NOBAMED Paul Danz AG

NOBADRAPE®
Drape with adhesive hole

REF 763075

Product Description, Intended use, Application
The 2-ply blue fenestrated drape (75 cm x 90 cm) is adhesive around the fenestration. It is individually packed in sterile packaging. The fenestration has a size of 6 cm x 8 cm. The drape is used for the sterile demarcation of the operation field.
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, polyester, hypopallergenic adhesive

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 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.

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