

NOBAMED Paul Danz AG

WATTETUPFER

REF 879006

Product Description, Intended use, Application

The disposable product WATTETUPFER is a white, soft, cotton ball made of pure cotton (0.6 g). The cotton wool is slightly rolled. The cotton wool ball is used for cleaning and disinfection purposes.

Composition

Cotton

Notes

Before use on open wounds, the product must be sterilized in accordance with a validated sterilization method. The product can be sterilized with moist heat at 121°C/ 134°C, 2 to 3 bar, according to DIN EN 17665, radiation according to DIN EN ISO 11137 or ethylene oxide according to DIN EN ISO 11135.

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.

Cotton wool according to BP or USP absorbent cotton

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

Packaging

Primary packaging: PE-bag

Secondary packaging: carton made of cellulose

Symbols used in labelling

Explanations at www.nobamed.com



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

Product Data Sheet: September 20, 2021 [REV 4] replaced: April 01, 2020 [Rev 3]