

1. General Product Description

DermaPlast® CombiFix is a first-aid wound bandage made of a non sticking wound dressing and an elastic cohesive bandage.

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

2. Application / Indication

DermaPlast® CombiFix is used for supply of abrasions, burns, cuts and contused wounds – easy and convenient application.

3. Presentation

Size bandage (width x length dilated)	Size wound dressing (width x length)	Piece in tubular bag/Folded box	Folded boxes/Transport cardboard box
4 cm x 4 m	3.5 cm x 5 cm	1	30
8 cm x 4 m	7.5 cm x 10 cm	1	15

4. Product Characteristics

Product composition: 1 cohesive bandage with natural rubber latex coating (CoFix)
 1 non sticking wound dressing with coverage (Comprigel)
 1 remove strip

Elongation longitudinal (bandage): 100%

Adhesion (bandage): self-adh

5. Labelling

LOT-Number, 7-digit

Expiration date:
Date specification with hourglass


e.g.:  2004 - 12

Shelf life: 3 years

6. Packaging

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

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Marketing

CHANGE CONTROL REPORT

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27.08.08	29.03.07	Kapitel 5: Erklärung der LOT-Nummer gestrichen	2

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