

Omnifix® Elastic

Spec.-No.: D 7.0402

Department: PHSA-RD

Date: 14.09.2016

1. General Product Description

Omnifix® Elastic is a self-adhesive non-woven roll made of non-woven and skin-friendly synthetic rubber-based adhesive; especially conformable and elastic, permeable to air and water vapour. The product is latex free.

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

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

2. Application / Indication

Omnifix® Elastic is intended to be used for the fixation of any kind of wound dressings (like wound pads, traditional gauzes, etc.), cannulas, probes, catheters, etc., especially for coverage of large surfaces.

3. Presentations

Non-sterile, individually packed.

Type	Dimensions
Omnifix® Elastic	2,5 cm x 10 m
Omnifix® Elastic	5 cm x 10 m
Omnifix® Elastic	5 cm x 5 m
Omnifix® Elastic	10 cm x 10 m
Omnifix® Elastic	15 cm x 10 m
Omnifix® Elastic	20 cm x 10 m
Omnifix® Elastic	30 cm x 10 m
Omnifix® Elastic	10 cm x 2 m
Omnifix® Elastic	10 cm x 5 m
Omnifix® Elastic	15 cm x 2 m
Omnifix® Elastic	15 cm x 4 m
Omnifix® Elastic	15 cm x 1,83 m
Omnifix® Elastic	10 cm x 1,83 m
Omnifix® Elastic	5 cm x 9,14 m
Omnifix® Elastic	10 cm x 9,14 m
Omnifix® Elastic	15 cm x 9,14 m

4. Product Characteristics

Material composition:

1	Backing material:	100% polyester, white spunlace non-woven
2	Adhesive:	Transparent, skin-friendly synthetic rubber adhesive, stripe coated
3	Silicone paper:	Siliconized paper, wave pre-cut

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5. Product Requirements

Total weight (backing material + adhesive):	71 ± 6,5 g/m ²
Adhesion on silk*	13 ± 4 N/25mm

*These values are valid for the original coated roll

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

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

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