

Eycopad® sterile



Spez.-Nr.: **D 2.2127**

Abteilung: CEO-DTW

Datum: 23.07.2019

1. General Product Description

Eycopad® are eye pads made of absorbent cotton wool with pure cotton gauze covering. The borders on two sides are open and not punched. Eycopad is soft and has a good absorbency and good padding properties.

Eycopad® carries the CE mark according to EU directive 93/42/EEC for medical devices. The product is classified as a class I sterile 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 not intentionally made with natural rubber latex and is without colophonium.

2. Application / Indication

Eycopad is a non-invasive single use, sterile eye pad made of absorbent cotton wool with pure cotton gauze covering, may be applied on intact or injured skin at the outer eye region on humans to act as mechanical barrier to protect the eye/outer eye region and to absorb body fluids on weeping and dry wounds for short term use. Change when indicated by healthcare professionals and instructed lay persons.

Eycopad is not for use on surgical wounds.

3. Presentations

Eycopad products:	REF	Content per folding box	Size of the eye pad (mm)
Eycopad sterile 56x70, P25	415540/8	25	56x70
Stérilux Eye pads sterile 56x70, P10	241222/4	10	56x70
Eycopad sterile 70x85, P25	417540/4	25	70x85

4. Product Characteristics

material:	
covering gauze 24 threads:	100 % Cotton fulfils the requirements EN 14079:2003 (after bleaching) Number of threads: Warp: 120/10 cm ± 6 Weft: 120/10 cm ± 6
cotton wool:	100 % Cotton in acc. with Eur. Ph. 8

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5. Product requirements

Size 56 ±2 x 70 ± 2 mm
70 ±2 x 85 ± 3 mm

Weight per eye pad size 56x70: 1,6 g +/-0,2
size 70x85: 2,3g +0,4/-0,2

Absorbing capacity ≥ 16 g water per g eye pad

Sinking time ≤ 10s

Sterilization: ETO sterilization according to DIN EN ISO 11135: 2014-10 with validated process

6. Labelling

Lot-No. with 9-digit code:

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

Expiry date:  Year-Month-Day
Example: 2023-03-01

Shelf life: 5 years

Production date  Year-Month-Day
Example: 2018-03-01

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

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7. Packaging

Individual sealed Eycopad® sterile, packed into folding boxes. The sterile packaging is in accordance with DIN EN ISO 11607: 2017-10. The transport carton sealed with adhesive tapes and packed onto Euro pallets.

Date: 23rd July 2019

PAUL HARTMANN AG
Product Development CEO-DTW

i.A.

A handwritten signature in black ink, appearing to read "T. Guter".

Thorsten Guter