

Medicomp® 40 g/m² unsterile

Spec.-No.: **D 5.2103b**

Department: CEO-DTW

Date: 2019-04-18

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® 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 outpatient and inpatient interventions. In case of direct wound contact Medicomp® have to be sterilized in a validated process.

3. Presentations

Medicomp® unsterile are available in the sizes 5 x 5 cm, 7,5 x 7,5 cm, 7,5 x 10 cm and 10 x 10 cm. All sizes are folded 4 ply.

4. Product Characteristics

Material:	nonwoven made of 67% viscose and 33% polyester (tolerance +/- 5%)
Area weight:	approx. 40 g/m ²
Water absorption capacity:	approx. 10 g/g
Sterilizability:	Steam sterilization according to DIN EN ISO 17665-1 with validated process Gas sterilization (ethylene oxide) according to DIN EN ISO 11135 with validated process Radiation sterilization according to DIN EN ISO 11137-1 with validated process

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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 or Year - Month - Day
 Example 2021 - 11
 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.

6. Packaging

Medicomp® unsterile are packed into paper bags of 100 pieces and a transport carton. The transport carton is sealed with adhesive tapes and packed onto Euro pallets.

Date: 18th April 2019

PAUL HARTMANN AG
 Product Development CEO-DTW

i.A.



Thorsten Guter