

Telasling® sterile (steam)



Spec.-No.: **D 2.2121b**

Department: CMO-DGM

Date: 2015-04-22

1. General Product Description

Telasling® gauze balls made of absorbent gauze (100% Cotton; 20 thread) according to EN 14079, made of one piece of gauze, with interwoven Telatrast® x-ray detectable thread.

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

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

2. Application / Indication

Telasling® gauze balls to stop bleeding and for wound treatment.

3. Presentations

Sterile, in 4layer packaging with lot coded double check card for theatre counts.

Size	Diameter [mm]
2 Walnut	ca. 20
3 Plum	ca. 32

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 17 threads: fulfills the requirements EN 14079 (after bleaching)

Sinking time: < 10 sec.

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

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

Area weight: ≥ 27 g/m²

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

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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.	4	999	01	00	1
Explanation	[4 = 2014]	[999 - 000]	Internal Code		
Definition	Year	Serial production order			

Expiry date:  Year Month
 Example: 2019 06
 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.

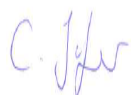
7. Packaging

Telasling® sterile, Telatrast® Modul System, gauze balls double 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 cartons, sealed with adhesive tape and packaged onto europallets.

Date: 01st June 2015

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