

Article code: **1303**  
Description: **Mouthpiece**

**Statistical information:**

Product class: II A  
Customs code: 90192000  
Country of origin: Poland  
Packaging: each 50 piece clean packed in a poly-bag  
Weight net of a one packed piece: 8g  
Weight of a 50 pieces bag: 0,4kg

**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 100% polypropylene (production process: injection molding);  
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