

Consumables

Adult Ambo Bag

No.	Item Specifications
1	Description of Function
1.1	An Ambu Bag (also known as a Bag Valve Mask or BVM or Ambu bag) is a hand-held device used to provide ventilation to a patient who is not breathing or who is breathing inadequately.
2	Operational Requirements
2.1	It shall be self-inflatable and must have pop up valve (non-return valve), attachment for oxygen tube & oxygen reservoir.
3	System Configuration
3.1	Ambu bag, complete unit.
4	Technical Specifications
4.1	Bag must be made up of medical grade silicon, latex free double layered which retain sensitivity and it must be resistant to rough use.
4.2	Inlet end of the bag must have separate port for Oxygen supplement.
4.3	Outer port must be such that re-breathing valve or non-return valve can be attached.
4.4	Must be supplied with Oxygen reservoir bag and shall deliver tidal volumes of 250/500/750 and 1000 ml.
4.5	It shall be autoclaveable.
4.6	It shall be adaptable to all type of face masks.
5	Accessories, spares and consumables
5.1	Set to be supplied in a heavy duty, re-sealable plastic pouch or clear top plastic box.
5.2	with adult face mask
6	Operating Environment
6.1	The system offered must be designed to store and be operated normally under the condition include Climate, temperature and relative humidity for Sudan.
7	Standards and Safety Requirements
7.1	Must submit ISO13485:2003/AC:2007 for Medical Devices AND
7.2	CE (93/42 EEC Directives) or USFDA or TUV approved product certificate.
8	Warranty
8.1	Comprehensive warranty for 1 year after acceptance.
9	Documentation
9.1	User's manual shall be supplied in English.

Neonate Ambo Bag

No.	Item Specifications
1	Description of Function
1.1	An Ambu Bag (also known as a Bag Valve Mask or BVM or Ambu bag) is a hand-held device used to provide ventilation to a patient who is not breathing or who is breathing inadequately.
2	Operational Requirements
2.1	It shall be self-inflatable and must have pop up valve (non-return valve), attachment for oxygen tube & oxygen reservoir.
3	System Configuration
3.1	Ambu bag, complete unit.
4	Technical Specifications
4.1	Bag must be made up of medical grade silicon, latex free double layered which retain sensitivity and it must be resistant to rough use.
4.2	Inlet end of the bag must have separate port for Oxygen supplement.
4.3	Outer port must be such that re-breathing valve or non-return valve can be attached.
4.4	Must be supplied with Oxygen reservoir bag and shall deliver tidal volumes of 250/500/750 and 1000 ml.
4.5	It shall be autoclaveable.
4.6	It shall be adaptable to all type of face masks.
5	Accessories, spares and consumables
5.1	Set to be supplied in a heavy duty, re-sealable plastic pouch or clear top plastic box.
5.2	with infant face mask sizes 00,01 & 02
6	Operating Environment
6.1	The system offered must be designed to store and be operated normally under the condition include Climate, temperature and relative humidity for Sudan.
7	Standards and Safety Requirements
7.1	Must submit ISO13485:2003/AC:2007 for Medical Devices AND
7.2	CE (93/42 EEC Directives) or USFDA or TUV approved product certificate.
8	Warranty

8.1	Comprehensive warranty for 1 year after acceptance.
9 Documentation	
9.1	User's manual shall be supplied in English.

Pediatric Ambo Bag

No.	Item Specifications
1 Description of Function	
1.1	An Ambu Bag (also known as a Bag Valve Mask or BVM or Ambu bag) is a hand-held device used to provide ventilation to a patient who is not breathing or who is breathing inadequately.
2 Operational Requirements	
2.1	It shall be self-inflatable and must have pop up valve (non-return valve), attachment for oxygen tube & oxygen reservoir.
3 System Configuration	
3.1	Ambu bag, complete unit.
4 Technical Specifications	
4.1	Bag must be made up of medical grade silicon, latex free double layered which retain sensitivity and it must be resistant to rough use.
4.2	Inlet end of the bag must have separate port for Oxygen supplement.
4.3	Outer port must be such that re-breathing valve or non-return valve can be attached.
4.4	Must be supplied with Oxygen reservoir bag and shall deliver tidal volumes of 250/500/750 and 1000 ml.
4.5	It shall be autoclaveable.
4.6	It shall be adaptable to all type of face masks.
5 Accessories, spares and consumables	
5.1	Set to be supplied in a heavy duty, re-sealable plastic pouch or clear top plastic box.
5.2	with Pediatric face mask
6 Operating Environment	
6.1	The system offered must be designed to store and be operated normally under the condition include Climate, temperature and relative humidity for Sudan.
7 Standards and Safety Requirements	
7.1	Must submit ISO13485:2003/AC:2007 for Medical Devices AND
7.2	CE (93/42 EEC Directives) or USFDA or TUV approved product certificate.
8 Warranty	
8.1	Comprehensive warranty for 1 year after acceptance.
9 Documentation	
9.1	User's manual shall be supplied in English.

Oxygen Mask (Adult)

No.	Specifications
	3-ply non-woven face mask
	comfortable wearing.
	Nose bar can be adaptable,comfortable,without glass fibres,latex free.
	PFE (Filtration efficiency of non oily particles) ≥30%
	BFE (Bacteria filtration efficiency) ≥95% (98%)
	Color: white,blue,green,red,pink,yellow can be available.
	Very low resistance to breathing,free from foreign smell,without any stimulating feeling.
	Non-woven Spun bonded Polypropylene+meltblown filter
	Adult size
	CE FDA approve

Oxygen Mask (Pediatric)

No.	Specifications
	3-ply non-woven face mask
	comfortable wearing.
	Nose bar can be adaptable,comfortable,without glass fibres,latex free.
	PFE (Filtration efficiency of non oily particles) ≥30%
	BFE (Bacteria filtration efficiency) ≥95% (98%)
	Color: white,blue,green,red,pink,yellow can be available.
	Very low resistance to breathing,free from foreign smell,without any stimulating feeling.
	Non-woven Spun bonded Polypropylene+meltblown filter
	Pediatric size
	CE FDA approve

Oxygen Mask (Neonate)

No.	Specifications
	3-ply non-woven face mask
	comfortable wearing.
	Nose bar can be adaptable,comfortable,without glass fibres,latex free.
	PFE (Filtration efficiency of non oily particles) ≥30%
	BFE (Bacteria filtration efficiency) ≥95% (98%)
	Color: white,blue,green,red,pink,yellow can be available.
	Very low resistance to breathing,free from foreign smell,without any stimulating feeling.
	Non-woven Spun bonded Polypropylene+meltblown filter
	Neonate size
	CE FDA approve

Endo-Tracheal Tube size 2.0 Fr

No.	Specifications
1	Description of Function
1.1	An endotracheal tube (ET tube):
	☐ Provides a passage for gases to flow between a patients lungs and an anaesthesia breathing system.
	☐ Allows one to provide positive pressure ventilation.
	☐ Protects the lungs from contamination from gastric contents and nasopharyngeal matter such as blood.
2	Operational Requirements
2.1	To be made of surgical quality medical grade silicone.
3	System Configuration
3.1	Endotracheal tube size 2.0 Fr.
4	Technical Specifications
4.1	ET tubes to be made of surgical quality medical grade silicone.
4.2	To be supplied in a box with a clear plastic lid.
5	Standards and Safety Requirements
5.1	Must submit ISO13485:2003/AC:2007 for Medical Devices AND
5.2	CE (93/42 EEC Directives) or USFDA approved product certificate.

Endo-Tracheal Tube size 2.5 Fr

No.	Specifications
1	Description of Function
1.1	An endotracheal tube (ET tube):
	☐ Provides a passage for gases to flow between a patients lungs and an anaesthesia breathing system.
	☐ Allows one to provide positive pressure ventilation.
	☐ Protects the lungs from contamination from gastric contents and nasopharyngeal matter such as blood.
2	Operational Requirements
2.1	To be made of surgical quality medical grade silicone.
3	System Configuration
3.1	Endotracheal tube size 2.5 Fr.
4	Technical Specifications
4.1	ET tubes to be made of surgical quality medical grade silicone.
4.2	To be supplied in a box with a clear plastic lid.
5	Standards and Safety Requirements
5.1	Must submit ISO13485:2003/AC:2007 for Medical Devices AND
5.2	CE (93/42 EEC Directives) or USFDA approved product certificate.

Endo-Tracheal Tube size 3.0 Fr

No.	Specifications
1	Description of Function
1.1	An endotracheal tube (ET tube):
	☐ Provides a passage for gases to flow between a patients lungs and an anaesthesia breathing system.
	☐ Allows one to provide positive pressure ventilation.
	☐ Protects the lungs from contamination from gastric contents and nasopharyngeal matter such as blood.

2	Operational Requirements
2.1	To be made of surgical quality medical grade silicone.
3	System Configuration
3.1	Endotracheal tube size 3.0 Fr.
4	Technical Specifications
4.1	ET tubes to be made of surgical quality medical grade silicone.
4.2	To be supplied in a box with a clear plastic lid.
5	Standards and Safety Requirements
5.1	Must submit ISO13485:2003/AC:2007 for Medical Devices AND
5.2	CE (93/42 EEC Directives) or USFDA approved product certificate.

Endo-Tracheal Tube size 3.5 Fr

No.	Specifications
1	Description of Function
1.1	An endotracheal tube (ET tube):
	☒ Provides a passage for gases to flow between a patients lungs and an anaesthesia breathing system.
	☒ Allows one to provide positive pressure ventilation.
	☒ Protects the lungs from contamination from gastric contents and nasopharyngeal matter such as blood.
2	Operational Requirements
2.1	To be made of surgical quality medical grade silicone.
3	System Configuration
3.1	Endotracheal tube size 3.5 Fr.
4	Technical Specifications
4.1	ET tubes to be made of surgical quality medical grade silicone.
4.2	To be supplied in a box with a clear plastic lid.
5	Standards and Safety Requirements
5.1	Must submit ISO13485:2003/AC:2007 for Medical Devices AND
5.2	CE (93/42 EEC Directives) or USFDA approved product certificate.

Endo-Tracheal Tube size 4.0 Fr

No.	Specifications
1	Description of Function
1.1	An endotracheal tube (ET tube):
	☒ Provides a passage for gases to flow between a patients lungs and an anaesthesia breathing system.
	☒ Allows one to provide positive pressure ventilation.
	☒ Protects the lungs from contamination from gastric contents and nasopharyngeal matter such as blood.
2	Operational Requirements
2.1	To be made of surgical quality medical grade silicone.
3	System Configuration
3.1	Endotracheal tube size 4.0 Fr.
4	Technical Specifications
4.1	ET tubes to be made of surgical quality medical grade silicone.
4.2	To be supplied in a box with a clear plastic lid.
5	Standards and Safety Requirements
5.1	Must submit ISO13485:2003/AC:2007 for Medical Devices AND
5.2	CE (93/42 EEC Directives) or USFDA approved product certificate.

Endo-Tracheal Tube size 4.5 Fr

No.	Specifications
1	Description of Function
1.1	An endotracheal tube (ET tube):
	☒ Provides a passage for gases to flow between a patients lungs and an anaesthesia breathing system.
	☒ Allows one to provide positive pressure ventilation.
	☒ Protects the lungs from contamination from gastric contents and nasopharyngeal matter such as blood.
2	Operational Requirements
2.1	To be made of surgical quality medical grade silicone.
3	System Configuration
3.1	Endotracheal tube size 4.5 Fr.

4	Technical Specifications
4.1	ET tubes to be made of surgical quality medical grade silicone.
4.2	To be supplied in a box with a clear plastic lid.
5	Standards and Safety Requirements
5.1	Must submit ISO13485:2003/AC:2007 for Medical Devices AND
5.2	CE (93/42 EEC Directives) or USFDA approved product certificate.

Endo-Tracheal Tube size 5.0 Fr

No.	Specifications
1	Description of Function
1.1	An endotracheal tube (ET tube):
	☒ Provides a passage for gases to flow between a patients lungs and an anaesthesia breathing system.
	☒ Allows one to provide positive pressure ventilation.
	☒ Protects the lungs from contamination from gastric contents and nasopharyngeal matter such as blood.
2	Operational Requirements
2.1	To be made of surgical quality medical grade silicone.
3	System Configuration
3.1	Endotracheal tube size 5.0 Fr.
4	Technical Specifications
4.1	ET tubes to be made of surgical quality medical grade silicone.
4.2	To be supplied in a box with a clear plastic lid.
5	Standards and Safety Requirements
5.1	Must submit ISO13485:2003/AC:2007 for Medical Devices AND
5.2	CE (93/42 EEC Directives) or USFDA approved product certificate.

Endo-Tracheal Tube size 5.5 Fr

No.	Specifications
1	Description of Function
1.1	An endotracheal tube (ET tube):
	☒ Provides a passage for gases to flow between a patients lungs and an anaesthesia breathing system.
	☒ Allows one to provide positive pressure ventilation.
	☒ Protects the lungs from contamination from gastric contents and nasopharyngeal matter such as blood.
2	Operational Requirements
2.1	To be made of surgical quality medical grade silicone.
3	System Configuration
3.1	Endotracheal tube size 5.5 Fr.
4	Technical Specifications
4.1	ET tubes to be made of surgical quality medical grade silicone.
4.2	To be supplied in a box with a clear plastic lid.
5	Standards and Safety Requirements
5.1	Must submit ISO13485:2003/AC:2007 for Medical Devices AND
5.2	CE (93/42 EEC Directives) or USFDA approved product certificate.

Endo-Tracheal Tube size 6.0 Fr

No.	Specifications
1	Description of Function
1.1	An endotracheal tube (ET tube):
	☒ Provides a passage for gases to flow between a patients lungs and an anaesthesia breathing system.
	☒ Allows one to provide positive pressure ventilation.
	☒ Protects the lungs from contamination from gastric contents and nasopharyngeal matter such as blood.
2	Operational Requirements
2.1	To be made of surgical quality medical grade silicone.
3	System Configuration
3.1	Endotracheal tube size 6.0 Fr.
4	Technical Specifications
4.1	ET tubes to be made of surgical quality medical grade silicone.
4.2	To be supplied in a box with a clear plastic lid.
5	Standards and Safety Requirements

5.1	Must submit ISO13485:2003/AC:2007 for Medical Devices AND
5.2	CE (93/42 EEC Directives) or USFDA approved product certificate.

Endo-Tracheal Tube size 6.5 Fr

No.	Specifications
1	Description of Function
1.1	An endotracheal tube (ET tube):
	☒ Provides a passage for gases to flow between a patients lungs and an anaesthesia breathing system.
	☒ Allows one to provide positive pressure ventilation.
	☒ Protects the lungs from contamination from gastric contents and nasopharyngeal matter such as blood.
2	Operational Requirements
2.1	To be made of surgical quality medical grade silicone.
3	System Configuration
3.1	Endotracheal tube size 6.5 Fr.
4	Technical Specifications
4.1	ET tubes to be made of surgical quality medical grade silicone.
4.2	To be supplied in a box with a clear plastic lid.
5	Standards and Safety Requirements
5.1	Must submit ISO13485:2003/AC:2007 for Medical Devices AND
5.2	CE (93/42 EEC Directives) or USFDA approved product certificate.

Endo-Tracheal Tube size 7.0 Fr

No.	Specifications
1	Description of Function
1.1	An endotracheal tube (ET tube):
	☒ Provides a passage for gases to flow between a patients lungs and an anaesthesia breathing system.
	☒ Allows one to provide positive pressure ventilation.
	☒ Protects the lungs from contamination from gastric contents and nasopharyngeal matter such as blood.
2	Operational Requirements
2.1	To be made of surgical quality medical grade silicone.
3	System Configuration
3.1	Endotracheal tube size 7.0 Fr.
4	Technical Specifications
4.1	ET tubes to be made of surgical quality medical grade silicone.
4.2	To be supplied in a box with a clear plastic lid.
5	Standards and Safety Requirements
5.1	Must submit ISO13485:2003/AC:2007 for Medical Devices AND
5.2	CE (93/42 EEC Directives) or USFDA approved product certificate.

Endo-Tracheal Tube size 7.5 Fr

No.	Specifications
1	Description of Function
1.1	An endotracheal tube (ET tube):
	☒ Provides a passage for gases to flow between a patients lungs and an anaesthesia breathing system.
	☒ Allows one to provide positive pressure ventilation.
	☒ Protects the lungs from contamination from gastric contents and nasopharyngeal matter such as blood.
2	Operational Requirements
2.1	To be made of surgical quality medical grade silicone.
3	System Configuration
3.1	Endotracheal tube size 7.5 Fr.
4	Technical Specifications
4.1	ET tubes to be made of surgical quality medical grade silicone.
4.2	To be supplied in a box with a clear plastic lid.
5	Standards and Safety Requirements
5.1	Must submit ISO13485:2003/AC:2007 for Medical Devices AND
5.2	CE (93/42 EEC Directives) or USFDA approved product certificate.

Endo-Tracheal Tube size 8.0 Fr

No.	Specifications
1	Description of Function
1.1	An endotracheal tube (ET tube):
	☑ Provides a passage for gases to flow between a patients lungs and an anaesthesia breathing system.
	☑ Allows one to provide positive pressure ventilation.
	☑ Protects the lungs from contamination from gastric contents and nasopharyngeal matter such as blood.
2	Operational Requirements
2.1	To be made of surgical quality medical grade silicone.
3	System Configuration
3.1	Endotracheal tube size 8.0 Fr.
4	Technical Specifications
4.1	ET tubes to be made of surgical quality medical grade silicone.
4.2	To be supplied in a box with a clear plastic lid.
5	Standards and Safety Requirements
5.1	Must submit ISO13485:2003/AC:2007 for Medical Devices AND
5.2	CE (93/42 EEC Directives) or USFDA approved product certificate.

Blind Stick

No.	Specifications
1	Description of Function
	an electronic talking stick for the blind and more particularly to a stick which talks to instruct a blind man to walk and go upstairs and downstairs, and to warn a blind man of dangerous depression in road, and which calls for help when a blind man who uses the stick falls.
	Device Specifications
	•Sensor Specifications, Vibratory Output Specifications, White cane specifications, Power & Battery Specifications, Environmental specifications
	Usability Requirements
	•Ergonomics, Aesthetics, Biocompatibility, Buttons & Controls, Splash Proofing Requirements
	Other Requirements
	•Product Packaging Requirements, Product Training Requirements, Maintenance Requirements, Conformance to Accessibility Specifications,
	CE Marking & Regulatory Requirements
	•Conformance to Medical Device (Class I) meeting IEC 60601-1 Ed3.0, IEC 62304 Ed1.0, ISO 14971:2007, IEC 60601-1-2 Ed3.0, IEC 60601-1-6 Ed3.0, BS EN 2182:1999, BS EN 1985:1999, BS EN 60601-2-37:2001, IEC 60529, ISO 10993-10,