

Technical Data Sheet

Dermaplast® / Cosmos® Aqua



Specifications: P 7.2420

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
1-2-3-4 from 04/07/2017	1-2-3 from 25/11/2017	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® Aqua are hypoallergenic adhesive wound plasters made of transparent Polyurethane film, with synthetic adhesive. Dermaplast® / Cosmos® Aqua are flexible and comfortable, water-proof and skin friendly plasters.

Dermaplast® / Cosmos® Aqua plasters carry 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® / Cosmos® Aqua plasters 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® Aqua plasters is ensured if the product is used in line with the intended purpose.

2. Application / Indication:

The product is intended to be used as a self-adhesive first aid dressing (strip or wound plaster) for the protection of minor injuries and absorption of exudate, suitable for patients with normal skin. The product is for single use.

3. Presentation:

Code	Description	Assortment	Dimensions of Folding box
535523	Cosmos	30 x 40 mm 40 x 60 mm 25 x 72 mm	75x20x105 +25mm eurohanger
535540	Dermaplast West	30 x 40 mm 40 x 60 mm 25 x 72 mm	75x20x105 +25mm eurohanger
535525	Dermaplast East	30 x 40 mm 40 x 60 mm 25 x 72 mm	75x20x105 +25mm eurohanger

4. Product Characteristics:

Material composition:

1	Backing material	Transparent Polyurethane film
2	Adhesive	Synthetic polyacrylate adhesive
3	Wound pad	Viscose-rayon, polyester, PES/PE
4	Protector paper	Silicone paper, white.

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5. Product requirements:

Mass per squaremeter*:	93 ± 7 g/m ²	TM00 0015-01_EN
Adhesion (PE) / Dry (pull-off angle:180°)*:	5 ± 2 N/25mm	MC-AD-11
Wound pad absorption:	>1000 g/m ²	TM00 0033_EN
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 5 years.

Example expiry date:



2016 – 06
Year – Month

7. Packaging:

Dermaplast® / Cosmos® Aqua plasters are single sealed and 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® Aqua plasters should be stored in cool and dry conditions in a good ventilated area.