



NOBAMED Paul Danz AG

NOBADRAPE®

Fenestrated drape

REF 762045

Product Description, Intended use, Application

The 2-ply blue drape (45 cm x 75 cm with 7 cm opening) is individually packed in sterile packaging. It is used for sterile covering of patients and equipment in the OR. The top layer consists of an absorbent polypropylene nonwoven. The bottom layer consists of a moisture-impermeable polyethylene film providing a reliable barrier protection. Easily removable control stickers on the packaging facilitate surgical documentation.

Composition

Polypropylene, polyethylene

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 Regulatory Requirements, Common Standards

Medical Device according to *MDD 93/42/EEC, MDR (EU) 2017/745*.

The product complies with the requirements of the **DIN EN 13795-1**, "Surgical clothing and drapes – Requirements and test methods – Part 1: Surgical drapes and gowns (requirements of the performance level 'high' and 'standard')".

Sterilization of the product complies with DIN EN 11135.

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

Packaging

Primary:	paper-film packaging
Secondary:	folding box made of cellulose
Tertiary:	carton made of cellulose

Symbols used in labelling

Explanation at www.nobamed.com



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, protect from sunlight.

Sterile device

Before using a sterile product, visually inspect the packaging to ensure that it is intact.

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.