

## Hydrofilm I.V. control



Spec.-No.: **D7.4019a**

Department: **SM-PDW**

Date: **22.02.2010**

### 1. General Product Description

Hydrofilm I.V. control is a sterile self-adhesive dressing for the fixation of peripheral intra venous cannulae. Hydrofilm I.V. control is made of 100% polyester non-woven coated with a hypoallergenic synthetic rubber based adhesive and laminated with a transparent semi-permeable, waterproof polyurethane film coated with a hypoallergenic acrylate adhesive. The non-woven material includes an opening which is covered with the polyurethane film. This allows the observation of the exit site.

Hydrofilm I.V. control carries the CE-mark according to EU directive 93/42/EEC for medical devices. The product is classified as a class I, rule 4 (1) medical device.

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

The safe use and effectiveness of Hydrofilm I.V. control, therefore, is ensured if the product is used in the line with the intended purpose.

### 2. Application / Indication

To fix peripheral intra venous cannulae and for the sterile treatment of the exit site.

### 3. Presentations

Sterile, individually sealed.

Ref. No.	Dimensions	Number peel pouches per folding box
685741/0	7 cm x 9 cm;	P50

### 4. Product Characteristics

Composition:

Backing– two layers:

- 1 – white plain spunlace non-woven  
100 % polyester
- 2 – transparent polyurethane film

Adhesives:

- 1 – hydroallergenic, transparent synthetic rubber based adhesive (injected in stripes)
- 2 – hydroallergenic acrylate adhesive

Liner: Silicone paper

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5. Product Requirements

Hydrofilm I.V. creates a strong and reliable fixation of the cannula.

Easy handling due to a two-step application system.

Moisture vapor transmission rate (MVTR) according to DIN EN 13726-2 > 1100 g/m<sup>2</sup>/24h

ETO sterilized

6. Labelling

Lot-No. with 9-digit code:  
e.g.:

X	XXX	XX	XXX
year	order number	week	for internal purposes only

Expiry date:  
e.g.                      2015    1  
                              year    month

Shelf life: 5 years

7. Packaging

Hydrofilm I.V. control is individually sealed in peel pouches; packed into folding boxes; transport carton acc. DIN; sealed with adhesive tapes, packed onto europallet.

Date: 2010-11-29



-Sybille Hörmann/SM-PDW-