

Telacomp[®] und Telacomp E[®] sterile,



Spec.-No.: **D 2.2121d**
Department: CMO-DGM
Date: 2014-07-28

1. General Product Description

Telacomp[®] and Telacomp E[®] gauze swabs made of absorbent gauze (100 % cotton, 17thread) according to EN 14079, folded edges and interwoven Telatrast x-ray detectable thread.

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

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

2. Application / Indication

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

3. Presentations

Telacomp[®] sterile, in 4layer packaging with lot coded double check card for theatre counts.

Telacomp E[®] sterile, in 3layer packaging with lot coded double check card for theatre counts.

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

17 thread:

Number of thread: Warp > 100/10 cm
Weft > 70/10 cm

Area weight: >= 23 g/m²

Tensile Strength dry: Warp >= 50 N/50 mm
Weft >= 30 N/50 mm

20 thread:

Number of thread: Warp >= 120/10 cm
Weft >= 80/10 cm

Area weight: >= 27 g/m²

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Tensile Strength dry: Warp ≥ 50 N/60 mm
Weft ≥ 35 N/50 mm

17threads and 20threads:

Material: fulfils the requirements EN 14079 (after bleaching)

Sinking time: < 10 sec.

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

Optical brighteners: none

Sterilization: Steamed water according to DIN EN ISO 17665
with validated process

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 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® and Telacomp E® sterile , Telatrast 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: 28th July 2014

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i.A.



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