

## Medicomp® 30 g/m<sup>2</sup> sterile



Spec.-No.: **D 5.2000a**

Department: CMO-DGM

Date: 2015-08-12

### 1. General Product Description

White non-woven, gauze-structured swabs made of viscose and polyester fibres; free of binding agents and optical brightening agents. Medicomp® arranged in a pre-displayed form, which allows easy taking out.

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 (see 2. Application/Indication).

### 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 sizes 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 sizes are folded 4 ply.

### 4. Product Characteristics

material:	non-woven made of viscose and polyester
area weight:	approx. 30 g/m <sup>2</sup>
water absorption capacity	approx. 11 g/g
Sterilization:	steam according to DIN EN ISO 17665 with validated process

### 5. 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
Example		2020	06
Shelf life:		5 years	

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

### 6. Packaging

Medicomp® sterile, sealed in peel pouches of 2 / 5 pieces according to DIN EN ISO 11607, packed into folding box and a transport carton. The transport carton is sealed with adhesive tapes and packed onto euro pallets.

Date: 12<sup>th</sup> August 2015

PAUL HARTMANN AG  
Product Development CMO-DGM

i.A.

A handwritten signature in black ink, appearing to read "T. Guter".

Thorsten Guter