

METALLINE® - Dressing Cloth, sterile

REF 23010 - 23012

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Translation: Peritus
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1. Composition of the product

The METALLINE® Dressing Cloths consist of:

- Viscose
- Polyester
- Viscose, aluminized by vapour deposition (aluminium).

This product data sheet covers the following item:

| | | |
|-----------|--------------------------------------|-------------|
| REF 23010 | Metalline® – Dressing Cloth, sterile | 60 x 80 cm |
| REF 23011 | Metalline® – Dressing Cloth, sterile | 80 x 120 cm |
| REF 23012 | Metalline® – Dressing Cloth, sterile | 40 x 60 cm |

2. Packaging, structure and composition

2.1 Unit Container

- see 2.2

2.2 Shelf Container

- cellulose pouch
- instructions for use consisting of cellulose
- polyethylene bag

2.3 Transit Container

- corrugated cardboard box (cellulose)

3. **Manufacture**

METALLINE® - Dressing Cloths are 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 parts 1-3.

4. **Description**

The METALLINE® Dressing Cloths are constructed with the following four layers:

- 1st layer: an aluminised, binder-bonded non-woven fabric (viscose)
- 2nd layer: binder-bonded non-woven fabric (viscose)
- 3rd layer: non-woven fabric bonded by hydroentanglement (viscose / polyester)
- 4th layer: binder-bonded non-woven fabric (viscose), with a water-repellent finish

The above 4 layers are joined together by roll lamination and/or application of an adhesive mass. The METALLINE® Dressing Cloth has two off-white fastening tapes of viscose (natural white) attached.

5. **Properties**

The METALLINE® Dressing Cloth is made from non-woven viscose material which is aluminized on the side that is applied to the wound. This creates a smooth wound contact layer which reduces the risk of the product adhering to the wound. The porosity of the aluminized surface promotes rapid absorption of wound exsudate. The wound dressing is permeable to air and water vapour.

6. **Intended purpose**

METALLINE® Dressing Cloths are intended for dressing large-area wounds, burns, acid burns, and abrasions. They are used in first aid and in other emergency conditions.

The dressing cloths are applied with the metallised (shiny) side on the wound.

7. **Medical device classification**

The METALLINE® Dressing Cloth is a medical device of Class IIb in terms of 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® Dressing Cloths are safe if the product is used for the purposes intended.

The purpose of this documentation and the statements made herein is to show that there is no risk involved in the use of the device METALLINE® Dressing Cloth 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 (in dry conditions), the product 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.

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Signed by
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