

# 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 <sup>2</sup>	TM00 0015-01_EN
Adhesion (PE) / Dry (pull-off angle:180°)*:	5 ± 2 N/25mm	MC-AD-11
Wound pad absorption:	>1000 g/m <sup>2</sup>	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.