

## Tamponing bandage sterile and non-sterile



Spec.-No.: D 2.4101  
 Department: CMO-DGM  
 Date: 2015-11-17

### 1. General Product Description

Tamponing bandage non-sterile / sterile made of pure Cotton; with fast edges.

Tamponing bandage non-sterile / sterile carries the CE mark according to EU directive 93/42/EEC for medical devices. A conformity assessment has been performed for Tamponing bandage non-sterile / sterile and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

The safe use of Tamponing bandage non-sterile / sterile, therefore, is ensured if the product is used in line with the intended purpose.

The product Tamponing bandage non-sterile is classified as a class I medical device.

The product Tamponing bandage sterile is classified as a class I (sterile) medical device.

### 2. Application / Indication

For tamponing small wounds and body cavities.

### 3. Presentation

sterile Tamponing bandage: 5 m length; 1 cm , 2 cm

non-sterile, Tamponing bandage: 5 m length; 1 cm, 2 cm width and 5cm width

### 4. Product characteristics

Material:

Tamponing bandage 100 % cotton, bleached, chemical properties acc. to DIN EN 14079

Plastic Box polystyrene / polyethylene

Construction: plain weave, fast edges

### 5. Product requirements

Sinking time\*: < 10 sec.

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

Number of thread: warp  $\geq 117/10$  cm  
 Weft  $74/10 \text{ cm} \pm 2$  (double weft)

Area weight:  $\geq 59 \text{ g/m}^2$

Tensile Strength dry:  $\geq 60\text{N}/50 \text{ mm}$

Optical brighteners\*: none

\*acc. to EN 14079

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Tamponing bandage non-sterile:

Sterilizability: Steam sterilization according to DIN EN ISO 17665-1 with validated process  
Gas sterilization according to DIN EN ISO 11135 with validated process  
Radiation sterilization according to DIN EN ISO 11137-1 with validated process

Tamponing bandage sterile:

Sterilization: Radiation sterilization according to DIN EN ISO 11137-1 with validated process

### 6. Labelling

Lot-No. With 9 digit code:

Lot. - No.	5	999	01	00	1
Explanation	[5 = 2015]	[999 - 000]	Internal Code		
Definition	Year	Serial production order			

The expiry date is printed near the symbol sand clock⌚. The shelf life of products is 5 years.

Expiry date ⌚ Year Month  
Example: 2020 06

The product will be sterile during this period as long as the packaging is not damaged and the storage conditions are kept.

### 7. Packaging

Tamponing bandages non-sterile packed in craft paper;  
Tamponing bandages sterile individually packed in plastic box and peel pouches. The sterile packaging is in accordance with DIN EN ISO 11607. Transport carton sealed with adhesive tapes and packed onto euro pallet.

Date: 17<sup>th</sup> November 2015

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i.A.



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