

## Omnisilk®



Spec.-No.: D 7.0601

Department: PHSA-RD

Date: 15.02.2017

### 1. General Product Description

Omnisilk® is a hypoallergenic surgical tape made of white artificial silk with synthetic rubber-based 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, does not absorb X-rays, ageing and temperature resistant. The product is latex free.

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

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

### 2. Application / Indication

Omnisilk® 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
Omnisilk®	1,25 cm x 5 m
Omnisilk®	2,5 cm x 5 m
Omnisilk®	5 cm x 5 m
Omnisilk®	1,25 cm x 9,2 m
Omnisilk®	2,5 cm x 9,2 m
Omnisilk®	5 cm x 9,2 m

### 4. Product Characteristics

Material composition:

1	Backing material:	100% acetate (synthetic silk), white
2	Adhesive:	Skin-friendly synthetic rubber-based adhesive, transparent, stripe and full coated
3	Spool:	Polyestylene

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## 5. Product Requirements

Total weight (backing material + adhesive):	105 ± 8 g/m <sup>2</sup>
Adhesion on Silk*:	16 ± 3 N/25mm*

\*Adhesion for parent roll

## 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:

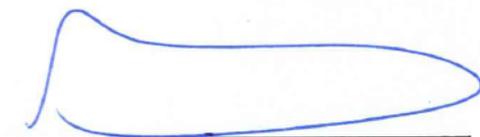
e.g.  2015 06  
year month

Shelf life: 5 years

## 7. Packaging

Omnisilk® spools 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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