

## Omniplast®



Spec.-No.: D 7.0101a  
Department: R&D - PHSA  
Date: 15.02.2017

### 1. General Product Description

Omniplast® is a hypoallergenic surgical adhesive tape made of textile fabric with synthetic adhesive, permeable to air and water vapour, adheres reliably, particularly tensile, can be removed painlessly and without leaving residues, easy to tear off because of zig-zag edges.

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

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

### 2. Application / Indication

For the full range of dressing fixation, securing probes, for patients with normal skin.

### 3. Presentations

On plastic spool, skin colored.

Type	Dimensions	Presentations
Omniplast®	1,25 cm x 5 m	24 Spools / 1 Spool
Omniplast®	2,5 cm x 5 m	12 Spools / 1 Spool
Omniplast®	5 cm x 5 m	6 Spools / 1 Spool
Omniplast®	1,25 cm x 9,2 m	24 Spools / 1 Spool
Omniplast®	2,5 cm x 9,2 m	12 Spools / 1 Spool
Omniplast®	5 cm x 9,2 m	6 Spools / 1 Spool

### 4. Product Characteristics

Material composition:

1	Backing material:	100% Viscose fabric, skin colour.
2	Adhesive:	White hypoallergenic synthetic rubber-based adhesive, stripes
3	Spool:	Polyestylene

### 5. Product Requirements

Mass per square meter :	190 ± 12 g/m²
Adhesion on Silk*	19 ± 4 N/25mm*

\*These values are valid for the original coated roll

## Omniplast®



Spec.-No.: D 7.0101a  
 Department: R&D - PHSA  
 Date: 15.02.2017


### 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:

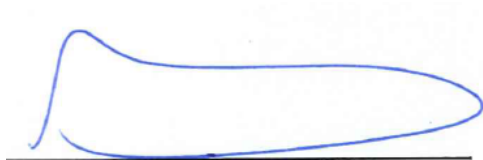
e.g.  2015 06  
 year month

Shelf life: 5 years

### 7. Packaging

Omniplast® on plastic spool packaged into folding box; transport carton acc. DIN, sealed with adhesive tapes, packaged onto europallet.

Date: 15.02.2017



Dr. Irene Mijangos  
 PHSA - RD  
 PAUL HARTMANN Spain