

NOBAMED Paul Danz AG

NOBADRAPE® Universal-Set

Product Description and Purpose

The sterile NOBADRAPE® Universal-Set allows a safe and reliable coverage of the patient and his environment during major surgical interventions.

The set consists of:

- 1 surgical adhesive strip 9 x 50 cm
- 4 hand towels
- 2 adhesive drapes 75 x 90 cm, absorbent patch 25 x 60 cm, tube holders
- 1 adhesive drape size M, 180 x 180 cm, absorbent patch 25 x 60 cm, tube holders
- 1 adhesive drape size L, 150 x 240 cm, absorbent patch 25 x 60 cm, tube holders
- 1 instrument table cover 150 x 190 cm

Composition

Polyethylene, polypropylene, viscose, polyester, cellulose

Normative and Legal Requirements

NOBADRAPE[®] Universal-Set is a medical product in accordance with the MDD, class Is, rule 1, and complies with the requirements of the directive 93/42/EEC and of the **EN 13795** "Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment" (requirements for performance levels 'high' and 'standard').

Sterilization of the product complies with DIN EN 11135.

The product does not contain dangerous toxic substances according to REACH. It has CE marking and DIN EN ISO 15223-1 labels on all its packaging.

Packaging

Primary packaging: paper-film

packaging

Secondary packaging: carton made or

cellulose

Storage

To be stored in a dry and dust-free environment, protected from sun radiation

The product is bearing the **C** € marking, in compliance with the directive's provisions









Date of Information: September 24, 2015 [REV 2]

replaced: March 3, 2015