

## Medicomp® sterile



Spec.-No.: **D 2.0014**  
 Department: CMO-DGM  
 Date: 2015-08-03

### 1. General Product Description

White nonwoven, gauze-structured swabs with high absorbency; free of binding agents and optical brightening agents.

Medicomp® carries the CE mark according to EU directive 93/42/EEC for medical devices. The product is classified as a class IIa medical device.

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

The safe use of Medicomp® therefore, is ensured if the product is used in line with the intended purpose.

### 2. Application / Indication

For general wound treatment, as swabs and sponges during out-patient and inpatient interventions.

### 3. Presentations

Medicomp® sterile are available in the formats 5 x 5 cm, 7,5 x 7,5 cm, 7,5 x 10 cm, 10 x 10 cm and 10 x 20 cm. All formats folded 4 ply.

### 4. Product Characteristics

material: nonwoven made of viscose and polyester

basis weight: approx. 30 g/m<sup>2</sup>  
40 g/m<sup>2</sup>

water absorption capacity: approx. 7 g/g

sterilization: steam according to DIN EN ISO 17665 with validated process

### 5. Labelling

Lot-No. with 9-digit code:

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

Expiry date  Year Month  
 Example 2020 06  
 Shelf life: 5 years

The product will be sterile during this period as long as the packaging is not damaged and the storage conditions are kept.

# Medicomp® sterile



Spec.-No.: **D 2.0014**  
Department: CMO-DGM  
Date: 2015-08-03

## 6. Packaging

Medicomp® sterile, sealed in packs of 2 / 5 / 10 pieces, packed into folding box. The sterile packaging is in accordance with DIN EN ISO 11607. Transport carton sealed with adhesive tapes and packed onto euro pallet.

Date: 3<sup>rd</sup> August 2015

PAUL HARTMANN AG  
Product Development CMO-DGM

i.A.



Thorsten Guter