

## Pur-Zellin® non-sterile and sterile



Spec.-No.: **D 3.3206**

Department: COM-DGM

Date: 2018-06-29

### 1. General Product Description

Pur-Zellin® are cellulose swab on a roll with a ready-to use pre-cut; made of highly bleached cellulose and available in sterile and non-sterile version. Use of Pur-Zellin® sterile in combination with the dispenser Pur-Zellin® Box for contamination protected storage acc. to RKI recommendation<sup>1</sup>.

Pur-Zellin® carries the CE-mark according to EU directive 93/42/ EEC for medical devices.

The product is classified as a class I (non-sterile Pur-Zellin®) and class Is (sterile Pur-Zellin®) medical device.

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

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

### 2. Application / Indication (Intended Purpose)

#### Sterile:

Single-use sterile cellulose swab for short-term (< 24h) treatment used for:

- cleansing the skin prior to injections and infusions in combination with the Pur-Zellin® Box
- as a mechanical barrier
- absorption of exudates

#### Non-sterile:

Single-use non-sterile cellulose swab for transient (< 60 min) treatment used:

- as a mechanical barrier
- for absorption of exudates

### 3. Presentations

Pur-Zellin® non-sterile and Pur-Zellin® sterile are available on a roll of 500 pieces. Each roll is individually sealed in a peel package.

### 4. Product Characteristics

Material composition: 100 % sulphate and sulphite pulp, bleached elemental chlorine free or total chlorine free. Cellulose according to DAB monograph "Hochgebleichter Verbandzellstoff" ["highly bleached cellulose"].

<sup>1</sup>Recommendation of the General Commission for Hospital Hygiene and Infectious Disease Prevention located at the Robert Koch Institute (RKI), Bundesgesundheitsblatt 2011 54:1135-1144 "Anforderungen an die Hygiene bei Punktionen und Injektionen"[Hygiene requirements for punctures and injections]

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### Product Requirements

	non-sterile	non-sterile (‘economy’)	sterile
Reference:	143 213	143 223	143 253
Weight per roll:	ca. 210 g	ca. 130 g	ca. 210 g
Sinking time:	max. 4,0 sec	max. 4,0 sec	max. 6,0 sec
Water absorption:	min. 10 g/g	min. 10 g/g	min. 10 g/g
Layers:	11	7	11

### **Sterile Pur-Zellin®:**

Sterilization: Radiation according to DIN EN ISO 11137-1 with validated process  
Do not (re-) sterilize product

### **Non-sterile Pur-Zellin® swabs**

(without packaging)

Sterilizability: Gas sterilization according to DIN EN ISO 11135 with validated process  
Radiation sterilization according to DIN EN ISO 11137-1 with validated process

## 5. Labelling

Lot-No. with 9-digit code for **Pur-Zellin®**:

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

The **sterile Pur-Zellin®** will be sterile during this period as long as the packaging is not damaged and the storage conditions are kept.











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Symbol	Description
	Protect from moisture
	Do not use if package is damaged or open
	Do not resterilize
	manufacturer
	reference number
	LOT number
	Product non-sterile
	Product sterile; radiation sterilization
	CE mark for medical devices in EU / EFTA
	Single use

### 6. Packaging

Non-sterile Pur-Zellin® is individually packaged in thermoform packaging.

Sterile Pur-Zellin® is individually packaged in thermoform packaging and additionally in PP bag. The sterile packaging is in accordance with DIN EN ISO 11607.

The peel packages are packed in transport cartons, sealed with adhesive tape and packed onto Euro pallets.

Date: 29<sup>th</sup> June 2018

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i.A.



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