



NOBAMED Paul Danz AG

RIBOSOFT®

REF 007006

Product Description, Intended use, Application

RIBOSOFT® bed sheet (light, 40 x 60cm) consists of a liquid-proof foil and a superabsorber enriched cellulose pulp filling. The filling is covered by a non-woven which is closed on all sides. The foil prevents the liquids from leaking out and so protects the bed-linen from becoming soiled. RIBOSOFT® is used in nursing care to absorb body fluids, e.g. in the case of incontinence, during dressing changes and during the use of moist dressing. The product is used in the hospital as well as in the domestic home care of outpatients.

Composition

Fresh cellulose, polypropylene, polyethylene, superabsorber

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

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

The absorption capacity according to ISO 11948 is 400 g.

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

Packaging

Primary packaging: PE bag

Secondary packaging: carton made of cellulose

Symbols used in labelling

Explanations at www.nobamed.com



Marking on all packaging levels with CE and according to DIN EN ISO 15223-1- and DIN EN 1041.

Storage and Transport

Dry and dustfree, protect from sunlight.

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.