

## Hydrofilm® Roll



Spec.-No.: D 7.4025

Department: SM-PDW

Date: 2008-12-12

### 1. General Product Description

Hydrofilm® Roll is a self-adhesive film dressing for fixation of primary wound dressings it is made of semi-permeable, waterproof polyurethane film, transparent; protect against bacterial penetration; with hypoallergenic adhesive, can be removed painlessly without leaving any residues. Hydrofilm® Roll is non-sterile dressing and can be cut to the needed length.

Hydrofilm® Roll carries the CE mark according to EU directive 93/42/ EEC for medical devices. The product is classified as a class I (non-sterile) medical device. A conformity assessment has been performed for Hydrofilm® Roll and it has been shown to be in compliance with all applicable requirements of the above mentioned directive. The safe use of Hydrofilm® Roll therefore, is ensured if the product is used in line with the intended purpose.

### 2. Application / Indication

Hydrofilm® Roll is a protective layer for the fixation of primary wound dressings, e.g. to cover gel-forming calcium alginate dressings.

### 3. Contra-indication

Hydrofilm® Roll should not be used on clinically infected, bleeding or highly exudating wounds

### 4. Presentations

Hydrofilm® Roll non-sterile, individually sealed

Dimensions:	5 cm x 10 m	boxes of 24 pcs
	10 cm x 2 m	boxes of 24 pcs
	10 cm x 10 m	boxes of 32 pcs
	15 cm x 10 m	boxes of 20 pcs

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Product Characteristics

## Composition:

- backing: semi-permeable, transparent polyurethane film
- adhesive: acrylic adhesive, hypoallergenic, colophonium-free
- handling aid two-piece supporting film
- Moisture vapour transition rate (MVTR) according to DIN EN 13726-2: 700 - 800 g/m<sup>2</sup> / 24h

5. Product Requirements

adhesive power 2,5 – 7,5 N / in

6. Labelling

Lot-No. with 8-digit code.

Expiry date: e.g.:  2013 12  
year month

Shelf life: 5 years

7. Packaging

Separate sealed in folding box; Transport carton acc. DIN, sealed with adhesive tapes; packed onto europallet.

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PAUL HARTMANN AG

- SM-PDW- Solution Management
- Product Development Wound Management

i. A.



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