

### 1. General Product Description

DermaPlast® Sensitive is a hypoallergenic, air permeable band-aid made of soft fleece.

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

### 2. Application / Indication

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

### 3. Presentation

#### **First aid dressing sliceable:**

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

**Centred wound pad:**

Size (width x length)	Color	Pieces/Folded box	Folded boxes/Transport cardboard box
3x4 cm	skin-colored	100	80
4x6 cm	skin-colored	100	40

**Express package strips single packaging:**

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

**Family package strips single packaging:**

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

**Omnistrip:**

Size (width x length)	Color	Pieces/Folded box	Folded boxes/Transport cardboard box
6 x 38 mm	skin-colored	12	40

4. Product Characteristics

Product composition: fleece (white or skin-colored)  
wound pad  
adhesive  
antiseptic  
cover

Material composition fleece white: polyester

Material composition fleece skin-colored:  
cellulose, polyester  
- all other presentations: polyester

Material composition wound pad: viscose, polyester, polyester-polyethylene-bicomponent fibre

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 fleece: white or 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® Sensitive are packaged in folded boxes. The transport cardboard box according to DIN is sealed with adhesive tapes. Packaging onto europallet.

Date: 27.06.2011

  
Marketing

**CHANGE CONTROL REPORT**

<b>Keywords :</b>	Technical Data Sheet		
<b>Release of</b>	<b>Substitutes release of</b>	<b>Change</b>	<b>No. of Pages</b>
20.10.06		new	3
27.08.08	20.10.06	Kapitel 6: Erklärung der LOT-Nummer gestrichen	3
27.06.2011	27.08.08	Größen 4 x 10cm weiss, / Zentriertes Kissen 2 x 4cm gestrichen & Ergänzung von Omnistrip	3

Date/Signature Written by:	Date/Signature Approved by:
E. Knill, R&D	A. Hartmann, Marketing

Abteilung	Datum	Unterschrift
Marketing	15.05.2012	Kästner, Nadja

Dieses Dokument ist Eigentum der IVF HARTMANN AG. Weitergabe an Dritte und nicht autorisiertes Kopieren sind nicht erlaubt.

