



NOBADRAPE® Fenestrated drape

REF 762075

Product Description and Purpose

The 2-ply blue drape with fenestration (75 cm x 90 cm, fenestration diameter: 10 cm) is individually packed in sterile packaging. It 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.

Contraindications

Known allergy to one of the ingredients listed below.

Composition

Polypropylene, polyethylene

Normative and Legal Requirements

NOBADRAPE® fenestrated drape is a medical product according to the directive 93/42/EEC and the regulation MDR (EU 2017/745) and is classified as class Is, according to rule 1.

It complies with the requirements of the EN 13795, "Surgical clothing and drapes – requirements and test methods – Part 1 Surgical drapes and gowns" (performance level 'standard' and 'high').

Sterilization of the product complies with DIN EN 11135.

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

Date of Information: January 08, 2021 [Rev5]
replaced: September 24, 2015 [Rev4]

It has CE marking and DIN EN ISO 15223-1 labels on all its packaging.

Packaging

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

Storage

To be stored in a dry and dust-free environment, protected against direct sunlight

The product bears the following symbols and labels:

