

Data sheet Specification of the product

1402 Article code:

Nebulizer "Standard" Description:

Statistical information:

Product class II A

90192000 Customs code: Country of origin: Poland

Packaging: each piece clean packed in a poly-bag, each

50 pieces packed in a carton-box.

395 mm x 290 mm x 165 mm Box size:

Weight net of a one packed piece: 28q 1,8kg Weight of a 50 pieces box:

produced under EN ISO 13485:2012 and Annex V, internal control Quality assurance:

documentation according to the production procedure; declaration

of conformity dtd. 01.01.2016

Material information: the top of the nebulizer and the element inside:

Polypropylene, the medicine container: polystyrene

100% latex 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