

NOBAMED Paul Danz AG

NOBAMASK®

REF 672041

Product Description, Intended use, Application

The disposable product NOBAMASK® is a white, rectangular 2-ply mouth-nose mask with arrangements of folds, made of special paper. It can be fixed to the ears by means of elastic loops. NOBAMASK® serves to reduce the transmission of contaminations by airway droplets.

Composition

Cellulose, polypropylene, elastomer

Incident reporting

According to MDR (EU) 2017/745, if serious incidents occur in relation to the device, they must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Normative and Regulative Requirements, Common Standards

Medical device according to the MDD 93/42/EEC and MDR (EU) 2017/745.

The product does not contain dangerous toxic substances according to REACH.

Packaging

Primary packaging: folding box

made of cellulose

Secondary packaging: Carton made

of cellulose

Symbols used in labelling

Explanations at <u>www.nobamed.com</u>







Marking on all packaging levels with CE and according to DIN EN ISO 15223-1 and DIN EN ISO 20417.

Storage and Transport

To be stored in a dry and dust-free environment

Single use device

Reusing a single use medical device can lead to microbiological danger. Reprocessing, for reuse can decrease the product's performance significantly.

Disposal

According to locally applicable legal regulations and standards of infection prophylaxis.