

1. General Product Description

DermaPlast® CoFix is a self-adhesive, elastic, air permeable gauze bandage.

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

2. Application / Indication

DermaPlast® CoFix is used for fixation of wound dressings and cannulae.

3. Presentation

White:

Size (width x length dilated)	Bandage/Folded box	Folded boxes/Transport cardboard box
1.5 cm x 4 m	2	60
2.5 cm x 4 m	2	72
4 cm x 4 m	1	50
6 cm x 4 m	1	120
8 cm x 4 m	1	140
10 cm x 4 m	1	120
4 cm x 20 m	1	42
6 cm x 20 m	1	24
8 cm x 20 m	1	24
10 cm x 20 m	1	18

Blue:

Size (width x length dilated)	Bandage/Folded box	Folded boxes/Transport cardboard box
4 cm x 4 m	1	80
6 cm x 4 m	1	60

4. Product Characteristics

Material composition:

37% cotton
20% polyamide

43% vis

Adhesive:

Cofix white: latexfree
Cofix blue: latex5. Product Requirements

Color: White or blue

Extensibility: 80%

6. Labelling

LOT-Number, 7-digit

Expiration date:
Date specification with hourglass

e.g.:  2004 - 12

Shelf life: 3 years

7. Packaging

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

Date: 22.08.11



Marketing

CHANGE CONTROL REPORT

Keywords :	Technical Data Sheet		
Release of	Substitutes release of	Change	No. of Pages
13.07.06		new	3
29.08.07	13.07.06	Adaption amount folded boxes/transport cardboard box at certain presentations	3
27.08.08	29.08.07	Kapitel 6: Erklärung de LOT-Nummer gestrichen	3
22.08.11	27.08.08	Kapitel 4: Material composition, new adhesive (latexfree) Kapitel 5: colours, only white and blue	3

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

Abteilung	Datum	Unterschrift
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