

Visulin®



Specification.- No.: **D 7.3301**

Department: **TME**

Date: 2004-02-10

CHANGE CONTROL REPORT

Page /Edition	replaces Page/Edition	Reason for Change
1-2 from 10.02.2004	-----	New Technical Data Sheet

Department	Date	Signature
Technical Medical Development (TME)	2004-02-10	<i>Schmidt</i>

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1. General Product Description

Visulin® is a selfadhesive, sterile and transparent wound dressing based on a polyurethane film coated with acrylic adhesive.

The film is permeable to air and moisture vapour. It is repellent to bacteria and liquids.

The application of Visulin® can easily be made with detachable support liners at two edges of the dressing.

Visulin® carries the CE mark according to EU directive 93/42/EEC for medical devices. The product is classified as a class IIa medical device.

A conformity assessment has been performed for Visulin® and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

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

2. Application / Indication

For fixation of peripheral, endovenous catheters, of absorbent dressings, of nozzles. Sterile covering and protection of dry, or slightly exuding and not infected wounds. The big dimensions of Visulin® dressings can also be used as drapes for incising.

3. Presentations

Sterile, individually sealed

Dimension:	8.5 x 6 cm
	10 x 6 cm
	14 x 10 cm
	26 x 15 cm
	26 x 30 cm

4. Product Characteristics

Composition:

- | | |
|-------------------|------------------------------------------------------|
| - backing: | polyurethane film |
| - adhesive: | acrylic adhesive, hypoallergenic, colophonium-free |
| - liner: | siliconized paper |
| - support system: | two siliconized liners on both edges of the dressing |

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5. Product requirements

moisture vapour transition rate (MVTR): $> 700 \text{ g} / \text{m}^2 / 24 \text{ h}$

Adhesive strength: $> 4 \text{ N} / \text{in}$

6. Labelling

Lot-No. with 8-digit code:


e.g.:

4
year

12
week of production

XXXXX
for internal purposes only

Expiry date:

e.g.:  2006 06
year month

Shelf life: 5 years

7. Packaging

Visulin® individually sealed in sterile primary packing and packed into folding box; transport carton acc. DIN, sealed with adhesive tapes, packed onto europallet.

Date: 2004-02-10

A handwritten signature in blue ink, appearing to read "C. Müller".

— Technical Medical Development —