STELLALINE Compresse non-adhérente absorbante, stérile
Non-adherent wound dressing

REF 17786 – 17788, 36037 – 36041, 36045, 36047

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1. Composition of the product

STELLALINE wound dressings are composed as follows:

- cotton layer: - 75% viscose
  - 25% polyester
- polyethylene film
- viscose layer
- polyethylene film

The product data sheet is valid for the following items:

REF 36037	Stellaline 1 Compresse non-adhérente absorbante, stérile	
	5 x 5 cm	26 pcs / SC
REF 17786	Stellaline 1 Compresse non-adhérente absorbante, stérile	
	5 x 5 cm	100 pcs / SC
REF 36047	Stellaline 1 Compresse non-adhérente absorbante, stérile	
	5 x 5 cm	400 pcs / SC
REF 36038	Stellaline 3 Compresse non-adhérente absorbante, stérile	
	7.5 x 7.5 cm	12 pcs / SC
REF 17787	Stellaline 3 Compresse non-adhérente absorbante, stérile	
	7.5 x 7.5 cm	100 pcs / SC
REF 36039	Stellaline 5 Compresse non-adhérente absorbante, stérile	
	10 x 10 cm	10 pcs / SC
REF 17788	Stellaline 5 Compresse non-adhérente absorbante, stérile	
	10 x 10 cm	100 pcs / SC
REF 36040	Stellaline 5 Compresse non-adhérente absorbante, stérile	
	10 x 10 cm	120 pcs / SC

REF 36045 Stellaline 6 Compresse non-adhérente absorbante, stérile
10 x 20 cm 5 pcs / SC
REF 36041 Stellaline 6 Compresse non-adhérente absorbante, stérile
10 x 20 cm 50 pcs / SC

2. Packaging, structure and composition

2.1 Unit container

- peel pouch (cellulose, polyethylene)

2.2 Shelf container

- folding box (cellulose)

2.3 Transit container

- corrugated cardboard box (cellulose)

3. Manufacture

STELLALINE wound dressings are produced according to specification in hygienic conditions, packed as described in their relevant packaging specification, and sterilized by ethylene oxide in compliance with DIN EN ISO 11135-1.

4. Description

STELLALINE wound dressings consist of a cotton layer composed of viscose and polyester, which has a perforated polyethylene film on one side and a blue impermeable viscose layer on the other side. The cotton is embossed with the perforated polyethylene film, and glued to the viscose layer by use of a polyethylene film.

5. Properties

Soft, absorbent dressings, available in different sizes.

6. Intended purpose

STELLALINE wound dressings are intended for management of superficial wounds, such as abrasions, and post-operative wounds.

7. Medical device classification

STELLALINE wound dressings are a medical device of Class Is in terms of Rule 4. (Council Directive 93/42/EEC concerning medical devices, Annex IX)

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

The starting materials used in the manufacture of STELLALINE wound dressings are safe if the product is used appropriately and for the purposes intended.

To date this company has received no notification of incidents involving this Lohmann & Rauscher product, neither has there been need for a recall for reasons of quality.

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 STELLALINE wound dressings 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, STELLALINE wound dressings have a shelf life of 5 years.

10. Disposal

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

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signed by
Dr. Martin Abel
(Medical & Regulatory Affairs)