

**Omnipor®**

 Spec.-No.: **D 7.0801**

 Department: **PHSA-RD**

 Date: **08.09.2016**

## 1. General Product Description

Omnipor® is a hypoallergenic surgical adhesive tape made of nonwoven and synthetic rubber-based adhesive. The product is latex free.

Omnipor® carries 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 Omnipor® and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

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

## 2. Application / Indication

Omnipor® is intended to be used for the fixation of any kind of wound dressings (like wound pads, traditional gauzes, etc.), cannulas, probes, catheters, bandages etc.; indicated for patients with sensitive skin.

## 3. Presentations

Non-sterile, individually packed.

Type	Dimensions
Omnipor®	1,25 cm x 5 m
Omnipor®	2,5 cm x 5 m
Omnipor®	5 cm x 5 m
Omnipor®	1,25 cm x 9,2 m
Omnipor®	2,5 cm x 9,2 m
Omnipor®	5cm x 9,2 m

## 4. Product Characteristics

Material composition:

1	Backing material:	Wet laid non-woven
2	Adhesive:	Transparent hypoallergenic synthetic rubber based adhesive
3	Spool:	Polyestyrene

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5. Product Requirements

Total weight (backing material + adhesive):	75 ± 5 g/m <sup>2</sup>
Adhesion on Silk:	13 ± 3 N/25mm

6. Labelling

Lot-No. with 9 digit code:

e.g.: X XXX XX XXX

<b>LOT</b>	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

Omnipor® spools are packed in folding boxes. Boxes are packed in transport carton acc. DIN, sealed with adhesive tapes, packed onto Euro pallet.

Date: 08.09.2016



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