

## Cosmopor® E



Specification.- No.: **D 7.0401**

Department: **TME**

Date: 2003-12-17

### CHANGE CONTROL REPORT

Page /Edition	replaces Page/Edition	Reason for Change
1-2 from 20.04.1999	-----	New Technical Data Sheet
1-2 from 28.06.2001	1-2 from 20.04.1999	Format 15 x 9 cm completes
1-2 from 05.09.2003	1-2 from 28.06.2001	Updated Version
1-2 from 17.12.2003	1-2 from 05.09.2003	Form and contents checked and updated

Department	Date	Signature
Technical Medical Development (TME)	2003-12-17	<i>Schmidt</i>

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### 1. General Product Description

Cosmopor® E is a sterile, self-adhesive wound dressing made of soft nonwoven, with an absorbent pad covered with a non-adherent porous wound contact layer; coated with skin friendly synthetic rubber based adhesive.

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

### 2. Application / Indication

For postoperative wound management and sterile dressing of minor injuries, e.g. in first aid.

### 3. Presentations

sterile, individually sealed

Dimensions:	7.2 x 5 cm	20 x 10 cm
	10 x 6 cm	25 x 10 cm
	15 x 6 cm	35 x 10 cm
	10 x 8 cm	
	15 x 8 cm	
	20 x 8 cm	

### 4. Product Characteristics

Composition:

backing:	polyester nonwoven
adhesive:	synthetic rubber based adhesive, colophony-free
wound pad:	absorbent viscose
covering:	polyethylene net
liner:	siliconized paper

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### 5. Product Requirements

wound pad:	mass per square meter:	approx. 185 g
	absorption capacity:	> 1100 g/m <sup>2</sup>
backing:	adhesive force:	min 13 N/25 mm
	mass per square meter:	approx. 80 g

### 6. Labelling

Lot-No. with 8-digit code:

e.g.:

1	25	XXXXX
year	week of production	for internal purposes only

Expiry date:

e.g.:

2006	06
year	month

Shelf life: 5 years

### 7. Packaging

Individually sealed in peelpouches, packed into folding box; transport carton acc. DIN, sealed with adhesive tapes, packed onto europallet.

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— Technical Medical Development —