements for altitude may be required, depending on the installation site.
	Labelling	**Primary packaging:** Unit of use: one (1) flowmeter stand in a box or case or bag with manufacturer's instructions for use, spare parts and accessories (when applicable). Gas type, calibration temperature and pressure should be specified on the label. **Labelling on the primary packaging:** Name and/or trademark of the manufacturer; manufacturer's product reference; type of product and main characteristics; lot number prefixed by the word "LOT" (or equivalent harmonized symbol) (if applicable); information for particular storage conditions(temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonized symbol); information for handling, if applicable (or equivalent harmonized symbol). **Over packaging:** Packaging unit. **Labelling on the packaging unit:** Labelling to be the same as primary packaging. **Extra information required:** number of units
ENVIRONMENTAL REQUIREMENTS		
	Context-dependent requirements	• 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.
TRAINING, INSTALLATION AND UTILIZATION		
	Pre-installation requirements (if relevant)	Verify fittings on oxygen sources (concentrator, wall outlet/central supply, etc.) and on the medical devices/equipment working with the flowmeter stand.

	Requirements for commissioning (if relevant)	Local clinical and technical staff to affirm completion of installation, proper operation, free from leaks. May require periodic recalibration.
	Training of user/s (if relevant)	• Training of users in operation and basic maintenance is required. • Training of technical staff in maintenance tasks is required.
	User care (if relevant)	• Pre-use checks • Proper connection • Cleaning with compatible products • Periodic functionality checks
WARRANTY AND MAINTENANCE		
	Warranty	2 years recommended, the product shall be in production and fully supported when procured.
	Maintenance tasks Type of service contract Spare parts availability post-warranty	Regular cleaning and functionality checks, calibration. Not required 5 years at least, starting from the installation.
	Software/hardware upgrade availability	N/A
DOCUMENTATION		
	Documentation requirements	— User and maintenance manuals, hard and soft copies, to be supplied in English. — Certificate of calibration and inspection to be provided. — List to be provided of equipment and procedures required for local calibration and routine maintenance. — List to be provided of common spares and accessories, with part numbers. — Contact details of manufacturer, supplier and local service agent to be provided.
DECOMMISSIONING		
	Estimated life span	5 years.
SAFETY AND STANDARDS		
	Risk classification	Class A (GHTF), Class I (USA), Class IIa (Europe, Australia), Class II (Canada, Japan).
	Regulatory approval / Certification	Proof of regulatory compliance (e.g., registration, clearance, approval) must be provided as appropriate per the product's risk classification (e.g., by a founding member of IMDRF - EU, USA, Canada, Australia, Japan).
	International standards and certification	Standards applicable to the manufacturer and the manufacturing process (compliance to the last available version is recommended, proof of compliance must be provided): — ISO 13485:2016 - Medical devices – Quality management systems – Requirements for regulatory purposes — ISO 14971:2019 - Medical devices – Application of risk management to medical devices Standards applicable to the product (where applicable, compliance to the last available version is recommended, proof of compliance must be provided): — Color coding ISO 32 for medical gases — Conforms to ISO, NFPA, and/or CGA standards, and/or UL or CSA approved — ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen — ISO 15002 Flow-metering devices for connection to terminal units of medical gas pipeline systems — ISO 18562 Biocompatibility evaluation of breathing gas pathways in healthcare applications — ISO 10524 Pressure regulators for use with medical gasses — ISO 18082 Anaesthetic and respiratory equipment – Dimensions of non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gasses — ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements — ISO 5359 Low-pressure hose assemblies for use with medical gases — ISO 32 color coding for medical gases
	Regional / Local standards	Country-specific and regional color gas coding and other standards apply and must be listed.
	Regulations	Country-specific and regional regulations apply and must be listed. Compliance to (where applicable, but not limited to, and last available version): **1. US regulations:** — 21 CFR part 820 — 21CFR part 868.2320 – Uncompensated Thorpe tube flowmeter — 21CFR part 868.2340 – Compensated Thorpe tube flowmeter **2. EU regulations:** — Regulation (EU) 2017/745. **3. Japan regulations:** — MHLW Ordinance No. 169 — 37132000 Flowmeter, oxygen therapy

4.4 HUMIDIFIER		
i.	Version number	1
ii.	Date of initial version	November 2023
iii.	Date of last modification	November 2023
iv.	Date of publication	November 2023
v.	Developed by	MINISTRY OF HEALTH
NAME, CATEGORY AND CODING		
	Generic name	Humidifier, non-heated, reusable
	Specific type or variation	Non-heated, reusable
	GMDN name	Non-heated respiratory humidifier
	GMDN code	35113
	UMDNS name	Humidifiers, non-heated
	UMDNS code	12051
	Alternative name/s	Oxygen humidifier, bubble humidifier, bubbling device.
	Keywords	Humidifier, non-heated, respiratory, artificial airway, bubble, oxygen.
	GMDN definition	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 gas tight 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.
PURPOSE OR USE		
	Clinical or other purpose	The humidifier is inserted in the inspiratory line of a breathing circuit to add moisture to the breathing gases for administration to a patient. The bubbling bottle humidifier is a sealed container filled with water and connected inline into the breathing circuit. The medical gas mixture flows through the water inside the bottle and is enriched in humidity. This type of humidifier does not heat the gas.
	Level of use	All levels: Dispensary (Level 2), Health center (Level 3), Sub-County (Level 4), County referral (level 5) and National referral (Level 6) hospitals.
	Clinical department / Ward	All departments where oxygen and/or respiratory support/therapy is delivered, including, but not limited to, intensive care units, inpatient ward, emergency, operating theatre, recovery room, observation, etc., and also emergency vehicles and home care.

	Overview of functional requirements	The non-heated, reusable humidifier provides humidity to the gas in the inspiratory line of the breathing circuit. It is a bubbling air/water contact system, composed of a bottle filled with water and connected inline into the breathing circuit.
TECHNICAL CHARACTERISTICS		
	Detailed requirements	Non-heated, reusable humidifier for oxygen therapy and ventilation/anesthesia inspiratory lines. Bubble-through humidification system. Graduated, transparent humidification bottle, unbreakable or shatter resistant. Graduation shall show minimum and maximum water level. Detachable metal or rigid durable polymer cap with gas connectors. Pressure relief safety valve, ≥ 14 kPa (0.1 bar, 2 psi) rating. (Diameter-Index Safety system) DISS connectors for inlet. 6 mm barbed connector for outlet. Humidification chamber working volume at least 150 ml, not greater than 500 ml. Flow rate capacity up to 15 Liters per minute. Must be capable of disinfection. Suppliers must define a decontamination procedure.
	Configuration options	• Humidification chamber working volume available at least 150 mL, not greater than 500 ml. • Graduation options available in metric both units.
	Displayed parameters	Graduated water level on the bottle.
	User adjustable settings	N/A
PHYSICAL/CHEMICAL CHARACTERISTICS		
	Components	Bottle, diffuser, tubing, O-ring/seals, inlet and outlet connectors, cover lid.
	Mobility, portability	Portable
	Raw materials	— Cap and connectors made of brass/steel/ other biocompatible metal or polymer certified for medical use (ISO 13485). — Bottle and tubes made of polypropylene, polycarbonate or equivalent biocompatible plastic/polymer certified for medical use, unbreakable or shatter resistant. — Pressure valve made of brass chromium plated or equivalent metal certified for medical use.
UTILITY REQUIREMENTS		
	Electrical, water and/or gas supply	Oxygen/other medical gas supply (centralized, cylinders or concentrators) and related equipment to deliver medical gas (mixer/blender, anesthesia, ventilator, etc.)

ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
	Accessories	— Adapters and swivel hose nipple connectors to mount the humidifier in oxygen therapy/ respiratory support circuits and in anesthesia/ ventilation circuits. — Spare O-ring/seal. — Outlet connector for 6 mm barbed connection to oxygen tubing included. — Additional adaptors from DISS to required connector for each gas port, as specified.
	Sterilization/disinfection process for accessories	Must be capable of disinfection. Supplier must define decontamination procedure.
PACKAGING		
	Sterility status on delivery	Sterile or certified clean and ready for use.
	Shelf life	At least 5 years for sterility of the new unpacked product.
	Transportation and storage	Sealed container. Capable of being transported and stored in ambient temperature of at least 0–50 °C, relative humidity of at least 15–95% non-condensing. Specific requirements for altitude may be required, depending on the installation site.
	Labelling	**Primary packaging:** Unit of use: one (1) humidifier in an individual sterilized or certified clan and ready for use peel pack (or equivalent packaging). **Labelling on the primary packaging:** Name and/or trademark of the manufacturer; manufacturer's product reference; type of product and main characteristics; 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; the word "sterile" (or equivalent harmonized symbol); sterilization method (or equivalent harmonized symbol); 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); the words "for single use" (or equivalent harmonized symbol); the words "check the integrity of the individual sterilized pack before use" (if space allows); the words "destroy after use" (if space allows). **Secondary packaging:** Protected unit: one (1) box containing multiple items in their primary packaging. **Labelling on the secondary packaging:** Labelling to be the same as primary packaging. **Extra information required:** Number of units per secondary packaging. Information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonized symbol). Information for handling, if applicable (or equivalent harmonized symbol). Manufacturer's instruction for use. Alternatively, the instruction for use can be indicated on a separate insert.
ENVIRONMENTAL REQUIREMENTS		
	Context-dependent requirements	• Capable of being stored in ambient temperature of at least 0–50 °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.
TRAINING, INSTALLATION AND UTILIZATION		
	Requirements for commissioning	Local clinical and technical staff to affirm completion of installation and proper operation.
	Training of user/s	• Training of users in operation and basic maintenance is not mandatory, but can be recommended, depending on the case, and shall be provided upon request. • Training of technical staff in advanced maintenance tasks is not mandatory, but can be recommended, depending on the case, and shall be provided upon request.
	User care	• Pre-use checks • Proper connection • Cleaning with compatible products, disinfecting after each use.
WARRANTY AND MAINTENANCE		
	Warranty	2 years. The product shall be in production and fully supported when procured.
	Maintenance tasks Spare parts availability post-warranty	Regular cleaning/sterilization and functionality checks. 5 years at least, starting from the installation.
DOCUMENTATION		
	Documentation requirements	— User and maintenance manuals, hard and soft copies, to be supplied in English. — List to be provided of common spares and accessories, with part numbers. — Contact details of manufacturer, supplier and local service agent to be provided.
DECOMMISSIONING		
	Estimated life span	5 years.
SAFETY AND STANDARDS		
	Risk classification	Class A (GHTF), Class I (USA), Class IIa (EU, Australia), Class II (Canada, Japan).

	Regulatory approval / Certification	Proof of regulatory compliance (e.g., registration, clearance, approval) must be provided as appropriate per the product's risk classification (e.g., by a founding member of IMDRF - EU, USA, Canada, Australia, Japan).
	International standards and certification	Standards applicable to the manufacturer and the manufacturing process (compliance to the last available version is required, proof of compliance must be provided): — ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes. — ISO 14971 Medical devices – Application of risk management to medical devices. — ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. Standards applicable to the product (where applicable, compliance to the last available version is required, proof of compliance must be provided) — Conforms to ISO, NFPA and/or CGA standards, and/or UL or CSA approved. — ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen. — ISO 18562 Biocompatibility evaluation of breathing gas pathways in healthcare applications. — ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements. — ISO 18190 Anaesthetic 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. — ISO 8185 Respiratory tract humidifiers for medical use – Particular requirements for respiratory humidification systems.
	Regional / Local standards	Country-specific and regional standards apply and must be listed
	Regulations	Country-specific and regional regulations apply and must be listed. Compliance to (where applicable, but not limited to, and last available version): **1. US regulations:** — 21 CFR part 820. — 21CFR 868.5450 – Respiratory gas humidifier. **2. EU regulations:** — Regulation (EU) 2017/745.

		3. Japan regulations: — MHLW Ordinance No. 169

4.5 OXYGEN SATURATION MONITOR, FINGER-TIP		
i.	Version number	1
ii.	Date of initial version	November 2023
iii.	Date of last modification	November 2023
iv.	Date of publication	November 2023
v.	Developed by	MINISTRY OF HEALTH
NAME, CATEGORY AND CODING		
	Generic name	Oxygen saturation monitor, fingertip.
	Specific type or variation	Battery-powered, portable.
	GMDN name	Pulse oximeter, battery-powered.
	GMDN code	45607
	UMDNS name	Oximeters, Pulse.
	UMDNS code	17148
	Alternative name/s	Pulse oximeter, battery-powered.
	Keywords	SpO2, oxygen, pulse oximetry, monitor, portable.
	GMDN definition	A portable, battery-powered, photoelectric device intended for the transcutaneous measurement and display of hemoglobin oxygen saturation (SpO2). The signals, typically produced by light-emitting diodes (LEDs) and a receiving detector in a probe, or directly built-in, are used to make the measurements using the principle of spectrophotometry. The oximeter displays the SpO2 values and may calculate/display other parameters, e.g., pulse rate, electrocardiogram (ECG). The device is typically applied to the fingertip or around the wrist; it may be used by health care facilities, emergency services, or in the home.
PURPOSE OR USE		
	Level of use	Level 2, 3, 4, 5, and 6 health facilities, specialized hospital, emergency vehicles and home care.
	Overview of functional requirements	Pulse oximeter contained in single small package, operated by placing on a patient's finger. The device is intended for spot checking adult and pediatric patients who are well or poorly perfused. The device measures and displays SpO2 and pulse rate.
TECHNICAL CHARACTERISTICS		
	Detailed requirements	• SpO2 and pulse rate monitor integrated into finger/toe clip. • Should be able to be used on adults and children

		• SpO2 range: 70–99% • SpO2 accuracy ± 2% • Pulse rate accuracy within ± 3 bpm • Should be able to detect in low perfusion conditions (as per ISO 80601-2-61) Its design must enable use in demanding environments, e.g., shock, vibration as per tests in ISO 80601-2-61, free fall tests equivalent to IEC 60068-2-31. Available probe sizes must accommodate finger/toe thicknesses at least including the range 8–25 mm. Automatic correction for movement, ambient light artefacts (as per ISO 80601-2-61) ISO 80601-2-61:2017 is applicable to pulse oximeter equipment intended for use under extreme or uncontrolled environmental conditions outside the hospital. Should be able to display %SpO2, pulse rate, signal quality, sensor error and low battery status. The display should be LCD and easy to read. Dimensions: • 58mm x 32mm x 34mm for adults • 48mm x26mm for pediatric **Electrical characteristics:** Batteries, single use. Hours of continuous use, or number of tests, per battery set should be stated. Batteries must allow at least 2,500 spot checks calculated at 30 seconds per spot check, or at least 21 hours of operation. Automatic power-off.
	Configuration / Options	Plethysmography waveform visualization. Internal data storage, for patient trends Adult, pediatric configurations required. Audible alarms.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
	Accessories	— One (1) carry/storage case. — Two (2) spare sets of batteries, if single use type (separately packed). — One (1) neck lanyard for carrying. — One (1) replacement flexible cover for patient finger contact.
	Cleaning and disinfection	Easy to clean and disinfect
	Spare parts	The following must be available from the supplier as and when required by the customer: disposable batteries
PACKAGING		
	Sterility status on delivery	Non sterile
	Transportation and storage	Capable of being transported and stored in ambient temperature of at least 0–50 °C, relative humidity of at least 15–95% non-condensing.
	Labelling	**Primary packaging:** Unit of use: one (1) pulse oximeter in a box or case

		or bag with manufacturer's instruction for use, spare parts and accessories (when applicable). **Labelling on the primary packaging:** Name and/or trademark of the manufacturer; manufacturer's product reference; type of product and main characteristics; lot number prefixed by the word "LOT" (or equivalent harmonized symbol) (if applicable); information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonized symbol); information for handling, if applicable (or equivalent harmonized symbol).
WARRANTY AND MAINTENANCE		
	Warranty	1 year mandatory
	Spare parts availability post-warranty	Spare sets of rechargeable or disposable batteries, reusable probes, extender cable. Replacement set of spare fuses (if non-resettable fuses are used), display, connectors, battery holder, control panel, casing, battery charger. Must be available for at least 2 years.
DOCUMENTATION		
	Documentation requirements	— Product description, operating and service manual, spare parts catalogue with part numbers and contact details for parts supply to be supplied in English. — Certificate of calibration and inspection to be provided. — List to be provided of equipment and procedures required for local calibration checks and routine maintenance. — Contact details of manufacturer, supplier and local service agent to be provided.
DECOMMISSIONING		
	Estimated life span	Expected lifetime of unit shall be 2 years.
SAFETY AND STANDARDS		
	Risk classification	Class B (GHTF Rule 10), Class II (USA), Class IIb (EU, Japan, Canada and Australia).
	Regulatory approval / Certification	Proof of regulatory compliance (e.g., registration, clearance, approval) must be provided as appropriate per the product's risk classification (e.g., by a founding member of IMDRF – EU, USA, Canada, Australia, Japan).
	International standards	Standards applicable to the manufacturer and the manufacturing process (compliance to the last available version is recommended, proof of compliance must be provided): — ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes. — ISO 14971 Medical devices – Application of risk management to medical devices.

		Standards applicable to the product (where applicable, compliance to the last available version is recommended, proof of compliance must be provided): — IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. — IEC 60601-1-1 Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems. — IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests. — ISO 80601-2-61 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment. — ISO/IEEE 11073-10404 Health informatics – Personal health device communication – Part 10404: Device specialization – Pulse oximeter. — IEC 60068-2-31 Environmental testing – Part 2-31: Tests – Test Ec: Rough handling shocks, primarily for equipment-type specimens. — IEC 62366-1 Medical devices – Part 1: Application of usability engineering to medical devices. — IEC 62133 – Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells. Part 1: Nickel, Part 2: Lithium.
	Regional / Local standards	Country-specific and regional standards apply and must be listed
	Regulations	Country of origin specific and regional regulations apply and must be listed

4.6 OXYGEN SATURATION MONITOR, PORTABLE HAND-HELD		
i.	Version number	1
ii.	Date of initial version	November 2023
iii.	Date of last modification	November 2023
iv.	Date of publication	November 2023
v.	Developed by	MINISTRY OF HEALTH
NAME, CATEGORY AND CODING		
	Generic name	Oxygen saturation monitor, hand-held.
	Specific type or variation	Battery-powered, portable.
	GMDN name	Pulse oximeter, battery-powered.
	GMDN code	45607
	UMDNS name	Oximeters, Pulse.
	UMDNS code	17148
	Alternative name/s	Pulse oximeter, battery-powered.
	Keywords	SpO2, oxygen, pulse oximetry, monitor, portable.
	GMDN definition	A portable, battery-powered, photoelectric device intended for the transcutaneous measurement and display of hemoglobin oxygen saturation (SpO2). The signals, typically produced by light-emitting diodes (LEDs) and a receiving detector in a probe, or directly built-in, are used to make the measurements using the principle of spectrophotometry. The oximeter displays the SpO2 values and may calculate/display other parameters, e.g., pulse rate, electrocardiogram (ECG). The device is typically applied to the fingertip or around the wrist; it may be used by health care facilities, emergency services, or in the home.
PURPOSE OR USE		
	Level of use	Level 2, 3, 4, 5, and 6 health facilities, specialized hospital, emergency vehicles and home care.
	Overview of functional requirements	— Portable pulse oximeter, handheld. — Continuously displays patient oxygen saturation in real time using an external probe on the skin. — Contains adjustable alarms to alert when either saturation or heart rate is high or low. — Supplied with reusable probes. — Settings and probes must be suitable for adult, pediatric and neonatal patients. — Operates from rechargeable and/or disposable batteries; supplied with battery charger if rechargeable.
TECHNICAL CHARACTERISTICS		
	Detailed requirements	**Operational characteristics:** SpO2 and pulse rate monitor, with plethysmography waveform, for adults, children and neonates, for all skin pigmentations.

		Weight range for each patient category must be stated. SpO2 detection to include the range: 70–100%. SpO2 resolution: 1% or less. SpO2 accuracy (in the range at least 70–100%): within ± 2% under ideal conditions of use, and within ± 3% for all patients and perfusion/movement conditions. If equipment is capable of a wider SpO2 detection range, the accuracy over that wider range shall be stated. Pulse rate detection to include the range: 30–240 bpm. Pulse rate resolution: 1 bpm or less. Pulse rate accuracy within ± 3 bpm. Data update period for valid data displayed ≤ 10 s. Display with main parameters: %SpO2, pulse rate, plethysmography waveform (and possibly other indicators of signal quality), alarm messages, battery state indication. Suitable for detection in low perfusion conditions (as per **ISO 80601-2-61**, test method must be described). Automatic correction for movement and ambient light artefacts (as per **ISO 80601-2-61**, test method must be described). Design must enable use in demanding environments, e.g., shock, vibration as per tests in **ISO 80601-2-61**, free fall tests equivalent to **IEC 60068-2-31**. Audible and visual alarms for low/high saturation and pulse rate, threshold set by user. Audible and visual alarms for sensor error or disconnected, system errors, low battery. Alarm override and temporary silencing function. Capable of working with, and supplied with, adult, pediatric and neonatal reusable probes. Enclosure to have ingress protection level IPX2 or better. Overall device and probe weight < 400g. Any aspects of usability as per **IEC 62366-1** must be described. Suitable for cleaning and disinfection. **Electrical characteristics:** Operated by replaceable battery power supply, either rechargeable or single use. Devices that operate from rechargeable or both battery types will be preferred. External or built-in AC battery charger, if rechargeable type. Plug style as per local supply. Charger, if used, to have protection against over-voltage and over-current line conditions and be certified to **IEC 60601-1**. Protection against defibrillator discharges and electrosurgical units.

	Configurations	Suitable for operation by battery and by mains power supply, if connected and/or recharging. — Internal data storage for patient trends and event log (optional). — Data interface, suitable for exporting data to external software (optional). — Availability of adult, pediatric and neonatal reusable sensors at least of the following types: finger clip and neonatal/infant foot clips (durable plastic built), silicone wrap, woven fabric, adhesive. — Automatic power-off function enabling/disabling, to allow continuous monitoring use.
	Displayed parameters	SpO2, plethysmography waveform, pulse rate, battery and system messages, alarms.
	User adjustable settings	Audiovisual adjustable alarms: high/low SpO2 and high/low pulse rate (operator variable settings).
PHYSICAL/CHEMICAL CHARACTERISTICS		
	Components (if relevant)	Oxygen saturation monitor body, plastic casing, removable battery cover, battery charger (separated or integrated component), probe connector, control panel, display, internal electronic board, reusable probes.
	Mobility, portability (if relevant)	Portable, handheld.
UTILITY REQUIREMENTS		
	Electrical, water and/or gas supply	Applicable to the battery charger or charging station. The requirements for power input voltage/frequency, 240 VAC 50 Hz; and plug type, British Standard. Depending on the local electrical supply availability and quality, voltage corrector/stabilizer/UPS can be recommended, in order to allow operation at ± 30% of local rated voltage, providing also protection for over current events. Electrical protection preferably by resettable circuit breakers in both live and neutral supply lines.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
	Accessories	— Carry case. To be supplied with reusable probes, adult, pediatric and neonatal sizes (depending on the intended use), recommended 2 or 3 probes of the needed type, probe cable length (including extender if supplied) > 1m. — The catalogue shall include various sizes, fitting all patients, of clip and wrap-up (silicone, woven fabric, adhesive and other material/design) probes.
	Cleaning and disinfection	Easy to clean and disinfect
	Spare parts	Spare sets of rechargeable or disposable batteries, reusable probes, extender cable.

		Replacement set of spare fuses (if non-resettable fuses are used), display, connectors, battery holder, control panel, casing, battery charger.
PACKAGING		
	Sterility status on delivery	Non sterile.
	Transportation and storage	Capable of being transported and stored in ambient temperature of at least 0–50 °C, relative humidity of at least 15–95% non-condensing.
	Labelling	**Primary packaging:** Unit of use: one (1) pulse oximeter in a box or case or bag with manufacturer's instruction for use, spare parts and accessories (when applicable). **Labelling on the primary packaging:** Name and/or trademark of the manufacturer; manufacturer's product reference; type of product and main characteristics; lot number prefixed by the word "LOT" (or equivalent harmonized symbol) (if applicable); information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonized symbol); information for handling, if applicable (or equivalent harmonized symbol).
TRAINING, INSTALLATION AND UTILIZATION		
	Training of user/s (if relevant)	• Training of users in operation and basic maintenance is mandatory. • Training of technical staff in advanced maintenance tasks is not mandatory, but is recommended.
	User care (if relevant)	• Pre-use checks • Proper connection, probe mounting and battery replacement/charging • Cleaning and disinfection with compatible products • Periodic functionality checks with appropriate testers • Periodic preventive maintenance and electrical safety checks
WARRANTY AND MAINTENANCE		
	Warranty Spare parts availability post-warranty	1 year mandatory Spare sets of rechargeable or disposable batteries, reusable probes, extender cable. Replacement set of spare fuses (if non-resettable fuses are used), display, connectors, battery holder, control panel, casing, battery charger.
DOCUMENTATION		
	Documentation requirements	— Product description, operating and service manual, spare parts catalogue with part numbers and contact details for parts supply to be supplied in English. — Certificate of calibration and inspection to be provided.

		— List to be provided of equipment and procedures required for local calibration checks and routine maintenance. — Contact details of manufacturer, supplier and local service agent to be provided
DECOMMISSIONING		
	Estimated life span	Expected lifetime of unit shall be 5 years.
SAFETY AND STANDARDS		
	Risk classification	Class B (GHTF Rule 10), Class II (USA), Class IIb (EU, Japan, Canada and Australia).
	Regulatory approval / Certification	Proof of regulatory compliance (e.g., registration, clearance, approval) must be provided as appropriate per the product's risk classification (e.g., by a founding member of IMDRF – EU, USA, Canada, Australia, Japan).
	International standards and certification	Standards applicable to the manufacturer and the manufacturing process (compliance to the last available version is recommended, proof of compliance must be provided): — ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes. — ISO 14971 Medical devices – Application of risk management to medical devices. Standards applicable to the product (where applicable, compliance to the last available version is recommended, proof of compliance must be provided): — IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. — IEC 60601-1-1 Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems. — IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests. — ISO 80601-2-61 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment. — ISO 80601-2-61 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment. — ISO/IEEE 11073-10404 Health informatics – Personal health device communication – Part 10404: Device specialization – Pulse oximeter.

		— IEC 60068-2-31 Environmental testing – Part 2-31: Tests – Test Ec: Rough handling shocks, primarily for equipment-type specimens. — IEC 62366-1 Medical devices – Part 1: Application of usability engineering to medical devices. — IEC 62133 – Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells. Part 1: Nickel, Part 2: Lithium.
	Regional / Local standards	Country-specific and regional standards apply and must be listed
	Regulations	Country of origin specific and regional regulations apply and must be listed

SECTION 5: SPECIFICATIONS FOR LIQUID OXYGEN CYLINDERS AND TANKS

5.1. SPECIFICATIONS FOR THE MEDICAL GAS CYLINDER TROLLEY

1. FOR THE 6.8 AND 8.5M3 CYLINDERS (FOR THE SINGLE CYLINDER TROLLEY)

a. Maximum carrying capacity 200kgs
b. Length is 1250mm, width 400mm, depth 235mm
c. Foot plate 245 mm
d. Castor Wheel type, anti –static and solid rubbers
e. Diameter 200mm for the front wheels swivel,100mm for the back wheels
f. Centre of the wheel should be steel
g. Self-lubricating bearing
h. Thickness of the rubber wheels 40mm for the front wheels,20mm for the back wheels
i. Number of the wheels should be 4 with the back wheels foldable
j. Construction using mild steel, painted
k. Secured brackets with a stainless-steel chain
l. Labelling parameters; Name and address of manufacturer

2. FOR THE 1.36 TO 3.4 M^3 CYLINDERS (FOR THE SINGLE CYLINDER TROLLEY)

a. Maximum carrying capacity 120kgs
b. Length is 1000mm, width 230mm, depth 130mm
c. Foot plate 125 mm
d. Wheel type, anti –static and solid rubbers
e. Diameter 120mm for the front wheels,100mm for the back wheels fixed with brakes
f. Centre of the wheel should be steel
g. Self-lubricating bearing
h. Thickness of the rubber wheels 20mm for the front wheels,20mm for the back wheels
i. Number of the wheels should be 4 with the back wheels foldable
j. Construction using mild steel, painted
k. Secured brackets with a stainless-steel chain
l. Labelling parameters; Name and address of manufacturer

5.2. SPECIFICATIONS FOR OXYGEN CYLINDER BRACKETS

— The material should be solid steel
— It should be adjustable and fasten able by chains
— Can be secured to any wall
— Should hold a maximum of 2 cylinders of large and medium sizes
— Fastening chain is 79cm and should be able to fasten large and medium cylinders
— Dimensions of the bracket; Length 60cm, Width 7 cm, Cylinder ark 24cm
— Construction is epoxy coated mild steel
— Chains should be galvanized iron
— Mounting 4 Rawl bolts

SPECIAL NOTES

ASSEMBLY/ INSTALLATION INSTRUCTIONS

a. Tanks/cylinders for liquid oxygen with appropriate valves, regulators, gauges, accessories and spare parts
b. Oxygen regulator complete with flow meter and humidifier
c. Wall-type Oxygen flow meter with humidifier, with appropriate wall mountings/brackets and accessories
d. Oxygen splitters with independent flow meters

Standards are applicable to the products, fittings and accessories *(compliance to the last available version is required, proof of compliance must be provided)*

— Country-specific and regional regulations apply and must be listed. Compliance to them (where applicable, but not limited to, and last available version) is mandatory.

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