

Technical Data Sheet

Dermoplast[®] / 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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Date: 04/07/2017

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.