



## Data sheet

### Specification of the product

Article code: **1711-PH**  
Description: **Pediatric mask with 6 diluters 24%-50%, 2,10m tubing and 15cm flex tube**

#### Statistical information:

Product class according to 93/42/EEC: 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 295 mm x 260 mm  
Weight net of a one packed piece: 105g  
Weight of a 25 pieces box: 3,005kg

#### Indications for use:

inhalation / insufflation of medical oxygen O<sub>2</sub>

#### Material information:

the main parts of product (mask and 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: aluminium  
Diluter: polypropylene  
Flex tube: polyethylene

#### 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

#### Conditions of use:

temperature: +5°C to +40°C

<b>Sterile:</b>	No
<b>Instruction for use:</b>	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.
<b>Recycling/ Wastes:</b>	use the national standards for the destruction of PVC medical products.
<b>Related documents:</b>	ISO certificates Declaration of conformity