

# Eycopad® sterile



Spec.-No.: **D 6.1100**  
 Department: CMO-DGM  
 Date: 2015-08-05

## 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 (see 2. Application/Indication).

The product is latex free and without colophonium.

## 2. Application / Indication

For eye dressings.

## 3. Presentations

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

## 4. Product Characteristics

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

## 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 per g Gauze

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

Area weight: >= 32 g/m<sup>2</sup>

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Tensile Strength dry: warp  $\geq$  60 N/50 mm  
 weft  $\geq$  50 N/50 mm

Optical brighteners: none

**Cotton wool:**

Area weight: approx. 360 g/m<sup>2</sup>

**Sterilization:** Steam sterilization according to DIN EN ISO 17665-1 with validated process

### 6. Labelling

Lot-No. with 9-digit code:

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

Expiry date:  Year Month  
 Example: 2020 6  
 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

Individual sealed Eycopad® sterile, packed into folding boxes. The sterile packaging is in accordance with DIN EN ISO 11607. The transport carton sealed with adhesive tapes and packed onto Euro pallets.

Date: 05<sup>th</sup> August 2015

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i.A.



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