



Data sheet

Specification of the product

Article code: **1713-PH**
Description: **Pediatric mask with variable diluter 24%-60%,
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: 80g
Weight of a 25 pieces box: 2,38kg

Indications for use:

inhalation / insufflation of medical oxygen O₂

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

Sterile:	No
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