



NOBADENT®

REF 149410

Product Description, Intended use, Application

The disposable product NOBADENT® is a white, soft, chlorine-free bleached cotton wool roll, size 1 cm x 4 cm. NOBADENT® is used for dental treatment in the dental field and serves to absorb saliva, secretion, and blood. The dental roll has a high absorption capacity, at the same time has a padding function and holding off function.

Composition

Cotton

Notes

The non-sterile cotton wool roll must be sterilized in accordance with a validated sterilization method before use on open wounds. 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: folding box of cellulose

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.