Item	Item Description	Other important features	Approximate forecast (based on past 24 months procurement)
20	Oxygen Analyzer, electrochem, handheld	NA	*100*

Supplier Offered Product Short Description	Picture	Model reference	Supplier Unit of Measure (UOM)	Price Per Unit FCA Shanghai (USD)	Total Cost Price FCA Shanghai (USD)
xtec MaxO2 ME Oxygen More with picture in		*MaxO2 ME*			

AIR FCA Nearest International Airport (Palletized)		SEA FCA Nearest International Seaport (Containerized)		Minimum order quantity (if applicable)
Name of the FCA (AIR) DELIVERY PLACE - Nearest Main Int. Airport, from the point of manufacture	Unit Price (Palletized)	Name of the FCA (SEA) DELIVERY PLACE - Nearest Main Int. Seaport, from the point of manufacture	Unit Price (Containerized)	
				1

Proposed Staircase Pricing (if any)	Other proposed discounts (if applicable)	Leadtime (in weeks)	Manufacturer name and address	Warranty period (in months)	pcs per carton
ock is available from our UK warehouse, but if 10			*d Street, (300 West,*	*24*	

Total cartons	*Unit Weight (kg per Carton)	*Total Weight (kg not including palletization)	L(CM)	W(CM)	H(CM)	*Unit Volume (M3 per Carton)	*Total Volume (M3 not including palletization)

Monthly Production Capacity	Additional Comments

Oxygen analyzer, electrochem, handheld	
Hand held, battery powered device that measures the oxygen concentration in a flow of gas from a medical gas source or, with adapters, through a medical gas-flow device such as a ventilator or anaesthesia system, or within an environment such as oxygen hood and infant incubator.	Yes: MaxO2 ME – pn.0110452
FEATURES:	
Hand held oxygen analyzer for continuous measurement of the oxygen concentration from a medical gas source.	Yes
Electrochemical cell oxygen sensing technology.	Yes
O2 measurement to include the range: 15 - 99%.	Yes, 0-100%
O2 resolution: 0.1%	Yes
O2 accuracy: ± 3 % or better.	Yes, +/- 1% of full scale at a constant temperature and pressure
Suitable for measuring gas supply with pressure up to 50 psi (344 kPa).	Only as a flowing gas, with no back pressure, as electrochecmical O2 sensors are sensitive to the partial pressure of O2
Response time ≤ 20s.	Yes, 90% of final value <15 seconds at 23°C
Warm-up time < 10s.	None required
Replaceable oxygen sensor cell, nominal operating life ≥ 1.5 years or 600,000 %O2-hours (oxygen percent hours), whichever is greater.	Yes, >1,500,000 oxygen percent hours
Indicate the expected operating life of the oxygen sensor cell:	Over 2 years in typical applications
Indicate the shelf life (or storage period) of the oxygen sensor cell: **Note**: This refers to the maximum amount of time after which the sensor should no longer be used due to it deteriorating over time.	Not specified, but we would recommend putting the sensor in to use within the 2 year warranty period
Calibration and self-test mode at ambient and 100% oxygen concentration.	Yes
Describe calibration (e.g. one point or two point calibration).	1 point calibration in either Air or 100% O2
Internal calibration timer, with reminder (alarm and/or display message).	Yes
Audible and visual alarms for low and high oxygen concentration.	Yes
Display visualizing O2 concentration, system messages and battery status.	Yes
ELECTRICAL CHARACTERISTICS	
Operated by battery power supply.	Yes, 4x Standard AA alkaline batteries
Internal replaceable batteries, either rechargeable or single use.	Yes, user replaceable Standard AA alkaline batteries
Battery life > 500 hours use.	Yes, 5000 hours (continuous monitoring, no alarms, no backlighting)
External or built-in AC battery charger, if rechargeable type.	Not applicable
Charger, if used, to have protection against over-voltage and over-current line conditions, and be certified to IEC 60601-1.	Not applicable
CASING AND ENVIRONMENT	
Suitable for cleaning and disinfection with hospital-grade cleaning products.	Yes
IPX1 ingress protection or better.	Yes, IPX1
***** REQUIRED ACCESSORIES, SUPPLIES AND/OR CONSUMABLES ***** **Oxygen analyzer to be supplied with:**	
Carrying case.	Not supplied
Supplied with connectors and/or adapters suitable for measurement of various medical gas supply sources, for example (but not limited to) oxygen concentrators, ventilators/anaesthesia machines and patient circuits (T-piece and/or in-line adapters), wall/column/cylinder supplies (compliance with ISO 7396 - 1).	Tee connection for ventilators is supplied as standard, an O2 concentrator adapter can be added to the offer
2 x sample line (if applicable).	Not applicable
1 x set spare rechargeable or 2 x sets single use batteries.	Supplied as standard with one saet of batteries, a spare set can be added to the offer
1 x battery charger (if applicable) with locally compatible plug.	Not applicable
Set of spare fuses (if non-resettable fuses are used).	Not applicable
1 x set user and maintenance manuals to be supplied in English, French and Spanish. If compete manuals are only available digitally, a quick reference guide and information sheet which clearly indicates the url to access complete manuals must be included with the device.	https://www.maxtec.com/product/analysis/oxygen-analyzers/maxo2-me/
1 x certificate of calibration and inspection.	Not supplied, as they are user calibrated devices
1 x list of all equipment and procedures required for routine maintenance.	Listed in IFU
1 x list of all spares and accessories, with part numbers and contact details for parts supply.	Listed on supplied price list
1 x document with contact details of manufacturer, supplier and local service agent.	Provided on document titled Contact Information

Quotation request - Oxyger

MANUFACTURER IDENTIFICATION

Name of manufacturer
Address of manufacturer
Country of manufacturer
If the manufacturer has a website, please provide the weblink:
If the manufacturer has an online catalogue, please provide link or copy of the document
Please provide a copy of the manufacturer requires ISO 13485 certification
If the supplier is not the manufacturer then the supplier requires any of: ISO 9001 certification, ISO 13485 certification or a
If the manufacturing process(es) is/are subcontracted provide: Subcontracted process Name and address and country of subcontractor Upload QMS certificate of subcontractor under the placeholder: "Item 10". Indicate the filename of the uploaded docume

DEVICE IDENTIFICATION

Product name:
Product reference/model number from supplier:
Product reference/model number from manufacturer, if different from supplier:
Please provide a copy of the general brochure of the offered product
Please provide a copy of the user/operator manual for the offered product
Provide here a generic product description.
Please provide an image of the products with a white background (Min: 2000 x 3000 pixels without compression. preferre

DEVICE CLASSIFICATION AND MARKET CLEARANCE

Confirm if the product has market clearance as a class IIa medical device under EU regulations. Then indicate the applicabl
If offering EC certified products under MDD 93/42/EEC. Please indicate when you plan to transition to the new MDR 2017/
Please provide a copy of the FDA certification
Please provide a copy of the market clearance from either Canada, Japan, or Australia

COMPLIANCE TO TECHNICAL STANDARDS

Please state compliance to the latest versions of the following international standards or to re laboratory or third party)

Test reports and/or certificates to prove compliance should be included in the submission. Indicate

ISO 14971 Medical Devices – Application of risk management to medical devices.
ISO 15001 Anaesthetic and respiratory equipment - Compatibility with oxygen.

IEC 60601-1 General requirements for basic safety and essential performance.
IEC 60601-1-2 General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic dist
Indicate here any other series standards the products complies with (e.g. ISO, IEC, etc.)
Confirm a Declaration of Conformity (DoC)
IF THE DEVICE CONTAINS **BATTERIES** OF ANY KIND - If yes, please provide MSDS
Does it comply with clause 38.3 of the recommendations on "Transport of Dangerous Goods" from the United Nations?
Does it comply with the latest IATA Dangerous Goods Regulations (DGR)?
Indicate the UN hazardous classification code here, if applicable:
Please provide a copy of the Material Safety Datasheet for the offered product
ENVIRONMENTAL CONDITIONS
Capable of being transported and stored in ambient temperature 5–50 °C, relative humidity 15–95% non condensing and
Suitable for continuous operation in ambient temperature 5–45 °C, relative humidity 15–90% non condensing and elevatio
WARRANTY AND MAINTENANCE
Warranty period should be minimal two (2) years including supplied accessories.
TRAINING, INSTALLATION, UTILISATION AND DECOMISSIONING
Indicate the product shelf life in months (if applicable).
Indicate the estimated lifespan of the device.
The supplier hereby commits to the availability of spare parts & consumables for the above indicated life-span:
Please provide a list of global distribution and service partners, by country, that are available for technical support, spare p
Please provide description of training modalities, remote assistance, and live or asynchronous online training available.
Indicate here specific disposal or decommissioning requirements
PACKAGING AND LABELLING
Gross weight (kg) and gross volume (m3) of one primary packaged.
Primary packaging: Unit of use:
Labelling on the primary packaging should indicate the name and/or trademark of the manufacturer in addition to: - Manufacturer's product reference: - Type of product and main characteristics: - If the device is CE marked indicate the CE mark and notified body number:
Labelling includes details necessary for users to identify the device and the contents of the packaging.
The label provides information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropria
The label provides information for handling, if applicable (or equivalent harmonised symbol).
Batch code, prefixed by the word "LOT" or the serial number.
Any symbol used on the labelling is in accordance with ISO 15223.
Indicate the Harmonized System Code (HS Code) for this product here:
Please provide sample primary and secondary labels

Please provide a copy of the Free Sales Certificate for this product
Please provide a copy of the Certificate of Origin for this product
Indicate with which labelling requirements the product is in compliance:
Products MDR - CE certified follow labelling regulations as stipulated in EU MDR 2017/745 Annex I, Chapter III, point 23.2. Follow below hyperlink for details on this regulation. https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0745&qid=1622012817907&from=EN#d1e32-9
Products MDD - CE certified follow labelling requirements as stipulated in EU MDD 93/42/EEC, Annex I, point 13.3. Follow below hyperlink for details on this regulation. https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:31993L0042&qid=1638369660570&from=EN
Products with market clearance from the USA FDA follow labelling requirements as stipulated in CFR code of regulations T Follow below hyperlink for details on this regulation. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-801
SUSTAINABILITY CONSIDERATIONS
SOCIAL CONSIDERATIONS
Does the manufacturer have a SA 8000 certification? If so, please provide a copy
Does the manufacturer invest in community development activities in the markets they source from and/or operate in?If s
Does the manufacturer have in place a documented system to ensure fair workplace and labour practices? If so, If so, plea
Does the manufacturer have any child labour policy?If so, please provide a copy
Does the manufacturer have the capacity to meet its client's demand with its own workforce or does it have to integrate v
Does the manufacturer have a system in place to check its employees' identity? If so, please provide information
Does the manufacturer have a system in place to check its employees' age? If so, please provide information
Does the manufacturer have unions/work committees? If so, please provide information
Does the manufacturer have any independent certifications on Safety Standards? If so, please provide information
Has the manufacturer signed up with the UN Global Compact initiative? https://www.unglobalcompact.org/. If so, please
ENVIRONMENTAL CONSIDERATIONS
Does the manufacturer have a documented environmental management system? If so, please provide information
Is the manufacturer ISO 14001 certified or in the process of obtaining ISO 14001 certification? If so, provide expiry date ar
Does the manufacturer have a sustainability/environmental policy? If so, please provide certificate
Does the manufacturer have a recycling programme in place? If so, please provide information
Is the packaging made of recycled or recyclable materials? If so, please provide information
Does the manufacturer maintain records of potentially hazardous environmental substances in the raw materials used in t
Is the device compliant with RoHS (EU Directive 2002/95/EC) on the restriction of the use of certain hazardous substances
Has the manufacturer started to monitor its carbon emissions in order to set reduction targets or objectives? If so, please
Is the manufacturer ISO 50001 certified or in the process of obtaining ISO 50001 certification? If so, please provide expiry