

NOBAMED Paul Danz AG

MUNDSPATEL

REF 922500

Product Description, Intended use, Application

The tongue depressor (adult size, 150 mm x 18 mm) is made of clean processed wood which is smoothly polished. It serves to inspect the pharyngeal space and to apply ointment. As it can be sterilized with ethylene oxide and moist heat ($121^{\circ}C$) the tongue depressor can also be used under aseptic conditions.

Composition Wood

Contraindications

The product should not be used in the case of a known allergy against the material.

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 MDD 93/42/EEC, MDR (EU) 2017/745.

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

Packaging

Primary:

folding box made of cellulose

Secondary:

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 15223-1and 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.