

1. General Product Description

DermaPlast® Textil is a hypoallergenic, air permeable band-aid made of elastic textile.

DermaPlast® Textil carries the CE mark according to EU directive 93/42/EEC for medical devices. The product is classified as a class I medical device. A conformity assessment has been performed for DermaPlast® Textil and it has been shown to be in compliance with all applicable requirements of the above mentioned directive. The safe use of DermaPlast® Textil, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

DermaPlast® Textil is used for the treatment of small injuries like cuts, burns and lacerations.

3. Presentation

First aid dressing sliceable:

Size (width x length)	Pieces/Folded box	Folded boxes/Transport cardboard box
4x10 cm	10	160
6x10 cm	10	200
8x10 cm	10	200
4 cm x 5 m	1	32
6 cm x 5 m	1	24
8 cm x 5 m	1	16

Express package strips single packaging:

Size (width x length)	Pieces/Folded box	Folded boxes/Transport cardboard box
19x72 mm	15	450

Family package strips single packaging:

Size (width x length)	Pieces/Folded box	Folded boxes/Transport cardboard box
3 sizes assorted	32	160

Centred wound pad:

Size (width x length)	Pieces/Folded box	Folded boxes/Transport cardboard box
3x4 cm	100	80
4x6 cm	100	40
2 sizes assorted: 3x4 cm and 4x6 cm	16	400

Finger tip dressing:

Size (width x length)	Pieces/Folded box	Folded boxes/Transport cardboard box
5x6 cm	12	400

Finger dressing:

Size (width x length)	Pieces/Folded box	Folded boxes/Transport cardboard box
2x16 cm	12	360

4. Product Characteristics

Product composition: textile
 wound pad
 adhesive
 antiseptic
 cover

Material composition textile: - presentation "centred wound pad" size 2x4 cm:
 cotton, viscose
 - all other presentations: cotton, polyamide

Material composition wound pad:

viscose,

Material composition adhesive: - presentation "centred wound pad" size 2x4 cm: acrylate
- all other presentations: synthetic caoutchouc

Material composition antiseptic: - presentation "centred wound pad" size 2x4 cm: without
- all other presentations: chlorhexidinum 0.15% m/m ut

Material composition cover: silicone paper

5. Product Requirements

Color textile: skin-colored
Color wound pad: white

6. Labelling

Presentation "centred wound pad" size 2x4 cm: LOT-Number, 7-digit

All other presentations: LOT-Number, 8-digit

Expiration date:
Date specification with hourglass

e.g.:  2004 - 12

Shelf life: 5 years

7. Packaging

DermaPlast® Textil are packaged in folded boxes. The transport cardboard box according to DIN is sealed with adhesive tapes. Packaging onto europallet.

Date: 27.08.08


Marketing

CHANGE CONTROL REPORT

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20.10.06		new	3
27.08.08	20.10.06	Kapitel 6: Erklärung der LOT-Nummer gestrichen	3

Date/Signature Written by:	Date/Signature Approved by:
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