

1. General Product Description

DermaPlast® Sparablanc textile is a tearable fixation plaster with an inelastic textile fabric.

DermaPlast® Sparablanc textile 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® Sparablanc textile and it has been shown to be in compliance with all applicable requirements of the above mentioned directive. The safe use of DermaPlast® Sparablanc textile, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

DermaPlast® Sparablanc textile is used as fixation for wound dressings, cushions and cannulae.

3. Presentation

Clips box:

Dimensions (width x length)	Roll/Printed FB	Printed FB/Plain FB	Plain FB/Transport cardboard box
1.25 cm x 5 m	1	10	24
2.5 cm x 5 m	1	10	12

Saving roll:

Dimensions (width x length)	Rolls/Folded box	Folded boxes/Transport cardboard box
1.25 cm x 5 m	10	36
2.5 cm x 5 m	10	24
5 cm x 5 m	10	12

4. Product Characteristics

Material composition textile fabric:

100% V

Adhesive: synthetic caoutchouc

Material composition dispenser:

Polystyr

5. Product Requirements

Color: skin-colored

6. Labelling

LOT-Number, 7-digit

Expiration date:
Date specification with hourglass

e.g.:  2004 - 12

Shelf life: 5 years

7. Packaging

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

Date: 26.08.08


Marketing

CHANGE CONTROL REPORT

Keywords :	Technical Data Sheet		
Release of	Substitutes release of	Change	No. of Pages
18.08.06		new	2
26.08.08	18.08.06	Kapitel 6: Erklärung zur LOT-Nummer gestrichen	2

Date/Signature Written by:	Date/Signature Approved by:
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Abteilung	Datum	Unterschrift
Marketing	15.05.2012	Kästner, Nadja

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