

PRODUCT DATA SHEET

STELLA® STRIPS

Standard – Large – Spot – Patch – 4 formats

Pansements adhesives hypoallergéniques

Non-irritant adhesive wound dressings

non-sterile

REF: 37240 - 37244

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Translation: C.M.Kelly/MI-MRA

1. Composition of the product

Stella® Strips consist of:

- a flesh-coloured polyethylene carrier film
- a polyacrylate adhesive (an aqueous acrylic copolymer emulsion)
- a non-woven wound pad of viscose and polyester with polyethylene netting as a wound contact layer
- covering paper, PE-coated and siliconized on one side

This product data sheet covers the following items:

REF 37240	Stella® Strips Standard	19 x 72 mm	individually in peel pouch
REF 37241	Stella® Strips Large	25 x 72 mm	individually in peel pouch
REF 37242	Stella® Strips Spot	Ø 22 mm	individually in peel pouch
REF 37243	Stella® Strips Patch	38 x 38 mm	individually in peel pouch
REF 37244	Stella® Strips 4 formats:	19 x 72 mm	10 pieces
	(all individually wrapped	25 x 72 mm	10 pieces
	in a peel pouch)	Ø 22 mm	6 pieces
		38 x 38 mm	4 pieces

2. Packaging, structure and composition:

2.1 Unit container

- peel pouch (cellulose)

2.2 Shelf container

- a cellulose folding box

2.3 Transit container

- a corrugated cardboard carton (cellulose)

3. Manufacture

Stella ® Strips are manufactured to specification under hygienic conditions and wrapped as described in their relevant packaging specifications.

4. Description

These are flesh-coloured adhesive wound dressings of various sizes and shapes, with rounded corners. The white wound pad is positioned in the center of the dressing.

The wound dressings are protected on their adhesive side with centrally overlapping siliconized paper. They are individually wrapped in peel pouches.

5. Properties

Stella ® Strips are adhesive wound dressings which are oblong, circular or square in shape. The dressing's carrier is made of a thin, elastic film which is coated on one side with a non-irritant polyacrylate adhesive mass. The film is regularly perforated. The wound pad in the center consists of a non-woven material capable of absorbing eight times its own weight. Thanks to the polyethylene netting acting as a wound contact layer, the wound pad does not stick to the wound. Fully protected on their adhesive side and individually wrapped in a peel pouch, the dressing's various shapes and sizes recommend themselves for the immediate care of minor everyday injuries. Stella ® Strips are water-resistant.

If necessary, Stella ® Strips can be sterilized by ethylene oxide in compliance with DIN EN 550.

6. Intended purpose

Stella ® Strips are intended for dressing minor superficial injuries.

7. Medical device classification

Used as a non-invasive medical device in wound management, Stella® Strips are in Class I according to Rule 4, Annex IX of the Council Directive 93/42/EEC concerning medical devices.

8. Biological evaluation and biocompatibility (DIN EN ISO 10 993)

Viscose and polyester form part of many surgical dressings and as such are described in monographs in national and international pharmacopoeia. They are known to be pharmacologically harmless and indifferent.

Polyethylene, too, is present in many surgical dressings and is also described in monographs.

The starting materials used to produce Stella ® Strips are of such purity that the correct use of the adhesive wound dressings for the purposes intended is considered safe.

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

The purpose of this documentation and of the statements made therein is to show that there is no risk involved in the use of Stella ® Strips and that - as it says in the Essential Requirements of the Council Directive 93/42/EEC concerning medical devices -Stella ® Strips "are designed, manufactured and packaged in such a way that they will not compromise the clinical condition or the safety of patients, or the safety and health of users or other persons when used under the conditions and for the purposes intended".

9. Stability

Stored appropriately –in cool conditions and protected in their original packaging from dirt, dust and humidity–Stella ® Strips have a shelf life of five (5) years.

10. Disposal

Incineration or landfill disposal of Stella ® Strips generates CO₂ and H₂O, of the packaging equally CO₂ and H₂O.

The user is advised to observe current legislation, norms and guidelines regulating the disposal of medical devices.

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signed by
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