

Data sheet Specification of the product

Article code: 1013-PH

Description: Nasal cannula for children 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

50 pieces packed in a carton-box .

Box size: 395 mm x 290 mm x 165 mm

Weight net of a one packed piece: 62g Weight of a 50 pieces box: 3,5kg

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: the product is made of medical PVC according to

European Pharmacopeia (4th edition) – see separate documents concerning PVC (production process: injection molding, extrusion); 100% latex free, 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