

# METALLINE<sup>®</sup> Bed Sheet, sterile

REF 23050

March 2016

Translation: MI /C. Zorn  
Revision: MI / M. Fuchs

---

## 1. Composition of the product

The METALLINE<sup>®</sup> Bed Sheet is constructed with the following four layers:

1<sup>st</sup> layer: an aluminised, binder-bonded non-woven fabric  
(viscose)

2<sup>nd</sup> layer: binder-bonded non-woven fabric (viscose)

3<sup>rd</sup> layer: non-woven fabric bonded by hydroentanglement  
(viscose / polyester)

4<sup>th</sup> layer: binder-bonded non-woven fabric (viscose),  
with a water-repellent finish

The above 4 layers are joined together by a dispersion adhesive.

## 2. Packaging, structure and composition

### 2.1 Unit Container

- see 2.2

### 2.2 Shelf Container

- gusseted bag (cellulose)
- polyethylene bag
- instructions for use made of cellulose

### 2.3 Transit Container

- corrugated cardboard box (cellulose)

### **3. Manufacture**

The METALLINE® Bed Sheet is manufactured to specification under hygienic conditions and packaged as described in their respective packaging specifications. The product is sterilized by radiation, according to DIN EN ISO 11137 part 1-3.

### **4. Description**

The METALLINE® Bed Sheet consists of 4 layers of non-woven fabric which are joined together by embossing (layer 1 and layer 2) and by gluing the longitudinal edges together (layer 2, 3 and 4).

### **5. Properties**

Thanks to their aluminized surface METALLINE® Bed Sheets do not stick to the wound and thus allow gentle bedding of the patient. Wound exudate diffuses immediately through the aluminized layer into the absorbent layer underneath and prevents the build-up of fluids.

### **6. Intended purpose**

METALLINE® Bed Sheets serve as sheets on which to place patients receiving open wound treatment for extensive burns, cauterizations and abrasions.

### **7. Medical device classification**

The METALLINE® Bed Sheet is a medical device of Class IIb according to Rule 4. (Council directive on Medical Devices 93/42/EEC, Annex IX)

### **8. Biological evaluation and biocompatibility (DIN EN ISO 10993)**

The starting materials used in the manufacture of METALLINE® Bed Sheet are safe if the product is used appropriately and for the purposes intended.

The purpose of this documentation and the statements made therein is to show that there is no risk involved in the use of the medical device METALLINE® Bed Sheet and that it is designed, manufactured and packaged in such a way that it will not compromise the clinical condition or the safety of patients, or the safety and health of users and other persons when used under the conditions and for the purposes intended.

**9. Stability**

Stored appropriately, the METALLINE® Bed Sheet has a shelf life of 5 years.

**10. Disposal**

The user is advised to observe current national legislation, norms, and guidelines regulating the disposal of medical waste.  
Packaging materials must also be disposed of in compliance with applicable national requirements.

Lohmann & Rauscher International GmbH & Co. KG  
D-56579 Rengsdorf  
Signed by  
Dr. Martin Abel  
(Medical & Regulatory Affairs)