NOBAMED Paul Danz AG

Processing instructions of NOBAMED Paul Danz AG
for **NOBA®** medical products **made of cellulose tissue**
that are to be sterilized before use.

The product must be sterilized before use. We confirm the one-time sterilizability with a procedure mentioned under the section 'sterilization'.

Instructions	
Initial treatment at the place of use (storage and transport)	The storage and transport conditions and the shelf-life of the non-sterile product are indicated on the package
Preparation of sterilization	Remove and discard the packaging of the product
Cleaning	Not applicable
Disinfection	Not applicable
Drying	Not applicable
Control and verification	The validation of the sterilization process and the product fall under the responsibility of the processor
Packaging	Suitable validated sterile packaging
Sterilization	For example • with moist heat according to DIN EN ISO 17665 or as per requirements of the European Pharmacopoeia with 15' to 20', 121°C to 134°C, 2 bar • or with one-time sterilizability with an ethylene oxide sterilization method in compliance with ISO 11135-1, e. g. max. 60 °C and max. 90 % RH. A sterilization below these limit values does not affect the products' functionality, nor do pressure or the rate of pressure change.
Storage and transportation	For the product the storage and transport conditions indicated on the original packaging are applicable.
Additional information	NOBA® medical products made of cellulose tissue are disposable products and cannot be reprocessed for product-related reasons. This does not refer to the process of first-time sterilization, if required before use. Our products are produced under controlled conditions. The bioburden of non-sterile products is $\leq 10^2$ cfu/g.

The above mentioned instructions have been compiled in accordance with EN ISO 17664-1 and have been validated as SUITABLE for the processing of NOBA® medical products made of cellulose tissue. It falls under the processor's responsibility to make sure that the actual process (with the equipment, materials and staff in the processing department) is adequate to achieve the desired results. This necessitates a validation and routine monitoring of the process on site.

Manufacturer: **NOBAMED Paul Danz AG**
Höltkenstraße 1-5, D-58300 Wetter (Ruhr)
phone (+49)02335/7609-0; fax (+49)02335/7609-420;
e-mail: info@nobamed-ag.com

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