

Technical Data Sheet

Dermaplast[®] / Cosmos[®] EFFECT

To cut



Specifications: P 7.6108
Department: RD-PHSA
Date: 04/07/2017

CHANGE CONTROL REPORT

Page /Edition	Replaces Page/Edition	Reason for Change
1-2-3 from 25/11/2013	-----	New Technical Data Sheet
1-2-3 from 04/07/2017	1-2-3 from 25/11/2013	Updated Technical Data Sheet

Department	Date	Signature
PHSA-RD, Product Developer, Gemma Galván	04/07/2017	

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1. General Product Description:

DermaPlast® / Cosmos® EFFECT to cut are hypoallergenic adhesive to cut made of hydrocolloid material. Suitable for different types of wounds.

DermaPlast® / Cosmos® EFFECT to cut carries the CE mark according to EU Directive 93/42/EEC for medical devices. The product is classified as a class **Ila** medical device.

A conformity assessment has been performed for DermaPlast® / Cosmos® EFFECT to cut and it has been shown to be in compliance with all the applicable requirements of the above-mentioned Directive. The safe use and effectiveness of DermaPlast® / Cosmos® EFFECT to cut is ensured if the product is used in line with the intended purpose.

2. Application / Indication:

Protection, treatment and absorption of exudates in case of corns, blisters or minor injuries.

3. Presentation:

Code	Description	Assortment	Dimensions of Plastic box
536640*	Dermaplast	65x90 mm (3st)	72,85 x 18,25 x 114,8mm + eurohanger
536063*	Cosmos	65x90 mm (3st)	72,85 x 18,25 x 114,8mm + eurohanger

*With scissors

4. Product Characteristics:

Material composition:

1	Backing material	Full hydrocolloid
2	Protector paper	Silicone paper, white.

5. Product requirements:

Peel adhesion (90°)*:	5,3 ± 2,5 N/25mm	TM00 0090-04
Static absorption Hydro:	3100 ± 1150 g/m ² /24h	TM00 0145
Bioburden:	≤ 100 cfu/g Absence of E.Coli, St, aureus, Ps.aeruginosa, Enterobacteria.	PH501/001 PH503/001

*These values are valid for the original coated roll (final product might have different values)

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6. Labelling:

Lot-No. with 9-digit code:

LOT	X	XXX	XX	12	X
	year	No.of production order of the article	Week of the year	Plant number	Control digit

Shelf Life: The shelf life is 3 years.

Example expiry date:



2016 – 06
Year – Month

7. Packaging:

DermaPlast[®] / Cosmos[®] EFFECT to cut are packed into folding boxes, transport carton acc. DIN, sealed with adhesive tapes, packed onto europallet.

➤ **Identification of each packaging :**

With 1 specific label with information of the product (Batch number, name of the product, expiry date, trade mark, number of boxes, code of the product).

DermaPlast[®] / Cosmos[®] EFFECT to cut should be stored in cool and dry conditions in a good ventilated area.