

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/m²

Water absorption min. 9 g/g

Fil-Zellin®



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

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: 31st May 2016

PAUL HARTMANN AG
 Product Development CMO-DGM

i.A.



Cathrin Jäger