# 1. TECHNICAL FILE

## 1.1. DESTINATION OF USE

The device is not invasive and it is used as ophthalmic dressing to protect the ocular lobe and to absorb any exudates

## 1.2. TECHNICAL DESCRIPTION

Sterile adhesive dressing oval-shaped, consisting of a support coated perforated non-woven fabric with hypoallergenic adhesive and stick with the central absorbent pad and viscose.

***GENERAL CARACHTERISTICS OF THE DEVICE***

- Conformable and flexible: it adapts perfectly to the eye area
- Breathable: the non-woven perforated guarantees a perfect flow of air and water vapor, respecting the skin perspiration
- hypoallergenic
- Does not release adhesive residue upon removal which is atraumatic
- Very absorbent: the central pad viscose enables rapid and effective absorption of exudates radiolucent
- Protected by easily removable card that guarantees a perfect application on the area to be treated

### *1.2.1. Materials part of the device*

**Device:** non woven (polyester 100 %)

**Central pad**: viscose 100% covered by non adherent film

**Adhesive:** acrylic hypoallergenic mass

**Coating:** virgin paper 100 % resin coated

### *1.2.2. Other technical carachteristics*

***Dimensions***

Dressing: 6.5 x 9.5 cm

Central pad: 6 x 4 cm

| *Components* | *Material* | *References* | *Measures* |
|---|---|---|---|
| Non woven | Polyester 100 % | Weight | 45 ± 5 g/m² |
| | | Thickness | 0.3 mm |
| | | Resistence to machine direction tensile | 90 ± 10 N/25 mm |
| | | Resistence to transverse direction tensile | 13 ± 3 N/25 mm |
| | | Loading machine direction breaking | 20± 2 N |
| | | Loading direction transverse rupture | 10± 3N |
| | | Elongation | 35 ± 5 % |
| | | MVTR vapor permeability | 3500 ± 500 g/m²/24 ore |
| Adhesive mass | polyacrylates | Weight | 30 - 35 g/m² |
| | | Adhesiveness | 13 ± 3 N/25 mm |
| | | Posting resistence | 4 ± 1 N/25 mm |
| Central pad | Viscose – perforated polyethylene films and PP | Weight | 150 ± 10 g/m² |
| | | Pad tickness | 2 mm |
| | | Absorbtion capacity | 25 g/100 cm² |
| | | Absorbtion time | < 1 sec |
| | | Film thickness | 0.0006 mm |
| | | Permeability to air on 20 cm² surface and a 200 Pa depression | 1080 ± 26 mm/sec |
| Coating | virgin paper 100 % resin coated | Weight | 72 ± 5 g/m² |

## 1.3. CONFIGURATIONS (REF. – SIZE – ECC)

The device is encoded to be marketed .

The encoding is composed by a fix part that identifies the product , while the variable part identify size or dimensions.

| Codes | Size | Packing |
|---|---|---|
| 1206540005M | 6.5 cm x 9.5 cm | Single bag in box of 100 pcs |
| 1206180005M | 6.5 cm x 9.5 cm | Single bag in box of 5 pcs |

## 1.4. PACKING

### *1.4.1. Primary packing*

***Devices in box of100 or 5 pcs***

Sterile adhesive eye pads are packaged in individual bags of medical paper cold welded, bearing the name of the manufacturer, the lot number, the date of sterilization and expiration and the word "latex free". The envelopes are then placed in boxes of 100 pieces or in lithographed cardboard boxes in number of 5 pieces. Both the box is the box contain all the information necessary to identify the DM in accordance with Directive 93/42 / EEC and Directive 2007/47 / EC

### *1.4.2. Secondary packing*

**Devices in box**

Cardboard box containing 20 boxes of 100 pieces each, and labeled the same as inside, in addition to the overall amount of content devices.

**Devices in box**

Cardboard box containing 12 packs of 5 pieces each, and labeled the same as inside, in addition to the overall amount of content devices.

## 1.5. PRODUCT STATUS

1.5.1. **Description of the method of sterilization**
The sterile device is sterilized with ethylene oxide by validated cycle in accordance with the applicable European regulations. (EN 11135)
1.5.2. **Validity of the device**
The sterile, preserved in its original packaging, is valid for 5 years from the date of sterilization
1.5.3. **Methodology for sterilization by the user**
N.A.
1.5.4. **Methodology for the user is responsible for re-sterilization (if applicable)**
In case of damage to the original package the device can not be re-sterilized

1.6. **Storage**
Store the device in its original packaging in a cool, dry place, away from heat or open flame. Do not expose to direct sunlight and avoid dusty environments.
Recommended storage temperature: between 0 ° C and 50 ° C

1.7. **COMPATIBILITY 'TO OTHER SUBSTANCES**
The device is compatible to most of the chemical substances with which it may come into contact in normal use practices. They are however to avoid prolonged exposure to extremes in pH solutions or strongly oxidizing, especially at high temperatures.

1.8. **Disposal**
Dispose of the device in accordance with local regulations on waste.

Data di emissione 24/03/14

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Responsabile Assicurazione Qualità
(Marco Gruppioni)