



**NOBAMED Paul Danz AG**

## **RIBOSOFT®**

**REF 007020**

### **Product Description, Intended use, Application**

RIBOSOFT® bed sheet (heavy, 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 Regulative 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 1000 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](http://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.