

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.

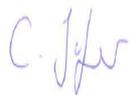
7. Packaging

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 fold-in boxes and transport cartons, sealed with adhesive tape and packaged onto europallets.

Date: 01st June 2015

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