

Telacomp® non-sterile



Spec.-No.: **D 2.0007c**
 Department: **CMO-DGM**
 Date: **2015-08-06**

1. General Product Description

Telacomp® gauze swabs made of absorbent gauze (100 % cotton) according to EN 14079, folded edges and interwoven Telatrast® x-ray detectable thread. Depending on the quantity of plies, the swabs can be unfolded once or several times without interfering fringe threads.

Telacomp® 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 Telacomp® and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

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

2. Application / Indication

Telacomp® gauze swabs for staunching bleeding and for wound treatment, for gripping or retaining body tissue during laparotomy.

3. Presentations

Telacomp® unsterile are available in the formats 5 x 5 cm, 7,5 x 7,5 cm, 10 x 10 cm, 10 x 12,5 cm and 10 x 20 cm. The formats are made of gauze with 17 threads or 20 threads according to EN 14079, folded 8 ply, 12 ply, 16 ply and 32 ply.

4. Product Characteristics

Material composition:

Gauze: 100% Cotton according EN 14079, chlorine free bleached

X-ray detectable thread: Polypropylene with min. content of 60 % BaSO₄

5. Product Requirements

Material: fulfills the requirements EN 14079 (after bleaching)

Sinking time: < 10 sec.

Water absorption capacity: 6 – 8 g water per g gauze

Optical brighteners: none

Sterilizing capability: Steam sterilization according to EN 17665 with validated process
 Gas sterilization according to EN 11135 with validated process
 Radiation sterilization according to EN 11137 with validated process

Before application, unsterile swabs have to be sterilized with validated processes.

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17 thread: warp: 100/10 cm ± 5
 weft: 70/10 cm ± 4

Area weight: ≥ 23 g/m²

Tensile strength dry: warp: ≥ 50 N/50 mm
 weft: ≥ 30 N/50 mm

Number of threads

20 thread: warp: 120/10 cm ± 6
 weft: 80/10 cm ± 5

Area weight: ≥ 27 g/m²

Tensile strength dry: warp: ≥ 60 N/50 mm
 weft: ≥ 35 N/50 mm

6. Labelling

Lot-No. with 9-digit code:

Lot. - No.	3	999	01	00	1
Explanation	[3 = 2013]	[999 - 000]	Internal Code		
Definition	Year	Serial production order			

Expiry date: ⌚ Year Month
 Example: 2019 06
 Shelf life: 5 years

7. Packaging

100 respectively 50 pieces of Telacomp® unsterile are packaged in sterilizable paper bags. Transport cartons are sealed with adhesive tape and packed onto euro pallets.

Date: 6th August 2015

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i.A.



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