

Cosmopor® E



Spec.-No.: D 7.0407

Department: PHSA-RD

Date: 09.09.2016

1. General Product Description

Cosmopor® E is a sterile, self-adhesive wound dressing made of soft non-woven, coated with skin friendly synthetic rubber based adhesive, with an absorbent pad covered with a non-adherent net as wound contact layer. The product is latex free.

Cosmopor® E carries the CE mark according to EU directive 93/42/EEC for medical devices. The product is classified as a Class I sterile medical device.

A conformity assessment has been performed for Cosmopor® E and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

The safe use and effectiveness of Cosmopor® E, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

Cosmopor® E is intended to be used as a self-adhesive sterile plaster for protection of post-surgical/primary wounds and for the absorption of exudate (wounds with a normal exudate production). It can also be used for the protection of wounds following treatments such as disinfection, wound cleansing etc.

3. Presentations

Sterile, individually sealed.

Type	Dimensions (cm)	Dimensions of wound pad (cm)
Cosmopor® E	7,2 x 5	4 x 2,5
Cosmopor® E	10 x 6	6,5 x 2,5
Cosmopor® E	10 x 8	6,5 x 3,8
Cosmopor® E	15 x 6	11 x 2,5
Cosmopor® E	15 x 8	11 x 3,8
Cosmopor® E	15 x 9	11 x 3,8
Cosmopor® E	20 x 8	16 x 3,8
Cosmopor® E	20 x 10	16 x 5,5
Cosmopor® E	25 x 10	20,5 x 5,5
Cosmopor® E	35 x 10	30,5 x 5,5

Cosmopor® E



Spec.-No.: D 7.0407
 Department: PHSA-RD
 Date: 09.09.2016

4. Product Characteristics

Material composition:

1	Backing material	White, perforated spunlaced non-woven, 100% polyester,
2	Adhesive	Synthetic rubber-based adhesive, transparent, stripe coated
3	Wound pad	The wound pad is composed by 2 layers: -Wound contact layer: permeable net made of polyethylene, which prevents the pad from sticking to the wound -Absorption layer: mainly made of viscose, which allows exudate to be absorbed
4	Silicone paper	White silicone glassine paper
5	Sealing paper	Printed paper, frame coated, cold seal, latex free

5. Product Requirements

Mass per square meter (cross direction):	68 ± 6,5 g/m ²
Mass per square meter (machine direction):	71 ± 6,5 g/m ²
Adhesion on silk*:	14 ± 3 N/25mm*
Wound pad absorption	900 ± 90 %
Sterilization method	EO

*These values are valid for the original coated roll

6. Labelling

Lot-No. with 9 digit code:

e.g.: X XXX XX XXX

LOT	X	XXX	XX	XXX
	year	for internal purposes only	week of production	for internal purposes only

Expiry date: 6-digit code:

e.g.  2015 06
 year month

Shelf life: 5 years

Cosmopor® E



Spec.-No.: D 7.0407

Department: PHSA-RD

Date: 09.09.2016

7. Packaging

Cosmopor® E is sealed individually in peel pouches. Peel pouches are packed in folding boxes. Boxes are packed in transport carton acc. DIN, sealed with adhesive tapes, packed onto Euro pallet.

Date: 09.09.2016



Dr. Irene Mijangos
PHSA – RD
PAUL HARTMANN Spain