

## Fil-Zellin®



Spec.-No.: **D 2.3120**  
Department: CMO-DGM  
Date: 2016-05-31

### 1. General Product Description

Fil-Zellin® are universal dressings with wound-compatible nonwoven layer and several layers of highly bleached cellulose as absorbent material; both materials are quilted together, may be cut into any shape without the layers losing their cohesion.

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

The safe use of Fil-Zellin® therefore, is ensured if the product is used in line with the intended purpose (see 2. Application/Indication).

### 2. Application / Indication

May be used universally for wound – compatible treatment of dry or secreting wounds or as carrier material for ointment and moist dressings.

### 3. Presentations

Fil-Zellin® rolls are available in the following dimensions:

10 cm x 10 m

15 cm x 10 m

30 cm x 10 m

### 4. Product Characteristics

Bleached cellulose tissue according to DAB monograph "Hochgebleichter Verbandzellstoff".

### 5. Product Requirements

Material:

- |                    |  |
|--------------------|--|
| - Absorbent layer: | Cellulose (Pulp), elemental chlorine free or total chlorine free with blue hotmelt marking |
| - Nonwoven layer:  | Viscose / polyester nonwoven (one layer)   |
| - Sewing thread:   | Spun rayon , white glaze   |

Total area weight: min. 210 g/m<sup>2</sup>

Water absorption min. 9 g/g

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### Labelling

Lot-No. with 9-digit code:

Lot. - No.	5	999	01	00	1
Explanation	[5 = 2015]	[999 - 000]	Internal Code		
Definition	Year	Serial production order			

Expiry date:.....  .....Year – Month or Year - Month - Day  
 Example:.....2020-03.....or..2020-03-01  
 Shelf Life: .....5 years

### 6. Packaging

Fil-Zellin® is individually packed into PE-bags and closed with paper clip. The PE-bags are packed in transport cartons, are sealed with adhesive tape and packed onto Euro pallets.

Date: 31<sup>st</sup> May 2016

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i.A.



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