



Data sheet

Specification of the product

Article code: **1012-650-KM**
Description: **2 packs of sterile water 650 ml + Adapter, with 2 nasal cannulas**

Statistical information:

Product class according to 93/42/EEC: II a
Customs code: 90192000
Country of origin: Poland
Packaging: each piece packed in a carton-box
Box size: 210 mm x 185 mm x 115 mm
Weight net of a one piece: 1,8kg
Weight of a box: 2,1kg

Indications for use: inhalation / insufflation of medical oxygen O₂

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);
Exception: the connector – made of polypropylene
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 carton-box;
2 labels on each carton-box
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