

DermaPlast® universal



Spec.-No.: D 7.0302a

Department: TME

Date: 01.03.2005

1. General Product Description

DermaPlast® universal are hypoallergenic plaster made of water and dirt-repellent polyethylene film; breathable and kind to the skin due to the synthetic rubber based adhesive.

DermaPlast® universal 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® universal and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

The safe use of DermaPlast® universal, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

For rapid treatment of minor injuries, suitable for patients with normal skin.

3. Presentations

6 cm x 1 m pieces of 10 cm that can be cut individually:

Plaster strips: 19 x 72 mm
(assortment) 25 x 72 mm

Plaster strips: 9 x 38 mm
(assortment) 16 x 57 mm
19 x 72 mm
25 x 72 mm
ø 22 mm

4. Product Characteristics

Material composition:

backing: polyethylene film, perforated, skin coloured

adhesive: synthetic rubber- based adhesive (stripe coating), colophonium- and latex-free

wound pad: Viscose / Polypropylene nonwoven

backing paper: siliconizes paper, white
approx. 60 g/m²

5. Product Requirements

Peel force: min. 19 N/25 mm

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6. Labelling

Lot-No. with 8-digit code:

e.g.:

LOT

9

year

44

week of production

XXXXX

for internal purposes only

Expiry date:

e.g.:



2004

year

06

month

Shelf life:

5 years

7. Packaging

DermaPlast® universal, single sealed (only strips) and pre-cut pieces; packaged into folding boxes, boxes per transport carton, transport carton acc. DIN, sealed with adhesive tapes, packed onto europallet.

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- Technical Medical Development TME -