**Resuscitator**

Product description:

Self-inflating ventilation bag used for manual ventilation assistance in patients with a body weight over 30kg in case of respiratory distress or failure.

Ventilation can be done with ambient air or with oxygen.

All parts must be manufactured from high-strength, long-life materials and require no special maintenance or storage conditions.

Resuscitator can be totally disassembled, easy to clean, disinfect and be autoclavable.

Material:

- self-refilling ventilation bag: silicone rubber

- Non-rebreathing patient valve: polycarbonate / translucent polysulfone

- Masks: silicone rubber / translucent polysulfone. Hooks made of silicon rubber

- Oxygen reservoir bag: translucent plastic

- Airways Guedel: translucent plastic.

Self-inflating bag

Compressible (one single flexible pouch)

Pressure release valve set at 40mbar which can be blocked if higher pressures are indicated.

Compressible self-refilling ventilation bag, capacity approx.: 1500 - 2000ml

Intake valve with nipple for O2 tubing.

Patient valves:

With removal expiratory outlet.

Non-rebreathing patient valve.

One way with single valve leaflet.

Oxygen reservoir bag

Oxygen reservoir bag, capacity approx.: 2000 - 2600ml.

Supplied with:

- Non-rebreathing patient valve.

- Compressible self-refilling ventilation bag, capacity approx.:1500 - 2000ml.

- Intake valve with nipple for O2 tubing.

- Oxygen reservoir bag, capacity approx.: 2000 - 2600ml.

- Masks translucent, 3 different sizes:

1 mask, size adult small/teenager.

1 mask, size adult medium.

1 mask, size adult large.

- Airways Guedel translucent, 3 different sizes:

1 airway Guedel, size 2 approximately 70mm.

1 airway Guedel, size 3 approximately 80mm.

1 airway Guedel, size 4 approximatey 90mm.

- Instructions for assembly, use and maintenance, and list of accessories and spare parts with product reference code, in 3 languages (English, French and Spanish).

Accessories/Spare parts/Consumables:

Masks, airways

Instructions for use:

Basic hospital equipment for health structures and emergency situations in wards, emergency room, operating theater, delivery room, intensive care unit, ambulance, etc.

Resuscitator is used to ventilate patients: children (with a body weight over 30 kg) and adults.

Resuscitator can be used to efficiently maintain ventilation, or as resuscitation in other critical situations.

Resuscitator should only be operated by a person who has received adequate training in resuscitation technique.

The resuscitator and the mask must be cleaned and disinfected after each use.

Recommendation: After dismantling and cleaning, the resuscitator must be reassembled and tested to make sure that it works correctly.

In view of its use, the item is considered an "emergency resuscitation item".

This means that it must always be readily available and in a good working condition.

It is recommended to follow the manufacturer's instructions manual.

Packaging & Labelling:

Unit presentation: 1 (one) Resuscitator in a plastic bag

Symbols used according ISO 15223

CE mark and notified body number

Regulation & conformity requirements:

CE mark conforming to Medical Device Directive (MDD) 93/42/EEC

CE certificate ( for class IIa, with Notified body number)

Classification:

Class IIa (MDD 93/42/EEC)

Safety & product Standards:

Must comply with following standards

ISO 13485:2003 Medical devices -- Quality management systems -- Requirements for regulatory purposes

ISO 10993-1:2009

ISO 5359:2008 Low-pressure hose assemblies for use with medical gases

ISO 80369-1:2010 Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirements

ISO/CD 80369-2 Small bore connectors for liquids and gases in healthcare applications -- Part 2: Connectors for breathing systems and driving gases application

ISO10651-4: 2002 Lung ventilators - Part 4: Particular requirements for operator-powered resuscitators