

Cosmopor® I.V.



Spec.-No.: D 7.0407c

Department: PHSA-RD

Date: 12.09.2016

1. General Product Description

Cosmopor® I.V. is a sterile dressing used for intravenous catheter and tubing fixation on the skin. Cosmopor® I.V. is a self-adhesive 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. An additional pad is included as a swab.

The product is latex free.

Cosmopor® I.V. 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® I.V. 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® I.V., therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

Cosmopor® I.V. is intended to be used for the fixation of peripheral intra venous cannulas.

3. Presentations

Sterile, individually sealed.

Type	Dimensions (cm)	Dimensions of wound pad (cm)
Cosmopor® I.V.	6 x 8	2,5 x 2

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: made of viscose, which allows exudate to be absorbed
4	Silicone paper:	White silicone glassine paper
5	Sealing paper:	Printed paper, frame coated, hot seal, latex free

5. Product Requirements

Total weight (backing material + adhesive):	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

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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

7. Packaging

Cosmopor® I.V. 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.

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