

Technical file



-product name: Nebulizer Mask

-1. model: GT012-110

2 . Purpose:

The Nebulizer Mask has a specially designed chamber with a nebulization rate of approximately 3 ml-10min, average particle size 2 microns - complete kit consisting of a nebulizer mask, nebulizer chamber and 200cm (± 10 cm) tube, with adjustable nose clip

3. Scope of the medical device / potential consumer:

The simple Nebulizer Mask is equipped with oxygen supply devices such as oxygen tube, mask, nebulizer chamber which can be used for particles delivery.

4. Class of potential risk of use:

Class IIa Rule 2 of Annex IX (MDD93/42/EEC)

5. Indications / contraindications / warnings when using a medical device

5.1 Contraindication

- 1) Use the product during the validity period
- 2) The product is forbidden for use if the individual package is damaged
- 3) Repeat use is forbidden.

5.2 Cautions

- This product has ethylene oxide sterilization, sterile products, valid for 5 years, For single patient use only.



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- it is prohibited to use when the single packing is damaged; destroyed it after use;
- The product should be used by the experienced medical personal, the specification of the Nebulizer Mask should be selected according to the patients' age and bodily form.
- The product should be handled according to the rules of hospital or environmental department.
- Avoid freezing and excessive heat.
- Be sure all connections are secure.

6. Specifications

L, XL adult, M child, S infant, XS newborn

Cover: green, transparent color

For each Nebulizer Mask, there are 1 oxygen tube and 1mask, nebulizer chamber.

The length of the oxygen tube is 2.0m. So the total length of the l oxygen tube is 200cm.

The oxygen tube can be green, transparent.

The sizes are : L, XL adult , M child , S infant ,XS newborn. Green and transparent are both available .

-Materials

PVC, Latex free

-method of sterilization: EO

-life time: 5 years.