



UTTAR PRADESH MEDICAL SUPPLIES CORPORATION LTD

(A Government of Uttar Pradesh Undertaking)

Regd. Office: SUDA Bhawan, 7/23, Sector-7, Gomti Nagar Extension, Lucknow-226 010

Corrigendum-3 dated 28.06.2021

With reference to tender no. UPMSCL/Drugs-114/464 dated 14 June, 2021 a corrigendum is being issued as follows:

Reference Of Tender Document	EXISTING	REVISED
LAST DATE AND TIME FOR ONLINE SUBMISSION OF TENDER	28 June, 2021, UPTO 15:00 Hrs	01 July, 2021, UPTO 17:00 Hrs
DATE AND TIME OF OPENING OF TECHNICAL BID-COVER 'A'	28 June, 2021 at 15:30 Hrs	01 July, 2021 at 17:30 Hrs

Following are corrigendum for Annexure-A of tender document:

Reference Of Tender Document	Drug Code	REVISED Item with Description	Revised Required Quantity (in no. of unit)	Specification
	con-01	Deleted		
	con-02	Deleted		
	con-03	Deleted		
	con-04	Deleted		
	con-05	Ambu Bag with Reservoir and Pediatric mask-250	200	Standard Quality
	con-06	Ambu Bag with Reservoir and Pediatric mask-750	350	Standard Quality
	con-07	Deleted		
	con-08	Endotracheal Tube (E.T.)-3 F	2500	Priority medical devices list for the COVID-19 response and associated technical specifications-INTERIM GUIDANCE-19 NOVEMBER 2020,World Health Organization 7.2.1
	con-09	Endotracheal Tube (E.T.)-3.5 F	2500	Priority medical devices list for the COVID-19 response and associated technical specifications-INTERIM GUIDANCE-19 NOVEMBER 2020,World Health Organization 7.2.1

Reference Of Tender Document	Drug Code	REVISED Item with Description	Revised Required Quantity (in no. of unit)	Specification
Annexure-A Schedule of requirement	con-10	Endotracheal Tube (E.T.)-4 F	4000	Priority medical devices list for the COVID-19 response and associated technical specifications-INTERIM GUIDANCE-19 NOVEMBER 2020,World Health Organization 7.2.1
	con-11	Endotracheal Tube (E.T.)-4.5 F	4000	Priority medical devices list for the COVID-19 response and associated technical specifications-INTERIM GUIDANCE-19 NOVEMBER 2020,World Health Organization 7.2.1
	con-12	Endotracheal Tube (E.T.)-5 F	4000	Priority medical devices list for the COVID-19 response and associated technical specifications-INTERIM GUIDANCE-19 NOVEMBER 2020,World Health Organization 7.2.1
	con-13	Endotracheal Tube (E.T.)-5.5 F	4000	Priority medical devices list for the COVID-19 response and associated technical specifications-INTERIM GUIDANCE-19 NOVEMBER 2020,World Health Organization 7.2.1
	con-14	Endotracheal Tube (E.T.)-6 F	2500	Priority medical devices list for the COVID-19 response and associated technical specifications-INTERIM GUIDANCE-19 NOVEMBER 2020,World Health Organization 7.2.1
	con-15	Endotracheal Tube (E.T.)-6.5 F	2500	Priority medical devices list for the COVID-19 response and associated technical specifications-INTERIM GUIDANCE-19 NOVEMBER 2020,World Health Organization 7.2.1
	con-16	Deleted		
	con-17	Deleted		
	con-18	Deleted		
	con-19	Glucometer strips (supply by Glucometer company)	1975200	Each 300 strip to be supplied with one free compatible Glucometer
	con-20	Deleted		
	con-21	Deleted		
	con-22	Deleted		
	con-23	Heat and Moisture Exchanger (HME) Filters	22100	For general specifications, please refer Priority medical devices list for the COVID-19 response and associated technical specifications-INTERIM GUIDANCE-19 NOVEMBER 2020,World Health Organization 3.3.5(MUST BE COMPATIBLE WITH PM CARES BEL VENTILATORS)
	con-24	HFNC Cannula and Circuits - Adult	17700	Should be compatible with PM CARES BEL ventilators
	con-25	HFNC Cannula and Circuits - Pediatric	17700	Should be compatible with PM CARES BEL ventilators
	con-26	HFNC Machine Filters	6700	Should be compatible with PM CARES BEL ventilators
	con-27	Deleted		
	con-28	Deleted		
	con-29	Deleted		
	con-30	Deleted		
	con-31	Intracath-26 F	22000	EU/CE/ISO/QMS Certified
con-32	Nasal Prongs Adult size	108000		
con-	Deleted			

Reference Of Tender Document	Drug Code	REVISED Item with Description	Revised Required Quantity (in no. of unit)	Specification
	33			
	con-34	Nasal Prongs paediatric size	6600	Specification: Priority medical devices list for the COVID-19 response and associated technical specifications- INTERIM GUIDENCE-19 NOVEMBER 2020 ,World health organization (3.3.2.1)
	con-35	Nebulisation Kits	8800	Standard nebulisation kits with pediatric mask
	con-36	Deleted		
	con-37	Deleted		
	con-38	Padiatric Non Rebreather Mask (NRBM)	18200	Specifications: Priority medical devices list for the COVID-19 response and associated technical specifications- INTERIM GUIDENCE-19 NOVEMBER 2020, World Health organization (3.3.2.2)
	con-39	Paediatric BP Cuff	2000	Standard Quality
	con-40	Deleted		
	con-41	Deleted		
	con-42	Deleted		
	con-43	Pediatric anesthesia circuit (Jackson- Reeves/ Mapelson -D) compitable with BEL, Agva and Jyoti CNG Ventilators	1200	Standard Quality
	con-44	Pediatric Catheter Mount	6000	Standard Quality
	con-45	Deleted		
	con-46	Deleted		
	con-47	Deleted		
	con-48	Deleted		
	con-49	Deleted		
	con-50	Deleted		
	con-51	Deleted		
	con-52	Deleted		
	con-53	Deleted		
	con-54	Deleted		
	con-55	Deleted		
	con-56	Deleted		
	con-57	Deleted		
	con-	Deleted		

Reference Of Tender Document	Drug Code	REVISED Item with Description	Revised Required Quantity (in no. of unit)	Specification
	58			
	con-59	Deleted		
	con-60	Deleted		
	con-61	T-piece	1200	Standard Quality
	con-62	Deleted		

All other terms & conditions of the tender document shall remain same.

**MANAGING DIRECTOR
UPMSCL**

7.2 Technical specifications for procurement

7.2.1 List of airway and ICU consumables and single-use medical devices

Item no.	WHO Item name	Required technical specifications
1	Compress, gauze net, with paraffin, 10 × 10 cm, sterile, single use	Used in the treatment of wounds, especially to dress and protect burns; prevents gauze dressings from adhering to the wound; allowing exuding serum, exudation or suppuration; It has cicatrising properties. Large-mesh netting impregnated with a soft paraffin-based material (with or without balsam of Peru). Radiolucent. Hypoallergenic. The paraffin compress is placed between two papers (parchment type) in a polyethylene or aluminium peel pack. Individually peel-packed in sterile heat-welded wrapping (it is preferred to metal boxes since it has better resistance to heat exposure). To be stored below 25–26 °C and in horizontal position.
2	Electro-conductive gel	Preferably capable to be used in applications such as electrocardiogram (ECG), electroencephalogram (EEG), ultrasound, transcutaneous electrical nerve stimulation (TENS).
4	Airway, nasopharyngeal, sterile, single use. Sizes from 20 Fr to 36 Fr (with 2 Fr increments)	A nasopharyngeal airway is recommended for use as an airway adjunct in the semi-conscious or unconscious patient with an intact gag reflex. Individually packaged sterile with a conveniently attached surgical lubricant for quick access to facilitate ease of insertion. Flexible and soft material for maximum patient comfort. Rounded tip allows for gentle insertion. Trumpet design for secure placement. Diameter and size labelled according to standards.
5	Airway, oropharyngeal, Guedel, adolescent, size 3 (80 mm), autoclavable	One-piece, semi-rigid, curved plastic tube, used to be inserted through the oropharynx to facilitate airway management. Guedel type. Flange surface is permanently marked with tube size/length in mm, and the manufacturer or supplier's name. It is bite resistant. Proximal (or buccal) end straight and reinforced. Distal end semi-rigid, curved, with atraumatic soft rounded edges.
6	Airway, oropharyngeal, Guedel, adult, size 4 (90 mm), autoclavable	One-piece, semi-rigid, curved plastic tube, used to be inserted through the oropharynx to facilitate airway management. Guedel type. Flange surface is permanently marked with tube size/length in mm, and the manufacturer or supplier's name. It is bite resistant. Proximal (or buccal) end straight and reinforced. Distal end semi-rigid, curved, with atraumatic soft rounded edges.
7	Airway, oropharyngeal, Guedel, adult, size 5 (100 mm), autoclavable	One-piece, semi-rigid, curved plastic tube, used to be inserted through the oropharynx to facilitate airway management. Guedel type. Flange surface is permanently marked with tube size/length in mm, and the manufacturer or supplier's name. It is bite resistant. Proximal (or buccal) end straight and reinforced. Distal end semi-rigid, curved, with atraumatic soft rounded edges.
8	Airway, oropharyngeal, Guedel, child, size 2 (70 mm), autoclavable	One-piece, semi-rigid, curved plastic tube, used to be inserted through the oropharynx to facilitate airway management. Guedel type. Flange surface is permanently marked with tube size/length in mm, and the manufacturer or supplier's name. It is bite resistant. Proximal (or buccal) end straight and reinforced. Distal end semi-rigid, curved, with atraumatic soft rounded edges.
9	Laryngeal mask airway (LMA), size 2, sterile, single use	Standard laryngeal mask airway used for patients undergoing general anaesthesia or as a resuscitation device in ICU departments. Maximum cuff volume: 10 mL.

Item no.	Dimensions/sizes/presentation	Material	Standards for product safety, performance and quality assurance, as requested or equivalent
1	Width: 10 cm. Length: 10 cm.	Compress: 100% cotton fabric, wide meshed tulle (threads every 2–3 mm). Paraffin substance: 100–180 g/m ² . Mixture of balsam of Peru (approximately 1 g) and soft paraffin q. suff. (approximately 100 g). Initial sterilization method: ethylene oxide gas or ionizing radiation or equivalent method.	EN 14079: Dressing gauze thread count. EN 868 (1 to 7) and EN-10993-10 for biological evaluation.
2	1000 mL.	Medical grade conductive gel.	ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.
4	Sizes: 20, 22, 24, 26, 28, 30, 32, 34, 36 Fr.	Latex-free.	ISO 5364:2016(en) Anaesthetic and respiratory equipment – Oropharyngeal airways ISO 4135:2001(en) Anaesthetic and respiratory equipment
5	Size/length/ISO graduation/inner diameter/colour code/patient: no. 3/80 mm/8/4.5 mm/green/for small adult.	Polyethylene vinyl acetate (EVA) and polyvinyl chloride (PVC); siliconized; transparent; medical grade. Hygienically clean for medical use. It must resist steam sterilization at 121 °C or 134 °C.	EN 12181 or ISO 5364: Oropharyngeal airways. ISO 10993-1: Biological safety testing.
6	Size/length/ISO graduation/inner diameter/colour code/patient: no. 4/90 mm/9/4.5 mm/yellow/for adult.	Polyethylene vinyl acetate (EVA) and polyvinyl chloride (PVC); siliconized; transparent; medical grade. Hygienically clean for medical use. It must resist steam sterilization at 121 °C or 134 °C.	EN 12181 or ISO 5364: Oropharyngeal airways. ISO 10993-1: Biological safety testing.
7	Size/length/ISO graduation/inner diameter/colour code/patient: no. 5/100 mm/10/5.0 mm/red/for large adult.	Polyethylene vinyl acetate (EVA) and polyvinyl chloride (PVC); siliconized; transparent; medical grade. Hygienically clean for medical use. It must resist steam sterilization at 121 °C or 134 °C.	EN 12181 or ISO 5364: Oropharyngeal airways. ISO 10993-1: Biological safety testing.
8	Size/length/ISO graduation/inner diameter/colour code/patient: no. 2/70 mm/7/4.0 mm/white/for young adult.	Polyethylene vinyl acetate (EVA) and polyvinyl chloride (PVC); siliconized; transparent; medical grade. Hygienically clean for medical use. It must resist steam sterilization at 121 °C or 134 °C.	EN 12181 or ISO 5364: Oropharyngeal airways. ISO 10993-1: Biological safety testing.
9	Mask size 2: children 10–20 kg.	Flexible medical grade PE. Latex-free.	ISO 11712:2009(en) Anaesthetic and respiratory equipment – Supralaryngeal airways and connectors.

Item no.	WHO Item name	Required technical specifications
10	Laryngeal mask airway (LMA), size 3, sterile, single use	Standard laryngeal mask airway used for patients undergoing general anaesthesia or as a resuscitation device in ICU departments. Maximum cuff volume: 20 mL.
11	Laryngeal mask airway (LMA), size 4, sterile, single use	Standard laryngeal mask airway used for patients undergoing general anaesthesia or as a resuscitation device in ICU departments. Maximum cuff volume: 30 mL.
12	Syringe, 10 mL, three pieces, Luer type, sterile, single use	Three pieces syringe: barrel with Luer nozzle, piston, and stopper. Barrel: permanent and legible graduated scale in mL with intervals of 0.20 or 0.50 mL. Increment of each mL to be numbered. Concentric or eccentric Luer lock or Luer slip nozzle. Length with a maximum usable capacity of at least 10% more than the nominal capacity. Plunger stopper with backstop. Double sealing ring on plunger. Initial sterilization method: ethylene oxide gas or equivalent. Individually peel-packed in paper and/or plastic.
13	Catheter, nasal, 40 cm, with lateral eyes, sterile, single use. Set with different sizes	Nasal catheter for the administration of medical oxygen. Open distal end with multiple lateral holes, or a central eye and distal cross perforation. Proximal end features a straight conical connector available. Each set include different sizes. At least the following sizes provided in each set: 10 Fr, 12 Fr, 14 Fr, 16 Fr, 18 Fr.
14	Endotracheal tube introducer, bougie, sterile, single use	To assist with endotracheal intubations is used to guide the tube properly into the airway. Blue or yellow tube with graduated marking. Curved tip with distal rounded smooth tip. Initial sterilization method: ethylene oxide gas or Gamma radiation or equivalent as appropriate and applicable. Individually peel-packed in paper and/or plastic. At least the following sizes included in the set provided: 10 and 15 Fr.
15	Endotracheal tube introducer, stylet, sterile, single use, 10 Fr	Flexible and malleable guide (stylet) to be inserted into the endotracheal tube to guide it properly during the intubation. It has a soft and round end-tip. It can be shaped as needed. It has graduated marking. Manufacturer name and tube size are indicated on the tube. Initial sterilization method: ethylene oxide gas or Gamma radiation or equivalent as appropriate and applicable. Individually peel-packed in paper and/or plastic.
16	Endotracheal tube introducer, stylet, sterile, single use, 14 Fr	Flexible and malleable guide (stylet) to be inserted into the endotracheal tube to guide it properly during the intubation. It has a soft and round end-tip. It can be shaped as needed. It has graduated marking. Manufacturer name and tube size are indicated on the tube. Initial sterilization method: ethylene oxide gas or Gamma radiation or equivalent as appropriate and applicable. Individually peel-packed in paper and/or plastic.

Item no.	Dimensions/sizes/presentation	Material	Standards for product safety, performance and quality assurance, as requested or equivalent
10	Mask size 3: children/adult 30–50 kg.	Flexible medical grade PE. Latex-free.	ISO 11712:2009(en) Anaesthetic and respiratory equipment – Supralaryngeal airways and connectors.
11	Mask size 4: adult 50–70 kg.	Flexible medical grade PE. Latex-free.	ISO 11712:2009(en) Anaesthetic and respiratory equipment – Supralaryngeal airways and connectors.
12	Barrel nominal capacity: 10 mL.	Barrel: polyethylene (PE) or polypropylene (PP) or polystyrene (PS); sufficiently transparent. Piston: polypropylene (PP) or equivalent. Latex-free/PVC-free.	Barrel graduation: ISO 7886-1:2017: Sterile hypodermic syringe for single use: Part 1: syringe for manual use. Needle, Luer type: ISO 80369-7:2016: Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications. Sterilization method: ISO 11135:2014: Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.
13	Length: 40 cm. ID: 10 Fr, 12 Fr, 14 Fr, 16 Fr and 18 Fr.	PVC. Proximal end: polyester piece of foam.	ISO/DIS 23368: Anaesthetic and respiratory equipment – Low flow nasal cannula for oxygen therapy. ISO/DIS 17256: Anaesthetic and respiratory equipment – Respiratory therapy tubing and connectors.
14	Standard size: 10 Fr and 15 Fr, approximately 60–70 cm long.	Flexible, medical grade, radiopaque, braided polyester base with a resin coating.	ISO 5361:2016: Anaesthetic and respiratory equipment – Tracheal tubes and connectors. ISO 10993-1:2018: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.
15	Size 1: For endotracheal tube with internal diameter of 3.5–4.5 mm. Length: 30–45 cm, approximately. Diameter: 10 Fr (3.3 mm).	Stylet: malleable metal alloy covered by polyvinyl chloride (PVC) coated, latex-free; white; disinfectant resistant; withstand steam sterilization.	ISO 5361:2016: Anaesthetic and respiratory equipment – Tracheal tubes and connectors. ISO 10993-1:2018: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.
16	Size 2: For endotracheal tube with internal diameter of 4.5–6.0 mm. Length: 30–45 cm, approximately. Diameter: 14 Fr (4.6 mm).	Stylet: malleable metal alloy covered by polyvinyl chloride (PVC) coated, latex-free; white; disinfectant resistant; withstand steam sterilization.	ISO 5361:2016: Anaesthetic and respiratory equipment – Tracheal tubes and connectors. ISO 10993-1:2018: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.

Item no.	WHO Item name	Required technical specifications
17	Tube, endotracheal, No. 2, with cuff, sterile, single use	<p>Endotracheal tube designed to be introduced into the trachea via the mouth or nose, ensuring an unobstructed upper airway to convey gases and vapours to and from the lungs during anaesthesia, resuscitation and other situations where the patient is not properly ventilated.</p> <p>It consists in a thin, flexible, transparent and single hollow cylinder, with an anatomical curvature Magill-type of 37.5°, black and legibly depth markings and graduation in cm, with radio-opaque continuous line mark, with cuff and pilot balloon, with a standard connector in the proximal end.</p> <p>The proximal end of the tube safely fits the connector from which size is selected according to the tube size. The connector is straight and double-ended, with the proximal end being an outer, standard 15 mm internal diameter, conical tip that allows the tube to be connected to the ventilation system (breathing circuit or manual resuscitator).</p> <p>The distal end of the tube is open and bevelled (obliquely cut), atraumatic, with Murphy's eye.</p> <p>The endotracheal tubes are standard in all aspects: dimension, markings and connectors.</p> <p>Initial sterilization method: ethylene oxide gas or Gamma radiation.</p> <p>Individually peel-packed in paper and/or plastic.</p>
18	Tube, endotracheal, No. 2.5, with cuff, sterile, single use	<p>Endotracheal tube designed to be introduced into the trachea via the mouth or nose, ensuring an unobstructed upper airway to convey gases and vapours to and from the lungs during anaesthesia, resuscitation and other situations where the patient is not properly ventilated.</p> <p>It consists in a thin, flexible, transparent and single hollow cylinder, with an anatomical curvature Magill-type of 37.5°, black and legibly depth markings and graduation in centimetres, with radio-opaque continuous line mark, with cuff and pilot balloon, with a standard connector in the proximal end.</p> <p>The proximal end of the tube safely fits the connector from which size is selected according to the tube size. The connector is straight and double-ended, with the proximal end being an outer, standard 15 mm internal diameter, conical tip that allows the tube to be connected to the ventilation system (breathing circuit or manual resuscitator).</p> <p>The distal end of the tube is open and bevelled (obliquely cut), atraumatic, with Murphy's eye.</p> <p>The endotracheal tubes are standard in all aspects: dimension, markings and connectors.</p> <p>Initial sterilization method: ethylene oxide gas or Gamma radiation.</p> <p>Individually peel-packed in paper and/or plastic.</p>
19	Tube, endotracheal, No. 3, with cuff, sterile, single use	<p>Endotracheal tube designed to be introduced into the trachea via the mouth or nose, ensuring an unobstructed upper airway to convey gases and vapours to and from the lungs during anaesthesia, resuscitation and other situations where the patient is not properly ventilated.</p> <p>It consists in a thin, flexible, transparent and single hollow cylinder, with an anatomical curvature Magill-type of 37.5°, black and legibly depth markings and graduation in cm, with radio-opaque continuous line mark, with cuff and pilot balloon, with a standard connector in the proximal end.</p> <p>The proximal end of the tube safely fits the connector from which size is selected according to the tube size. The connector is straight and double-ended, with the proximal end being an outer, standard 15 mm internal diameter, conical tip that allows the tube to be connected to the ventilation system (breathing circuit or manual resuscitator).</p> <p>The distal end of the tube is open and bevelled (obliquely cut), atraumatic, with Murphy's eye.</p> <p>The endotracheal tubes are standard in all aspects: dimension, markings and connectors.</p> <p>Initial sterilization method: ethylene oxide gas or Gamma radiation.</p> <p>Individually peel-packed in paper and/or plastic.</p>
20	Tube, endotracheal, No. 3.5, with cuff, sterile, single use	<p>Endotracheal tube designed to be introduced into the trachea via the mouth or nose, ensuring an unobstructed upper airway to convey gases and vapours to and from the lungs during anaesthesia, resuscitation and other situations where the patient is not properly ventilated.</p> <p>It consists in a thin, flexible, transparent and single hollow cylinder, with an anatomical curvature Magill-type of 37.5°, black and legibly depth markings and graduation in cm, with radio-opaque continuous line mark, with cuff and pilot balloon, with a standard connector in the proximal end.</p> <p>The proximal end of the tube safely fits the connector from which size is selected according to the tube size. The connector is straight and double-ended, with the proximal end being an outer, standard 15 mm internal diameter, conical tip that allows the tube to be connected to the ventilation system (breathing circuit or manual resuscitator).</p> <p>The distal end of the tube is open and bevelled (obliquely cut), atraumatic, with Murphy's eye.</p> <p>The endotracheal tubes are standard in all aspects: dimension, markings and connectors.</p> <p>Initial sterilization method: ethylene oxide gas or Gamma radiation.</p> <p>Individually peel-packed in paper and/or plastic.</p>

Item no.	Dimensions/sizes/presentation	Material	Standards for product safety, performance and quality assurance, as requested or equivalent
17	<p>Tube: Size: 2. Internal diameter: 2.0 mm. External diameter: 3.0 mm. Length: 160 mm, minimum.</p> <p>Connector: Proximal end: standard Internal diameter: 15 mm. Distal end (fits the tube): length: 9 mm, minimum.</p>	<p>Tube: polyvinyl chloride (PVC) or polyurethane; medical grade; transparent. Connector: polyvinyl chloride (PVC); medical grade; transparent or blue.</p>	<p>ISO 5361:2016: Anaesthetic and respiratory equipment – Tracheal tubes and connectors. ISO 10993-1:2018: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.</p>
18	<p>Tube: Size: 2.5. Internal diameter: 2.5 mm. External diameter: 3.5 mm. Length: 140 mm, minimum.</p> <p>Connector: Proximal end: standard internal diameter: 15 mm. Distal end (fits the tube): length: 9 mm, minimum.</p>	<p>Tube: polyvinyl chloride (PVC) or polyurethane; medical grade; transparent. Connector: polyvinyl chloride (PVC); medical grade; transparent or blue.</p>	<p>ISO 5361:2016: Anaesthetic and respiratory equipment – Tracheal tubes and connectors. ISO 10993-1:2018: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. ISO 11135:2014: Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.</p>
19	<p>Tube: Size: 3. Internal diameter: 3 mm. External diameter: 4.2 mm. Length: 160 mm, minimum.</p> <p>Connector: Proximal end: standard internal diameter: 15 mm. Distal end (fits the tube): length: 9 mm, minimum.</p>	<p>Tube: polyvinyl chloride (PVC) or polyurethane; medical grade; transparent. Connector: polyvinyl chloride (PVC); medical grade; transparent or blue.</p>	<p>ISO 5361:2016: Anaesthetic and respiratory equipment – Tracheal tubes and connectors. ISO 10993-1:2018: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. ISO 11135:2014: Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.</p>
20	<p>Tube: Size: 3.5. Internal diameter: 3.5 mm. External diameter: 4.8 mm. Length: 140 mm, minimum.</p> <p>Connector: Proximal end: standard internal diameter: 15 mm. Distal end (fits the tube): length: 9 mm, minimum.</p>	<p>Tube: polyvinyl chloride (PVC) or polyurethane; medical grade; transparent. Connector: polyvinyl chloride (PVC); medical grade; transparent or blue.</p>	<p>ISO 5361:2016: Anaesthetic and respiratory equipment – Tracheal tubes and connectors. ISO 10993-1:2018: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. ISO 11135:2014: Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.</p>

Item no.	WHO Item name	Required technical specifications
21	Tube, endotracheal, No. 4, with cuff, sterile, single use	<p>Endotracheal tube designed to be introduced into the trachea via the mouth or nose, ensuring an unobstructed upper airway to convey gases and vapours to and from the lungs during anaesthesia, resuscitation and other situations where the patient is not properly ventilated.</p> <p>It consists in a thin, flexible, transparent and single hollow cylinder, with an anatomical curvature Magill-type of 37.5°, black and legibly depth markings and graduation in cm, with radio-opaque continuous line mark, with cuff and pilot balloon, with a standard connector in the proximal end.</p> <p>The proximal end of the tube safely fits the connector from which size is selected according to the tube size. The connector is straight and double-ended, with the proximal end being an outer, standard 15 mm internal diameter, conical tip that allows the tube to be connected to the ventilation system (breathing circuit or manual resuscitator).</p> <p>The distal end of the tube is open and bevelled (obliquely cut), atraumatic, with Murphy's eye.</p> <p>The endotracheal tubes are standard in all aspects: dimension, markings and connectors.</p> <p>Initial sterilization method: ethylene oxide gas or Gamma radiation.</p> <p>Individually peel-packed in paper and/or plastic.</p>
22	Tube, endotracheal, No. 5, with cuff, sterile, single use	<p>Endotracheal tube designed to be introduced into the trachea via the mouth or nose, ensuring an unobstructed upper airway to convey gases and vapours to and from the lungs during anaesthesia, resuscitation and other situations where the patient is not properly ventilated.</p> <p>It consists in a thin, flexible, transparent and single hollow cylinder, with an anatomical curvature Magill-type of 37.5°, black and legibly depth markings and graduation in cm, with radio-opaque continuous line mark, with cuff and pilot balloon, with a standard connector in the proximal end.</p> <p>The proximal end of the tube safely fits the connector from which size is selected according to the tube size. The connector is straight and double-ended, with the proximal end being an outer, standard 15 mm internal diameter, conical tip that allows the tube to be connected to the ventilation system (breathing circuit or manual resuscitator).</p> <p>The distal end of the tube is open and bevelled (obliquely cut), atraumatic, with Murphy's eye.</p> <p>The endotracheal tubes are standard in all aspects: dimension, markings and connectors.</p> <p>Initial sterilization method: ethylene oxide gas or Gamma radiation.</p> <p>Individually peel-packed in paper and/or plastic.</p>
23	Tube, endotracheal, No. 4, with cuff, sterile, single use	<p>Endotracheal tube designed to be introduced into the trachea via the mouth or nose, ensuring an unobstructed upper airway to convey gases and vapours to and from the lungs during anaesthesia, resuscitation and other situations where the patient is not properly ventilated.</p> <p>It consists in a thin, flexible, transparent and single hollow cylinder, with an anatomical curvature Magill-type of 37.5°, black and legibly depth markings and graduation in cm, with radio-opaque continuous line mark, with cuff and pilot balloon, with a standard connector in the proximal end.</p> <p>The proximal end of the tube safely fits the connector from which size is selected according to the tube size. The connector is straight and double-ended, with the proximal end being an outer, standard 15 mm internal diameter, conical tip that allows the tube to be connected to the ventilation system (breathing circuit or manual resuscitator).</p> <p>The distal end of the tube is open and bevelled (obliquely cut), atraumatic, with Murphy's eye.</p> <p>The cuff, situated at the distal end of the tube, provides an airtight seal between the tube and the tracheal wall. It seals the lungs against the liquid secretions sloshing around in the upper airway. And, it ensures that the environment below the cuff can be pressurised and ventilated with a carefully controlled gas mixture.</p> <p>The cuff has a low pressure in order to avoid inadequate pressure on the tracheal mucous membrane to prevent damage or even necrosis. It typically has a capacity of 10 mL.</p> <p>The cuff is inflated via a small-bore inflation tube welded to the outside of the tracheal tube or built into its wall.</p> <p>The pilot balloon indicates the cuff distension. One end is connected to the cuff through a thin inflation tube located close to the proximal end. The other end has a spring-loaded, one-way valve that maintains a pre-set pressure in the circuit, and has Luer tip connector for syringes.</p> <p>The endotracheal tubes are standard in all aspects: dimension, markings and connectors.</p> <p>Initial sterilization method: ethylene oxide gas or Gamma radiation.</p> <p>Individually peel-packed in paper and/or plastic.</p>

Item no.	Dimensions/sizes/presentation	Material	Standards for product safety, performance and quality assurance, as requested or equivalent
21	<p>Tube: Size: 4. Internal diameter: 4 mm. External diameter: 5.4 mm. Length: 200 mm, minimum.</p> <p>Connector: Proximal end: standard internal diameter: 15 mm. Distal end (fits the tube): length: 11 mm, minimum.</p>	<p>Tube: polyvinyl chloride (PVC) or polyurethane; medical grade; transparent. Connector: polyvinyl chloride (PVC); medical grade; transparent or blue.</p>	<p>ISO 5361:2016: Anaesthetic and respiratory equipment – Tracheal tubes and connectors. ISO 10993-1:2018: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. ISO 11135:2014: Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.</p>
22	<p>Tube: Size: 5. Internal diameter: 5.0 mm. External diameter: 6.9 mm. Length: 250 mm, minimum.</p> <p>Connector: Proximal end: standard internal diameter: 15 mm. Distal end (fits the tube): length: 12 mm, minimum.</p>	<p>Tube: polyvinyl chloride (PVC) or polyurethane; medical grade; transparent. Connector: polyvinyl chloride (PVC); medical grade; transparent or blue.</p>	<p>ISO 5361:2016: Anaesthetic and respiratory equipment – Tracheal tubes and connectors. ISO 10993-1:2018: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. ISO 11135:2014: Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.</p>
23	<p>Tube: Size: 4. Internal diameter: 4.0 mm. External diameter: 6.7 mm. Length: 210 mm, minimum.</p> <p>Connector: Proximal end: standard internal diameter: 15 mm. Distal end (fits the tube): length: 11 mm, minimum.</p> <p>Cuff: Diameter: 10.5 mm.</p>	<p>Tube: polyvinyl chloride (PVC) or polyurethane; medical grade; transparent. Connector: polyvinyl chloride (PVC); medical grade; transparent or blue. Cuff: siliconized rubber, or siliconized polyvinyl chloride (PVC). Pilot balloon: siliconized latex, or siliconized polyvinyl chloride (PVC).</p>	<p>ISO 5361:2016: Anaesthetic and respiratory equipment – Tracheal tubes and connectors. ISO 10993-1:2018: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. ISO 11135:2014: Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.</p>

Item no.	WHO Item name	Required technical specifications
24	Tube, endotracheal, No. 5, with cuff, sterile, single use	<p>Endotracheal tube designed to be introduced into the trachea via the mouth or nose, ensuring an unobstructed upper airway to convey gases and vapours to and from the lungs during anaesthesia, resuscitation and other situations where the patient is not properly ventilated.</p> <p>It consists in a thin, flexible, transparent and single hollow cylinder, with an anatomical curvature Magill-type of 37.5°, black and legibly depth markings and graduation in cm, with radio-opaque continuous line mark, with cuff and pilot balloon, with a standard connector in the proximal end.</p> <p>The proximal end of the tube safely fits the connector from which size is selected according to the tube size. The connector is straight and double-ended, with the proximal end being an outer, standard 15 mm internal diameter, conical tip that allows the tube to be connected to the ventilation system (breathing circuit or manual resuscitator).</p> <p>The distal end of the tube is open and bevelled (obliquely cut), atraumatic, with Murphy's eye.</p> <p>The cuff, situated at the distal end of the tube, provides an airtight seal between the tube and the tracheal wall. It seals the lungs against the liquid secretions sloshing around in the upper airway. And, it ensures that the environment below the cuff can be pressurised and ventilated with a carefully controlled gas mixture.</p> <p>The cuff has a low pressure in order to avoid inadequate pressure on the tracheal mucous membrane to prevent damage or even necrosis. It typically has a capacity of 10 mL.</p> <p>The cuff is inflated via a small-bore inflation tube welded to the outside of the tracheal tube or built into its wall.</p> <p>The pilot balloon indicates the cuff distension. One end is connected to the cuff through a thin inflation tube located close to the proximal end. The other end has a spring-loaded, one-way valve that maintains a pre-set pressure in the circuit, and has Luer tip connector for syringes.</p> <p>The endotracheal tubes are standard in all aspects: dimension, markings and connectors.</p> <p>Initial sterilization method: ethylene oxide gas or Gamma radiation.</p> <p>Individually peel-packed in paper and/or plastic.</p>
25	Tube, endotracheal, No. 6, with cuff, sterile, single use	<p>Endotracheal tube designed to be introduced into the trachea via the mouth or nose, ensuring an unobstructed upper airway to convey gases and vapours to and from the lungs during anaesthesia, resuscitation and other situations where the patient is not properly ventilated.</p> <p>It consists in a thin, flexible, transparent and single hollow cylinder, with an anatomical curvature Magill-type of 37.5°, black and legibly depth markings and graduation in cm, with radio-opaque continuous line mark, with cuff and pilot balloon, with a standard connector in the proximal end.</p> <p>The proximal end of the tube safely fits the connector from which size is selected according to the tube size. The connector is straight and double-ended, with the proximal end being an outer, standard 15 mm internal diameter, conical tip that allows the tube to be connected to the ventilation system (breathing circuit or manual resuscitator).</p> <p>The distal end of the tube is open and bevelled (obliquely cut), atraumatic, with Murphy's eye.</p> <p>The cuff, situated at the distal end of the tube, provides an airtight seal between the tube and the tracheal wall. It seals the lungs against the liquid secretions sloshing around in the upper airway. And, it ensures that the environment below the cuff can be pressurised and ventilated with a carefully controlled gas mixture.</p> <p>The cuff has a low pressure in order to avoid inadequate pressure on the tracheal mucous membrane to prevent damage or even necrosis. It typically has a capacity of 10 mL.</p> <p>The cuff is inflated via a small-bore inflation tube welded to the outside of the tracheal tube or built into its wall.</p> <p>The pilot balloon indicates the cuff distension. One end is connected to the cuff through a thin inflation tube located close to the proximal end. The other end has a spring-loaded, one-way valve that maintains a pre-set pressure in the circuit, and has Luer tip connector for syringes.</p> <p>The endotracheal tubes are standard in all aspects: dimension, markings and connectors.</p> <p>Initial sterilization method: ethylene oxide gas or Gamma radiation.</p> <p>Individually peel-packed in paper and/or plastic.</p>

Item no.	Dimensions/sizes/presentation	Material	Standards for product safety, performance and quality assurance, as requested or equivalent
24	<p>Tube: Size: 5. Internal diameter: 5.0 mm. External diameter: 6.7 mm. Length: 250 mm, minimum.</p> <p>Connector: Proximal end: standard internal diameter: 15 mm. Distal end (fits the tube): length: 12 mm, minimum.</p> <p>Cuff: Diameter: 13 mm.</p>	<p>Tube: polyvinyl chloride (PVC) or polyurethane; medical grade; transparent. Connector: polyvinyl chloride (PVC); medical grade; transparent or blue. Cuff: siliconized rubber, or siliconized polyvinyl chloride (PVC). Pilot balloon: siliconized latex, or siliconized polyvinyl chloride (PVC).</p>	<p>ISO 5361:2016: Anaesthetic and respiratory equipment – Tracheal tubes and connectors. ISO 10993-1:2018: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. ISO 11135:2014: Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.</p>
25	<p>Tube: Size: 6. Internal diameter: 6.0 mm. External diameter: 8.0 mm. Length: 290 mm, minimum.</p> <p>Connector: Proximal end: standard internal diameter: 15 mm. Distal end (fits the tube): length: 13 mm, minimum.</p> <p>Cuff: Diameter: 18.5 mm.</p>	<p>Tube: polyvinyl chloride (PVC) or polyurethane; medical grade; transparent. Connector: polyvinyl chloride (PVC); medical grade; transparent or blue. Cuff: siliconized rubber, or siliconized polyvinyl chloride (PVC). Pilot balloon: siliconized latex, or siliconized polyvinyl chloride (PVC).</p>	<p>ISO 5361:2016: Anaesthetic and respiratory equipment – Tracheal tubes and connectors. ISO 10993-1:2018: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. ISO 11135:2014: Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.</p>

Item no.	WHO Item name	Required technical specifications
26	Tube, endotracheal, No. 9, with cuff, sterile, single use	<p>Endotracheal tube designed to be introduced into the trachea via the mouth or nose, ensuring an unobstructed upper airway to convey gases and vapours to and from the lungs during anaesthesia, resuscitation and other situations where the patient is not properly ventilated.</p> <p>It consists in a thin, flexible, transparent and single hollow cylinder, with an anatomical curvature Magill-type of 37.5°, black and legibly depth markings and graduation in cm, with radio-opaque continuous line mark, with cuff and pilot balloon, with a standard connector in the proximal end.</p> <p>The proximal end of the tube safely fits the connector from which size is selected according to the tube size. The connector is straight and double-ended, with the proximal end being an outer, standard 15 mm internal diameter, conical tip that allows the tube to be connected to the ventilation system (breathing circuit or manual resuscitator).</p> <p>The distal end of the tube is open and bevelled (obliquely cut), atraumatic, with Murphy's eye.</p> <p>The cuff, situated at the distal end of the tube, provides an airtight seal between the tube and the tracheal wall. It seals the lungs against the liquid secretions sloshing around in the upper airway. And, it ensures that the environment below the cuff can be pressurised and ventilated with a carefully controlled gas mixture.</p> <p>The cuff has a low pressure in order to avoid inadequate pressure on the tracheal mucous membrane to prevent damage or even necrosis. It typically has a capacity of 10 mL.</p> <p>The cuff is inflated via a small-bore inflation tube welded to the outside of the tracheal tube or built into its wall.</p> <p>The pilot balloon indicates the cuff distension. One end is connected to the cuff through a thin inflation tube located close to the proximal end. The other end has a spring-loaded, one-way valve that maintains a pre-set pressure in the circuit, and has Luer tip connector for syringes.</p> <p>The endotracheal tubes are standard in all aspects: dimension, markings and connectors.</p> <p>Initial sterilization method: ethylene oxide gas or Gamma radiation.</p> <p>Individually peel-packed in paper and/or plastic.</p>
27	Tube, endotracheal, No. 7, with cuff, sterile, single use	<p>Endotracheal tube designed to be introduced into the trachea via the mouth or nose, ensuring an unobstructed upper airway to convey gases and vapours to and from the lungs during anaesthesia, resuscitation and other situations where the patient is not properly ventilated.</p> <p>It consists in a thin, flexible, transparent and single hollow cylinder, with an anatomical curvature Magill-type of 37.5°, black and legibly depth markings and graduation in cm, with radio-opaque continuous line mark, with cuff and pilot balloon, with a standard connector in the proximal end.</p> <p>The proximal end of the tube safely fits the connector from which size is selected according to the tube size. The connector is straight and double-ended, with the proximal end being an outer, standard 15 mm internal diameter, conical tip that allows the tube to be connected to the ventilation system (breathing circuit or manual resuscitator).</p> <p>The distal end of the tube is open and bevelled (obliquely cut), atraumatic, with Murphy's eye.</p> <p>The cuff, situated at the distal end of the tube, provides an airtight seal between the tube and the tracheal wall. It seals the lungs against the liquid secretions sloshing around in the upper airway. And, it ensures that the environment below the cuff can be pressurised and ventilated with a carefully controlled gas mixture.</p> <p>The cuff has a low pressure in order to avoid inadequate pressure on the tracheal mucous membrane to prevent damage or even necrosis. It typically has a capacity of 10 mL.</p> <p>The cuff is inflated via a small-bore inflation tube welded to the outside of the tracheal tube or built into its wall.</p> <p>The pilot balloon indicates the cuff distension. One end is connected to the cuff through a thin inflation tube located close to the proximal end. The other end has a spring-loaded, one-way valve that maintains a pre-set pressure in the circuit, and has Luer tip connector for syringes.</p> <p>The endotracheal tubes are standard in all aspects: dimension, markings and connectors.</p> <p>Initial sterilization method: ethylene oxide gas or Gamma radiation.</p> <p>Individually peel-packed in paper and/or plastic.</p>

Item no.	Dimensions/sizes/presentation	Material	Standards for product safety, performance and quality assurance, as requested or equivalent
26	<p>Tube: Size: 9. Internal diameter: 9.0 mm. External diameter: 12.0 mm. Length: 350 mm, minimum.</p> <p>Connector: Proximal end: standard Internal diameter: 15 mm. Distal end (fits the tube): length: 16 mm, minimum.</p> <p>Cuff: Diameter: 28 mm.</p>	<p>Tube: polyvinyl chloride (PVC) or polyurethane; medical grade; transparent. Connector: polyvinyl chloride (PVC); medical grade; transparent or blue. Cuff: siliconized rubber, or siliconized polyvinyl chloride (PVC). Pilot balloon: siliconized latex, or siliconized polyvinyl chloride (PVC).</p>	<p>ISO 5361:2016: Anaesthetic and respiratory equipment – Tracheal tubes and connectors. ISO 10993-1:2018: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. ISO 11135:2014: Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.</p>
27	<p>Tube: Size: 7. Internal diameter: 7.0 mm. External diameter: 9.3 mm. Length: 320 mm, minimum.</p> <p>Connector: Proximal end: standard internal diameter: 15 mm. Distal end (fits the tube): length: 16 mm, minimum.</p> <p>Cuff: Diameter: 24 mm.</p>	<p>Tube: polyvinyl chloride (PVC), or polyurethane; medical grade; transparent. Connector: polyvinyl chloride (PVC); medical grade; transparent or blue. Cuff: siliconized rubber, or siliconized polyvinyl chloride (PVC). Pilot balloon: siliconized latex, or siliconized polyvinyl chloride (PVC).</p>	<p>ISO 5361:2016: Anaesthetic and respiratory equipment – Tracheal tubes and connectors. ISO 10993-1:2018: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. ISO 11135:2014: Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.</p>

Item no.	WHO Item name	Required technical specifications
28	Tube, endotracheal, No. 8, with cuff, sterile, single use	<p>Endotracheal tube designed to be introduced into the trachea via the mouth or nose, ensuring an unobstructed upper airway to convey gases and vapours to and from the lungs during anaesthesia, resuscitation and other situations where the patient is not properly ventilated.</p> <p>It consists in a thin, flexible, transparent and single hollow cylinder, with an anatomical curvature Magill-type of 37.5°, black and legibly depth markings and graduation in cm, with radio-opaque continuous line mark, with cuff and pilot balloon, with a standard connector in the proximal end.</p> <p>The proximal end of the tube safely fits the connector from which size is selected according to the tube size. The connector is straight and double-ended, with the proximal end being an outer, standard 15 mm internal diameter, conical tip that allows the tube to be connected to the ventilation system (breathing circuit or manual resuscitator).</p> <p>The distal end of the tube is open and bevelled (obliquely cut), atraumatic, with Murphy's eye.</p> <p>The cuff, situated at the distal end of the tube, provides an airtight seal between the tube and the tracheal wall. It seals the lungs against the liquid secretions sloshing around in the upper airway. And, it ensures that the environment below the cuff can be pressurised and ventilated with a carefully controlled gas mixture.</p> <p>The cuff has a low pressure in order to avoid inadequate pressure on the tracheal mucous membrane to prevent damage or even necrosis. It typically has a capacity of 10 mL.</p> <p>The cuff is inflated via a small-bore inflation tube welded to the outside of the tracheal tube or built into its wall.</p> <p>The pilot balloon indicates the cuff distension. One end is connected to the cuff through a thin inflation tube located close to the proximal end. The other end has a spring-loaded, one-way valve that maintains a pre-set pressure in the circuit, and has Luer tip connector for syringes.</p> <p>The endotracheal tubes are standard in all aspects: dimension, markings and connectors.</p> <p>Initial sterilization method: ethylene oxide gas or Gamma radiation.</p> <p>Individually peel-packed in paper and/or plastic.</p>
29	Syringe, feeding, 1 mL, LDT, ENFit, sterile, single use	<p>Low dose tip (LDT) syringe used for the administration of oral medication or delivery of enteral nutrition by connection to an enteral administration device.</p> <p>It consists of a calibrated hollow barrel (cylinder) made of plastic and a moveable plunger.</p> <p>The tip is designed to mate only with enteral administration devices and is specifically incompatible with Luer (6%) connectors and intravenous devices.</p> <p>Initial sterilization method: ethylene oxide gas.</p> <p>Individually peel-packed in paper and/or plastic.</p>
30	Syringe, feeding, 10 mL, ENFit, sterile, single use	<p>Syringe used for the administration of oral medication or delivery of enteral nutrition by connection to an enteral administration device.</p> <p>It consists of a calibrated hollow barrel (cylinder) made of plastic and a moveable plunger.</p> <p>The tip is designed to mate only with enteral administration devices and is specifically incompatible with Luer (6%) connectors and intravenous devices.</p> <p>Initial sterilization method: ethylene oxide gas.</p> <p>Individually peel-packed in paper and/or plastic.</p>
31	Syringe, feeding, 2.5 mL, LDT, ENFit, sterile, single use	<p>Low dose tip (LDT) syringe used for the administration of oral medication or delivery of enteral nutrition by connection to an enteral administration device.</p> <p>It consists of a calibrated hollow barrel (cylinder) made of plastic and a moveable plunger.</p> <p>The tip is designed to mate only with enteral administration devices and is specifically incompatible with Luer (6%) connectors and intravenous devices.</p> <p>Initial sterilization method: ethylene oxide gas.</p> <p>Individually peel-packed in paper and/or plastic.</p>
32	Syringe, feeding, 20 mL, ENFit, sterile, single use	<p>Syringe used for the administration of oral medication or delivery of enteral nutrition by connection to an enteral administration device.</p> <p>It consists of a calibrated hollow barrel (cylinder) made of plastic and a moveable plunger.</p> <p>The tip is designed to mate only with enteral administration devices and is specifically incompatible with Luer (6%) connectors and intravenous devices.</p> <p>Initial sterilization method: ethylene oxide gas.</p> <p>Individually peel-packed in paper and/or plastic.</p>

Item no.	Dimensions/sizes/presentation	Material	Standards for product safety, performance and quality assurance, as requested or equivalent
28	<p>Tube: Size: 8. Internal diameter: 8.0 mm. External diameter: 10.7 mm. Length: 340 mm, minimum.</p> <p>Connector: Proximal end: standard internal diameter: 15 mm. Distal end (fits the tube): length: 16 mm, minimum.</p> <p>Cuff: Diameter: 26 mm.</p>	<p>Tube: polyvinyl chloride (PVC), or polyurethane; medical grade; transparent. Connector: polyvinyl chloride (PVC); medical grade; transparent or blue. Cuff: siliconized rubber, or siliconized polyvinyl chloride (PVC). Pilot balloon: siliconized latex, or siliconized polyvinyl chloride (PVC).</p>	<p>ISO 5361:2016: Anaesthetic and respiratory equipment – Tracheal tubes and connectors. ISO 10993-1:2018: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.</p>
29	<p>Barrel: 1 mL; graduations every 0.1 mL.</p>	<p>Barrel: transparent polypropylene, ending with a female ENFit tip, LDT to decrease the dead space. Plunger: polypropylene or polyethylene coloured to be distinguished from injection syringes. Gasket: synthetic elastomer (latex-free).</p>	<p>ISO 80369-3:2016: Small-bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications. ISO 18250-3:2018: Medical devices – Connectors for reservoir delivery systems for healthcare applications – Part 3: Enteral applications.</p>
30	<p>Barrel: 10 mL; graduations every 0.5 mL.</p>	<p>Barrel: transparent polypropylene, ending with a female ENFit tip. Plunger: polypropylene or polyethylene coloured to be distinguished from injection syringes. Gasket: synthetic elastomer (latex-free).</p>	<p>ISO 80369-3:2016: Small-bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications. ISO 18250-3:2018: Medical devices – Connectors for reservoir delivery systems for healthcare applications – Part 3: Enteral applications.</p>
31	<p>Barrel: 2.5 to 3 mL; graduations every 0.1 mL.</p>	<p>Barrel: transparent polypropylene, ending with a female ENFit tip, LDT to decrease the dead space. Plunger: polypropylene or polyethylene coloured to be distinguished from injection syringes. Gasket: synthetic elastomer (latex-free).</p>	<p>ISO 80369-3:2016: Small-bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications. ISO 18250-3:2018: Medical devices – Connectors for reservoir delivery systems for healthcare applications – Part 3: Enteral applications.</p>
32	<p>Barrel: 20 mL; graduations every 0.5 mL.</p>	<p>Barrel: transparent polypropylene, ending with a female ENFit tip. Plunger: polypropylene or polyethylene coloured to be distinguished from injection syringes. Gasket: synthetic elastomer (latex-free).</p>	<p>ISO 80369-3:2016: Small-bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications. ISO 18250-3:2018: Medical devices – Connectors for reservoir delivery systems for healthcare applications – Part 3: Enteral applications.</p>

Item no.	WHO Item name	Required technical specifications
33	Syringe, feeding, 5 mL, LDT, ENFit, sterile, single use	<p>Low dose tip (LDT) syringe used for the administration of oral medication or delivery of enteral nutrition by connection to an enteral administration device.</p> <p>It consists of a calibrated hollow barrel (cylinder) made of plastic and a moveable plunger.</p> <p>The tip is designed to mate only with enteral administration devices and is specifically incompatible with Luer (6%) connectors and intravenous devices.</p> <p>Initial sterilization method: ethylene oxide gas.</p> <p>Individually peel-packed in paper and/or plastic.</p>
34	Syringe, feeding, 60 mL, ENFit, sterile, single use	<p>Syringe used for the administration of oral medication or delivery of enteral nutrition by connection to an enteral administration device.</p> <p>It consists of a calibrated hollow barrel (cylinder) made of plastic and a moveable plunger.</p> <p>The tip is designed to mate only with enteral administration devices and is specifically incompatible with Luer (6%) connectors and intravenous devices.</p> <p>Initial sterilization method: ethylene oxide gas.</p> <p>Individually peel-packed in paper and/or plastic.</p>
35	Tube, feeding, nasogastric, 12 Fr and 14 Fr, 90 cm, ENFit tip, sterile, single use	<p>Used for short-term gastro-enteral feeding and drug administration when connected to feeding syringes; or, for ventricular lavage. It is intended mainly for newborn and infant patients.</p> <p>The nasogastric tube is introduced via the nasopharynx into the gastrointestinal (GI) tract.</p> <p>It consists in a thin, flexible, transparent and single hollow cylinder with radio-opaque line marked from the distal end.</p> <p>The distal end is a soft and rounded closed-ended tip, with two laterals opposite alternated eyelets.</p> <p>The proximal end with a connector, ENFit tip, and a stopper, allows the tube to be connected to feeding syringes.</p> <p>Visible international-recognized colour code on cup connector.</p> <p>Initial sterilization method: ethylene oxide gas.</p> <p>Individually peel-packed in paper and/or plastic.</p>
36	Tube, feeding, nasogastric, 6 Fr, 8 Fr and 10 Fr, 50 cm, ENFit tip, sterile, single use	<p>Used for short-term gastro-enteral feeding and drug administration when connected to feeding syringes; or, for ventricular lavage. It is intended mainly for newborn and infant patients.</p> <p>The nasogastric tube is introduced via the nasopharynx into the gastrointestinal (GI) tract.</p> <p>It consists in a thin, flexible, transparent and single hollow cylinder with radio-opaque line marked from the distal end.</p> <p>The distal end is a soft and rounded closed-ended tip, with two laterals opposite alternated eyelets.</p> <p>The proximal end with a connector, ENFit tip, and a stopper, allows the tube to be connected to feeding syringes.</p> <p>Visible international-recognized colour code on cup connector.</p> <p>Initial sterilization method: ethylene oxide gas.</p> <p>Individually peel-packed in paper and/or plastic. Each set provided is composed by at least the following sizes: 6 Fr, 8 Fr and 10 Fr.</p>
37	Stethoscope, binaural, adult/child	<p>A mechanical listening device designed for listening to sounds from the heart and lungs. It typically comprises a membrane at the listening head connected by a split "Y" tube to the headgear with ear olives that are placed into the user's ears. Sensitivity 3.2dB in a range from 50–500 Hz for cardiology. The Y tube treated rubber with large diameter of 10 mm.</p> <p>Binaural device, with non-folding smooth spring frame.</p> <p>Double head chest piece.</p> <p>Plain spring non-folding frame.</p> <p>Plastic ear tips. Ear clips included.</p> <p>Vinyl stethoscope tubing.</p> <p>Combined bell and diaphragm sprague type.</p> <p>Approximate length of 1 m.</p>

Item no.	Dimensions/sizes/presentation	Material	Standards for product safety, performance and quality assurance, as requested or equivalent
33	Barrel: 5 mL; graduations every 0.2 mL.	Barrel: transparent polypropylene, ending with a female ENFit tip, LDT to decrease the dead space. Plunger: polypropylene or polyethylene coloured to be distinguished from injection syringes. Gasket: synthetic elastomer (latex-free).	ISO 80369-3:2016: Small-bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications. ISO 18250-3:2018: Medical devices – Connectors for reservoir delivery systems for healthcare applications – Part 3: Enteral applications.
34	Barrel: 60 mL; graduations every 1 mL.	Barrel: transparent polypropylene, ending with a female ENFit tip. Plunger: polypropylene or polyethylene coloured to be distinguished from injection syringes. Gasket: synthetic elastomer (latex-free).	ISO 80369-3:2016: Small-bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications. ISO 18250-3:2018: Medical devices – Connectors for reservoir delivery systems for healthcare applications – Part 3: Enteral applications.
35	Sizes: 12 Fr and 14 Fr. Length: 90 cm.	Polyvinyl chloride (PVC); medical grade.	ISO 80369-3:2016: Small-bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications. ISO 18250-3:2018: Medical devices – Connectors for reservoir delivery systems for healthcare applications – Part 3: Enteral applications. ISO 11135:2014: Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.
36	Sizes: 6 Fr, 8 Fr and 10 Fr. Length: 50 cm.	Polyvinyl chloride (PVC); medical grade.	ISO 80369-3:2016: Small-bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications. ISO 18250-3:2018: Medical devices – Connectors for reservoir delivery systems for healthcare applications – Part 3: Enteral applications. ISO 11135:2014: Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.
37	Length: approximately 1 m.	As appropriate to guarantee flexibility in use.	No specific product standard for stethoscopes.

Item no.	WHO Item name	Required technical specifications
38	Bag, collecting, urine, with outlet tap, with non-return valve, 2000 mL, adult, non-sterile, single use	Used to fit gastric tube (aspirating/feeding tube) or Incontinence condom. Drainable bag for collecting urine with permanent and legible graduations every 100 mL. With reinforced eyelets for hanging. With a drainage valve (outlet tap) which permits the bag to be emptied without disconnecting, maintaining sterility. It is fitted to an outlet tube. With a non-return valve, located inside the urine collector bag at the upper part (urine entry point), which prevents urine backflow into the indwelling urinary catheter. It is fitted with a kink resistant, transparent plastic inlet tube, with universal connector and protective cap.
39	Catheter, urethral, Foley, 2-way, sterile, single use, different sizes	A soft thin rubber tube with a balloon at the nelaton tip, designed for insertion in the bladder cavity, via the urethra, in order to drain off urine, instill a liquid or irrigate the bladder. A standard catheter consists of a hollow 2-way cylindrical tube with one central channel for urinary drainage; bladder side ending, Foley type, with a rounded atraumatic end tip (nelaton tip), with two opposing eyelets and one balloon; collector side ending that is a universal and hollow truncated cone (funnel) to connect the urine bag, splot, syringe or irrigating device; and the balloon port, side channel ending with a non-return valve and a Luer tip connector. Catheter size is expressed in French gauge or Charrier (Fr or CH) and colour coded; balloon expansion capacity is expressed in mL. Dimensions and colour code must be legible and visible on the connectors. Preferable intended use for this size: children, medium- or long-term catheterization. Initial sterilization method: ethylene oxide gas or equivalent if applicable. Individually peel-packed in paper and/or plastic. Double-packaged: protected with an interior layer and an outer peel pack. Each set provided is composed by at least the following external diameter sizes: 10 Fr, 12 Fr, 14 Fr, 16 Fr and 18 Fr.
40	Cricothyrotomy, set, emergency, 6 mm, sterile, single use	Set/kit to apply an incision made through the skin and cricothyroid membrane to establish a patent airway during specific life-threatening situations, such as airway obstruction. The cricothyrotomy set should be composed at least by the following devices: <ul style="list-style-type: none"> • One 6.0 mm, cuffed cricothyroidotomy tube • One cricothyroidotomy, tube holder • One dilator • One scalpel blade, No. 15 preferably, for handle No. 3 preferably, sterile, single use • One suture, surgical, synthetic, non absorbable, monofilament, DEC 3.5 (0), 45 cm, with needle, 3/8 circle, 29.9 mm, cutting point • One syringe, 10 mL, two or three pieces, Luer type, sterile, single use • One HME filter.
41	Lubricating jelly	Lubricating jelly is a sterile, water-soluble, latex-free, alcohol-free gel intended for use on intact skin, on mucous membranes and in natural body orifices. Sterile, greaseless lubricating jelly used in many clinical procedures such as: nasopharyngeal airway insertion, feeding tube insertion, endoscopy and ultrasound intracavitary examinations. Great viscosity for better resolution.
42	Central venous catheters kit, single use, sterile	Central venous catheters kit with: finder needle, syringe, wire, dilator, lidocaine, scalpel, needle, thread.
43	Tape, surgical, hypoallergenic, .025 x 5 m	Hypoallergenic surgical tape is designed to be commonly used in any operating theatre, in emergency departments (i.e during first aid to hold a bandage) and ICU departments. It should be made to firmly adhere to the skin or dressing materials and at the same time to be easily removed without the risk of damaging sensitive skin. Moreover, the surgical tape should be designed to permit the air to reach the skin (to be "breathable"). Hypoallergenic tape is usually more (but not exclusively) used in infants and elderly management, and for post-surgery application. Hypoallergenic Surgical tapes should be tested and proved not to cause any skin reactions. Surgical tape should be also preferably water-resistant.

Item no.	Dimensions/sizes/presentation	Material	Standards for product safety, performance and quality assurance, as requested or equivalent
38	Capacity, bag: 2000 mL. Length, tube: 85–95 cm. Diameter, tube: 6.5 mm, approximately.	Bag: polyvinyl chloride (PVC), polypropylene or ethylene vinyl acetate (EVA); medical grade. Tube, connector and protective cap: polyvinyl chloride (PVC); medical grade.	ISO 8669-2:1996: Urine collection bags – Part 2: Requirements and test methods.
39	Length: 30 cm. External diameter sizes provided: 10 Fr, 12 Fr, 14 Fr, 16 Fr and 18 Fr. Balloon expansion capacity: 3 to 5 mL.	Silicone-coated natural latex.	ISO 20696:2018: Sterile urethral catheters for single use. ISO 11135:2014: Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.
40	Many.		
41	Available in different formats and different tubes volume capacity.		
42	Kit.	Different materials, including polyurethane.	ISO 10555-6:2015(en) Intravascular catheters – Sterile and single-use catheters.
43	Width: 2.5 cm. Roll length: 500 cm.	Different materials, latex-free and up to at least 90% allergens free.	ASTM F2258 - 05(2015) Standard test method for strength properties of tissue adhesives in tension.

Item no.	WHO Item name	Required technical specifications
44	Drape, surgical, non-woven, sterile, single use	Single-use sterile device used to maintain aseptic conditions in an operative area. Should be made of two or three layers, non-woven fabric material. Easy to be draped and traction resistant material. Designed with or without a hole, depending on use.
45	Forceps Magill, 24 cm	Angled forceps designed to guide a tracheal tube into the larynx or a nasogastric tube into the esophagus. They could be also used to remove foreign bodies. Devices used mainly in emergency and ICU departments.
46	Basin kidney, stainless steel, 825 mL	Basin with a kidney-shaped base and sloping walls used in medical and surgical wards to receive soiled dressings and other medical waste. Reusable, autoclavable kidney dish.

Item no.	Dimensions/sizes/presentation	Material	Standards for product safety, performance and quality assurance, as requested or equivalent
44	Different sizes available, depending on exigencies and request. Most common measures are (approximately): 50 × 70 cm; 70 × 90 cm; 90 × 140 cm; 140 × 250 cm.	Non-woven fabric, made of synthetic fibres, typically cellulose and/or polyester and/or polyethylene.	ISO 22610:2006(en) Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment – Test method to determine the resistance to wet bacterial penetration.
45	Length approximately 24 cm.	Stainless steel.	ASTM F899 - 20 Standard specification for wrought stainless steels for surgical instruments ISO 7153-1:2016 Surgical instruments – Materials – Part 1: Metals.
46	Volume capacity approximately 825 mL.	Stainless steel.	ISO 7153-1:2016 Surgical instruments – Materials – Part 1: Metals.

3.3.2 Oxygen delivery devices

3.3.2.1 Nasal oxygen cannula with prongs

Nasal oxygen cannula with prongs		
1	Specifications	<p>Cannula with nasal prongs designed for easy administration of medicinal oxygen through patient nostrils; single use.</p> <p>Low-resistance tubing, round shape section, designed for low-flow procedures, typically 0–15 L/min, where the delivered gas does not meet all the inspiratory demand and entrains ambient air.</p> <p>The twin prongs nasal tips are soft and smoothly finished to ensure equal oxygen flow to both nostrils. They are connected to a lip support and harness (one tube right/left side).</p> <p>The harness is fully adjustable (over the patient's ear) with a double tubing (right and left side), interlinked through a moulded Y-connector to the oxygen supply line.</p> <p>All tubing is soft and flexible, kink resistant, with star lumen, and with proximal end with a universal, funnel-shaped connector to oxygen source.</p> <p>Tubing compatibility with standard oxygen connection tubing, 3–5 mm internal diameter and 7–8 mm external diameter, and 15/22 mm diameter ventilation tubing; available with "standard" and "universal" hose end connector.</p> <p>Individually packed in a sealed plastic envelope.</p> <p>Non-sterile.</p> <p>Box of 50 or 100 units.</p>
2	Sizes	<p>Adult: outer diameter of the prong: 6 mm; tube length: 1.5–2 m.</p> <p>Paediatric: outer diameter of the prong: 3.7 mm; tube length: 1.5–2 m.</p>
3	Material	Rubber or soft plastic tubing and prongs, semi-rigid and allowing freedom of movement, PVC or other material, FDA Title 21/USP VI compliant and certified for medical use, hardness > 60 Shore A (ASTM D-2240).
4	Primary packaging label	<p>Single use.</p> <p>Name and/or trademark of the manufacturer.</p> <p>Model or product reference.</p> <p>Information for particular storage conditions (temperature, pressure, light, humidity).</p>
5	Standards, for the manufacturer	Certified quality management system for medical devices (e.g. ISO 13485). General quality management (e.g. ISO 9001). Application of risk management to medical devices (e.g. ISO 14971).
6	Regulatory approval/certification	<p>Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country.</p> <p>Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).</p>
7	Standards, for product performance	<p>Compliance to the following international standards or to regional or national equivalent (including the technical tests for safety and performance from accredited laboratory or third party) for:</p> <p>ISO 11712:2009 Anaesthetic and respiratory equipment – Supralaryngeal airways and connectors.</p> <p>ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen.</p> <p>ISO 18562 Biocompatibility evaluation of breathing gas pathways in healthcare applications.</p> <p>ISO 18190 Anaesthetic and respiratory equipment – General requirements for airways and related equipment.</p> <p>ISO 18562-1 Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 1: Evaluation and testing within a risk management process.</p> <p>ISO/DIS 23368 Anaesthetic and respiratory equipment – Low flow nasal cannula for oxygen therapy.</p> <p>ISO/DIS 17256 Anaesthetic and respiratory equipment – Respiratory therapy tubing and connectors.</p> <p>ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.</p>
<i>Any variation to be indicated in the offer.</i>		

3.3.2 Oxygen delivery devices

3.3.2.1 Nasal oxygen cannula with prongs

Nasal oxygen cannula with prongs		
1	Specifications	<p>Cannula with nasal prongs designed for easy administration of medicinal oxygen through patient nostrils; single use.</p> <p>Low-resistance tubing, round shape section, designed for low-flow procedures, typically 0–15 L/min, where the delivered gas does not meet all the inspiratory demand and entrains ambient air.</p> <p>The twin prongs nasal tips are soft and smoothly finished to ensure equal oxygen flow to both nostrils. They are connected to a lip support and harness (one tube right/left side).</p> <p>The harness is fully adjustable (over the patient's ear) with a double tubing (right and left side), interlinked through a moulded Y-connector to the oxygen supply line.</p> <p>All tubing is soft and flexible, kink resistant, with star lumen, and with proximal end with a universal, funnel-shaped connector to oxygen source.</p> <p>Tubing compatibility with standard oxygen connection tubing, 3–5 mm internal diameter and 7–8 mm external diameter, and 15/22 mm diameter ventilation tubing; available with "standard" and "universal" hose end connector.</p> <p>Individually packed in a sealed plastic envelope.</p> <p>Non-stérile.</p> <p>Box of 50 or 100 units.</p>
2	Sizes	<p>Adult: outer diameter of the prong: 6 mm; tube length: 1.5–2 m.</p> <p>Paediatric: outer diameter of the prong: 3.7 mm; tube length: 1.5–2 m.</p>
3	Material	Rubber or soft plastic tubing and prongs, semi-rigid and allowing freedom of movement, PVC or other material, FDA Title 21/USP VI compliant and certified for medical use, hardness > 60 Shore A (ASTM D-2240).
4	Primary packaging label	<p>Single use.</p> <p>Name and/or trademark of the manufacturer.</p> <p>Model or product reference.</p> <p>Information for particular storage conditions (temperature, pressure, light, humidity).</p>
5	Standards, for the manufacturer	Certified quality management system for medical devices (e.g. ISO 13485). General quality management (e.g. ISO 9001). Application of risk management to medical devices (e.g. ISO 14971).
6	Regulatory approval/certification	<p>Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country.</p> <p>Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).</p>
7	Standards, for product performance	<p>Compliance to the following international standards or to regional or national equivalent (including the technical tests for safety and performance from accredited laboratory or third party) for:</p> <p>ISO 11712:2009 Anaesthetic and respiratory equipment – Supralaryngeal airways and connectors.</p> <p>ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen.</p> <p>ISO 18562 Biocompatibility evaluation of breathing gas pathways in healthcare applications.</p> <p>ISO 18190 Anaesthetic and respiratory equipment – General requirements for airways and related equipment.</p> <p>ISO 18562-1 Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 1: Evaluation and testing within a risk management process.</p> <p>ISO/DIS 23368 Anaesthetic and respiratory equipment – Low flow nasal cannula for oxygen therapy.</p> <p>ISO/DIS 17256 Anaesthetic and respiratory equipment – Respiratory therapy tubing and connectors.</p> <p>ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.</p>
<i>Any variation to be indicated in the offer.</i>		

3.3.2.2 Mask with reservoir bag

Mask with reservoir bag		
1	Specifications	<p>Non-rebreather mask with reservoir bag, used to deliver medical oxygen directly to the upper airway of the patient; single use.</p> <p>It includes two unidirectional valves, one that closes during inspiration to prevent room air mixing with oxygen in a reservoir bag; and one that closes during exhalation to prevent exhaled respiratory gases from entering the reservoir bag (non-rebreathing oxygen face mask).</p> <p>Mask is soft, transparent, well-fitting moulded, with two side vents.</p> <p>The nose clip is soft, malleable and adjustable.</p> <p>The tubing (oxygen line) is non-kinking, well-fitted.</p> <p>Tubing compatibility with standard oxygen connection tubing, 3–5 mm internal diameter and 7–8 mm external diameter, and 15/22 mm diameter ventilation tubing; available with “standard” and “universal” hose end connector.</p> <p>Individually packed.</p> <p>Non-sterile.</p> <p>Box of 50 or 100 units.</p>
2	Sizes	<p>Adult.</p> <p>Paediatric: tube length: 1.5–2 m.</p>
3	Material	Mask and tubing PVC or other material, FDA Title 21/USP VI compliant and certified for medical use, hardness > 60 Shore A (ASTM D-2240).
4	Primary packaging label	<p>Single use.</p> <p>Name and/or trademark of the manufacturer.</p> <p>Model or product reference.</p> <p>Information for particular storage conditions (temperature, pressure, light, humidity).</p>
5	Standards, for the manufacturer	Certified quality management system for medical devices (e.g. ISO 13485). General quality management (e.g. ISO 9001). Application of risk management to medical devices (e.g. ISO 14971).
6	Regulatory approval/certification	<p>Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country.</p> <p>Proof of regulatory compliance, as appropriate, per the product’s risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).</p>
7	Standards, for product performance	<p>Compliance to the following international standards or to regional or national equivalent (including the technical tests for safety and performance from accredited laboratory or third party) for:</p> <p>ISO 11712:2009 Anaesthetic and respiratory equipment – Supralaryngeal airways and connectors.</p> <p>ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen.</p> <p>ISO 18562 Biocompatibility evaluation of breathing gas pathways in healthcare applications.</p> <p>ISO 18190 Anaesthetic and respiratory equipment – General requirements for airways and related equipment.</p> <p>ISO 18562-1 Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 1: Evaluation and testing within a risk management process.</p> <p>ISO/DIS 23368 Anaesthetic and respiratory equipment – Low flow nasal cannula for oxygen therapy.</p> <p>ISO/DIS 17256 Anaesthetic and respiratory equipment – Respiratory therapy tubing and connectors.</p> <p>ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.</p>
<i>Any variation to be indicated in the offer.</i>		