

Article code: **1085-PH**
Description: **Rebreathing mask, adult size, with 2,10m tubing**

Statistical information:

Product class: II A
Customs code: 90192000
Country of origin: Poland
Packaging: each piece clean packed in a poly-bag, each 25 pieces packed in a carton-box .
Box size: 390 mm x 300 mm x 260 mm
Weight net of a one packed piece: 93g
Weight of a 25 pieces box: 2,7kg

Quality assurance: produced under EN ISO 13485:2012 and Annex V, internal control documentation according to the production procedure; declaration of conformity dtd. 01.01.2016

Material information: Mask,tubing: 100% medical PVC according to European Pharmacopeia 100% Latex free, 100% Phthalate free concerning PVC (production process: injection molding, extrusion);
Other materials:
Connector: polypropylene
Strap: rubber mix (no latex include)
Nose clip: aluminum
Bag: PVC foil 100% Phthalate free

Labeling/Lot number: 1 label with the description in 7 languages according to the valid production procedure inside of each poly-bag;
2 labels on each carton
Each label includes the changing Lot number. The lot number includes 6 signs: the first 2 means the production year, the next the production month and the last 2 the day the begin of the production.

Expiratory date: (see Labeling)

Storage: keep the goods in a dry and clean room acc. to the local standards for medical devices; temperature condition +5 degrees C- +40 degrees C

Instruction for use: due to easy use the product is self explanatory.
The exact usage of the product depends on the type of the therapy and the instruction of a physician.
This product is a single patient use product. There must be assured, the condition and the cleanliness of the product is good enough before twice use.

Recycling/ Wastes: use the national standards for the destruction of PVC medical products.

Related documents: ISO certificates
Declaration of conformity