

Telasling® sterile (EO)



Spec.-No.: **D 2.2122b**

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

Size	Diameter [mm]
4 Egg	ca. 39
5 Extra	ca. 46
6 Fist	ca. 50

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

Number of threads: warp: 120/10 cm ± 6
weft: 80/10 cm ± 5

Telasling® sterile (EO)



Spec.-No.: **D 2.2122b**

Department: **CMO-DGM**

Date: **2015-04-22**

Area weight:	$\geq 27 \text{ g/m}^2$
Tensile Strength dry:	warp $\geq 60 \text{ N/50 mm}$ weft $\geq 35 \text{ N/50 mm}$
Optical brighteners:	none
Sterilization:	Ethylene oxide according to DIN EN ISO 11135 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.

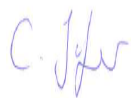
7. Packaging

Telasling® sterile 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 carton, sealed with adhesive tape and packaged onto europallets.

Date: 01st June 2015

PAUL HARTMANN AG
Product Development CMO-DGM

i.A.



Cathrin Jäger