

Technical Data Sheet

Dermaplast[®] / Cosmos[®] EFFECT

“Minor injuries”



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	

Technical Data Sheet

Dermaplast® / Cosmos® EFFECT

“Minor injuries”



Specifications: P 7.6108

Department: RD-PHSA

Date: 04/07/2017

1. General Product Description:

DermaPlast® / Cosmos® EFFECT Minor injuries wound plasters are hypoallergenic adhesive wound plasters made of PU Film and hydrocolloide. DermaPlast® / Cosmos® EFFECT Minor injuries are suitable for different types of wounds.

DermaPlast® / Cosmos® EFFECT Minor injuries 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 Minor injuries 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 Minor injuries is ensured if the product is used in line with the intended purpose.

2. Application / Indication:

Protection and treatment and absorption of exudates in case of minor injuries.

3. Presentation:

Code	Description	Assortment	Dimensions of Plastic box
536740	Dermaplast West	65 x 22 mm (3st) 70 x 35 mm (2st) 30 x 40 mm (2st)	72,85 x 18,25 x 114,8mm + eurohanger

4. Product Characteristics:

Material composition:

1	Backing material	Transparent Polyurethane film
2	Wound pad	Hydrocolloid
3	Protector paper	Silicone paper, white.

Technical Data Sheet

Dermaplast® / Cosmos® EFFECT

“Minor injuries”



Specifications: P 7.6108

Department: RD-PHSA

Date: 04/07/2017

5. Product requirements:

Mass per squaremeter backing material*:	93 ± 7 g/m ²	TM00 0015-01_EN
Adhesion (PE) backing material*:	5 ± 2 N/25mm	MC – AD11
Adhesion (silk) backing material*:	4 ± 1,5 N/25mm	MC – AD21
MVTR backing material*:	>400 g/m ² /24h	TM00 0188
Static absorption Hydro:	3150 ± 1150 g/m ² /24h	TM00 0154
Peel adhesion Hydro (90°)*:	5,3 ± 2,5 N/25mm	TM00 0090-04
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)

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 Minor injuries 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 Minor injuries should be stored in cool and dry conditions in a good ventilated area.