



Omnistrip®



Spec.-No.:	D 7.2205
Department:	CMO-DMW
Date:	2015-03-18

1. General Product Description

Omnistrip® is made of a carded polyester-/polyamide skin-coloured non-woven, which is coated with an acrylic adhesive.

Omnistrip® has rounded ends, is conformable and stretchable, with a high porosity, permeability and breathability and good adherence to the skin.

Omnistrip® carries the CE mark according to EU directive 93/42/ EEC for medical devices. The product is classified as a class IIa medical device.

A conformity assessment has been performed for Omnistrip® and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

The safe use and effectiveness of Omnistrip®, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

Omnistrip® is a wound closure strip, for atraumatic closure of minor wounds, surgical incisions in primary healing wounds; also to protect the wound margins against tension and stabilize fresh scars.

3. Presentations

Sterile, sealed in peel-pack:

dimensions:	3 mm x 76 mm	1 x 5 stripes	P50
	6 mm x 38 mm	1 x 6 stripes	P50
	6 mm x 38 mm	1 x 6 stripes	P2
	6 mm x 76 mm	1 x 3 stripes	P50
	6 mm x 76 mm	1 x 3 stripes	P2
	6 mm x 101 mm	2 x 5 stripes	P50
	12 mm x 101 mm	2 x 3 stripes	P50
	25 mm x 127 mm	2 x 2 stripes	P50

4. Product Characteristics

Material:	
- backing:	Skin-coloured carded polyester-/polyamide non-woven, binder bonded
- adhesive:	acrylic pressure sensitive adhesive
- liner:	siliconized paper



Technical Data Sheet

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5. Product Requirements

peel adhesion:	2.2 – 15 N/25mm
sterilization:	beta- sterilized

6. Labelling

Lot-No. with 9-digit code:

e.g.:

LOT	1	XXX	XX	XXX
	year	for internal purposes	week of production	for internal purposes only

expiry date:

e.g.: ⌚ 2016 - 06
year month

shelf life: 5 years

7. Packaging

Omnistrip® packed into peel-pouches and packaged into folding boxes, transport carton acc. DIN, sealed with adhesive tapes, packed onto europallet.

Date: 2015-03-18

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i. A.

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