

Eycopad® non-sterile



Spec.-No.: **D 6.1100a**

Department: CMO-DGM

Date: 2015-04-21

1. General Product Description

Eycopad® are eye pads made of absorbent cotton wool with pure cotton gauze covering; especially soft and absorbent; excellent cushioning effect retained over long periods.

Eycopad® carries the CE mark according to EU directive 93/42/EEC for medical devices. The product is classified as a class I medical device.

A conformity assessment has been performed for Eycopad® and it has been shown to be in compliance with all applicable requirements of the above mentioned directive. The safe use of Eycopad® therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

For eye dressings.

3. Presentations

Dimensions: 56 x 70 mm
70 x 85 mm

4. Product Characteristics

material: covering gauze 24 threads: 100 % Cotton
cotton wool: 100 % Cotton

dimensions: 56 x 70 mm ± 4 mm
70 x 85 mm ± 4 mm

5. Product Requirements

Covering gauze 24 threads:

Material: fulfills the requirements EN 14079 (after bleaching)

Sinking time: <10 sec.

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

Number of threads warp 120/100 mm ± 6
weft 120/100 mm ± 6

Area weight ≥32 g/m²

Tensile strength warp ≥ 60 N/50 mm
weft ≥ 50 N/50 mm

Optical brighteners: none

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Sterilizing capability: Steam sterilization according to EN 17665 with validated process
 Gas sterilization according to EN 11135 with validated process
 Radiation sterilization according to EN 11137 with validated process

Cotton wool: approx. 360 g/m²

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 06
 Shelf Life: 5 years

7. Packaging

Eycopad® non sterile, packed into folding boxes; transport carton sealed with adhesive tapes and packed onto Euro pallets.

Date: 21th April 2015

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i.A.



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