

Product Information for Oxygen Consumables

Endotracheal tube

Description:

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

Specification and minimal standards

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.

The connector is straight and double-ended, with the proximal end being an outer, standard 15 mm internal diameter, conical tip.

The distal end of the tube is open and bevelled (obliquely cut), atraumatic, with Murphy's eye.

MDD(MDR) CE/ FDA ISO 13485 Sterilization Certificate



Infusion giving set, with burette, sterile, single use

Description:

Sterile IV giving set with graduated chamber (burette) enabling precise volume and slow administration of infusion or injectable medicine.

Specification and minimal standards

Components: Tube, Plastic Perforator, Air inlet, Graduated chamber (burette), Security gauge, Drop-counting chamber, Flow regulator, Injection portal, Terminal connection (stopper)

Tube: plastic (PVC: polyvinyl chloride). Transparent (allowing the detection of air bubbles). Resistant to kinking. Length is approximately 150cm (overall IV giving set length approximately 170cm). Internal / external diameter is approximately 3mm / 4mm.

Graduated chamber (burette): plastic (PS: polystyrene). Transparent. Capacity: approximately 100-150ml.

ISO 8536-4 Infusion equipment for medical use



Infusion giving set, sterile, single use

Description:

Sterile single use device used for parenteral administration of infusions (IV fluids) by gravity.

Specification and minimal standards

Components: Perforator, Air inlet, Drop counting chamber, Tubing, Precision flow regulator

Drop counting chamber: Transparent drip chamber, calibrated at 20 drops/ml, with 15-20 μ m fluid filter.

Tubing: Transparent tubing, minimum length 150cm, with injection site latex or latex-free (or Y-injection port), with distal connector preferably Luer Lock connector.

ISO 8536-4 Infusion equipment for medical use



Venturi mask and tubing, single use, non-sterile

Description:

Venturi mask is to provide oxygen at flow rates between 1 – 10 LPM. Allows for precise oxygen delivery by utilizing different sized jets to change FiO₂

Specification and minimal standards

Also known as an air-entrainment mask (with percent O₂ lock).

It delivers oxygen, with a specific concentration from 24–60% minimum.

The mask has an adjustable nose clip.

The kit of the mask includes the tubing, humidity cup and multiple jets, which are colour-coded and indicating the percentage of oxygen.

ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen

ISO 18190 Anaesthetic and respiratory equipment – General requirements for airways and related equipment.





Oxygen tubing, non-sterile

Description:

Tubing designed for external connection of an oxygen delivery source at one end and, at the patient end, a device used to administer oxygen such as a nasal oxygen cannula or oxygen mask.

Specification and minimal standards

Rubber or soft plastic tubing, semi-rigid, PVC

Tubing wall thickness between 1.58 mm (1/16 inch) and 2.38 (3/32 inch). Round shape section, internal diameter range 3–5 mm (1/8–3/16 inch), compatible with standard 6 mm barbed fitting. Anti-kink tubing, non-permanent deformation if kinked or bent too tight.

Terminated with “standard” connectors

ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen.



Resuscitator, manual, adult, set (including mask and bag)

Description:

Hand-operated resuscitator used for mechanical ventilation of adult and paediatric patients. Easy to disassemble and reassemble. Easy to clean and disinfect. Reusable.

Specification and minimal standards

Resuscitator shall be supplied as a complete set with:

- Compressible self-refilling ventilation bag with maximum capacity not less than 1300 mL. Dead volume: < 7 mL.
- One-way valve with or without pressure limiting. Pressure-limiting system: the elasticity of the bag's outer cover limits the airway pressure to approximately 7 kPa (70 cmH₂O) when squeezed normally with one hand.
- Patient connector, outside diameter: 22 mm; inside diameter: 15 mm.
- Inlet valve with nipple for oxygen tubing.
- Oxygen reservoir bag capacity according to patient size.

ISO 10651-4:2002* Lung ventilators – Part 4: Particular requirements for operator- powered resuscitators



Flowmeter stand (flow splitter) , 5 flowmeters

Description:

Flow splitter for oxygen delivery, 5 outlets and 1 inlet, with independent flowmeters. It can be connected to any low-pressure oxygen source, including concentrators, cylinders and a centralized system, and is suitable for table top or wall mounting.

Specification and minimal standards

Disinfectable with hospital grade detergents.

Inlet port to be compatible with all the international standards for oxygen fittings, included DISS, threaded and nonthreaded, 6 mm barbed – availability of different ports and/or adapters to be stated.

6 mm barbed outlet as standard

0–2 L/min, accuracy better than 10%, graduation 0.125 L/min or lower

Inlet pressure up to at least 138 kPa (1.4 bar, 20 psi).

ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen. ISO 15002 Flow-metering devices for connection to terminal units of medical gas pipeline systems.



Flowmeter, Thorpe tube

Description:

Medical gas flow meter (Thorpe tube design) to regulate and measure the flow rate of medical gas supplied to a patient

Specification and minimal standards

The Thorpe tube flowmeter is composed of inlet and outlet ports, a regulator, a valve and a clear tapered measuring tube.

Disinfectable with hospital grade detergents, accuracy 10%

Needle valve and body constructed of brass or aluminium.

Calibrated at 345–380 kPa (3.4–3.8 bar, 50–55 psi) inlet gauge pressure.

Inlet gauge pressure (nominal) > 380–413 kPa (3.8–4.1 bar, 55–60 psi), peak gauge inlet pressure 690 kPa (6.9 bar, 100 psi).

ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen.

ISO 15002 Flow-metering devices for connection to terminal units of medical gas pipeline systems



Product Information for Oxygen Equipment



Patient Monitoring, 6 Parameters with accessories

Description:

Patient vital signs monitor, 6 physiological parameters; ECG, heart rate, respiration rate, Non-invasive blood pressure and oxygen saturation ((SpO₂) and temperature. Suitable for adult, paediatric and neonatal patients, AC and battery powered, including accessories.

Specification and minimal standards

Continuous display on screen of patient ECG, respiration rate and heart rate, non-invasive blood pressure, body temperature and SpO₂.

See Annex C for detailed requirements



Laryngoscope, Set

Description:

To manipulate the tongue and enable a clear view of the trachea for surgical/mechanical ventilation/ intubation procedures.

Specification and minimal standards

For Adults and Children:

With a set of four stainless steel depressors, with halogen bulb

MacIntosh type:

Curved Nr 2, length approx. 110 mm Curved / Nr 3, length approx. 135 mm / Curved Nr 4, length approx. 155 mm

Miller type: Straight Nr 1, length approx. 100 mm

For Neonate:

With a set of two stainless steel depressors, with halogen bulb

Miller type: Straight Nr 0, length approximately 70mm / Straight Nr 1, length approximately 100mm

See Annex C for detailed requirements



Fingertip Pulse oximeter, battery-powered, with accessories

Description:

Finger clip mounting, battery powered, all-in-one pulse oximeter displaying patient oxygen saturation (SpO₂) and pulse rate.

Specification and minimal standards

SpO₂ and pulse rate monitor integrated into finger/toe clip.

Configurations required to apply to adults and children, and all skin pigmentations.

Suitable for spot check.

See Annex C for detailed requirements



Pulse oximeter, handheld, with accessories and probes

Description:

Handheld, portable, rechargeable battery powered pulse oximeter, for the noninvasive spot-checking or continuous monitoring of patient oxygen saturation (SpO₂), pulse rate and respiratory rate.

Specification and minimal standards

Capable of working with adult, paediatric and neonatal reusable probes

Function for continuous monitoring

See Annex C for detailed requirements



Oxygen Analyzer, ultrasonic, handheld

Description:

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.

Specification and minimal standards

A device that measures and displays the oxygen concentration using ultrasonic oxygen sensing technology.

See Annex C for detailed requirements



Oxygen Analyzer, electrochem, handheld

Description:

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.

Specification and minimal standards

Handheld oxygen analyser, displays the oxygen concentration measured in the flow of gas or the environment.

Electrochemical cell oxygen sensing technology.

See Annex C for detailed requirements



Pump,suction,surgical,electric

Description:

Mobile equipment used for blood, secretions and other liquids suction by means of an integrated vacuum pump; mainly used to evacuate gas, fluid, tissue, or foreign materials from the high airways by means of vacuum suction but also for medium level surgery interventions. Single or double bottle.

Specification and minimal standards

Generates suction by hand- or foot-operated pump electric action. AC line power operated

See Annex C for detailed requirements



Pump,suction,foot-operated

Description:

To aspirate fluids, secretions, or other foreign materials from a patient's airway by means of suction.

Specification and minimal standards

Generates suction by foot-operated pump manual action.

See Annex C for detailed requirements



Voltage Stabilizer, 1 phase, 1kVA, solid state

Description:

Device that helps to maintain a stable mains voltage, i.e. with the help, or as part, of a suitable secondary power supply. Should the voltage drop below a pre-set limit the device will increase the voltage in correspondence with the particular type of device it is protecting.

Specification and minimal standards

The solid state voltage regulator is fully electronic, without moving parts

See Annex C for detailed requirements

