

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:            | Polyestylene   |

Omnipor®



Spec.-No.: D 7.0801

Department: PHSA-RD

Date: 08.09.2016

## 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

| 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

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



Dr. Irene Mijangos  
PHSA - RD  
PAUL HARTMANN Spain