

## Telacomp<sup>®</sup> and Telacomp<sup>®</sup> E sterile (steam)



Spec.-No.: **D 2.2121e**  
Department: CMO-DGM  
Date: 2015-08-06

### 1. General Product Description

Telacomp<sup>®</sup> and Telacomp E<sup>®</sup> gauze swabs are made of absorbent gauze (100 % cotton, 17thread) according to EN 14079, folded edges and interwoven Telatrast<sup>®</sup> x-ray detectable thread. Depending on the quantity of plies, the swabs can be unfolded once or several times without interfering fringe threads

Telacomp<sup>®</sup> and Telacomp<sup>®</sup> E carry 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<sup>®</sup> and Telacomp<sup>®</sup> E and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

The safe use of Telacomp<sup>®</sup> and Telacomp<sup>®</sup> E therefore, is ensured if the product is used in line with the intended purpose (see 2. Application/Indication).

### 2. Application / Indication

Telacomp<sup>®</sup> and Telacomp<sup>®</sup> E gauze swabs for staunching bleeding and for wound treatment, for gripping or retaining body tissue during laparotomy.

### 3. Presentations

Telacomp<sup>®</sup> sterile, in 4 layer packaging with lot coded double check card for theatre counts.

Telacomp<sup>®</sup> E sterile, in 3 layer packaging with lot coded double check card for theatre counts.

Telacomp<sup>®</sup> sterile are available in the sizes 7,5 x 7,5 cm, 12 ply and 10 x 10 cm 16 ply.

Telacomp<sup>®</sup> E sterile are available in the sizes 5 x 5 cm, 7,5 x 7,5 cm, each 12 ply and 10 x 10 cm, 12 ply or 16 ply. The sizes are made of gauze with 17threads according to EN 14079.

### 4. Product Characteristics

Material composition:

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

X-ray detectable thread: Polypropylene with min. content of 60 % BaSO<sub>4</sub>

### 5. Product Requirements

Number of thread: Warp 100/10 cm ± 5  
Weft 70/10 cm ± 4

Area weight: ≥ 23 g/m<sup>2</sup>

Tensile Strength dry: Warp ≥ 50 N/50 mm  
Weft ≥ 30 N/50 mm

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Material: fulfills the requirements of EN 14079 (after bleaching)  
 Sinking time: < 10 sec.  
 Water absorption capacity: 6 – 8 g water per g gauze  
 Optical brighteners: none  
 Sterilization: Steam according to DIN EN ISO 17665-1 with validated process

### 6. 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 6  
 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.

### 7. Packaging

Different number of gauze swab pieces Telacomp<sup>®</sup> and Telacomp<sup>®</sup> E sterile, Telatrast<sup>®</sup> Modul System, double or single packaged in peel pouches. The sterile packaging is in accordance with DIN EN ISO 11607. The peel pouches are packaged in folding boxes and transport carton sealed with adhesive tape and packaged onto euro pallet.

Date: 06<sup>th</sup> August 2015

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i.A.



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