

**PRODUCT DESCRIPTION**

Sterile, self adhesive eye dressing with transparent shield.  
The product is a medical device belonging to Class I according to EU directive 93/42/EEC (Annex IX, rule 1).

**ARTICLES AND INTERNAL PRODUCT CODES**

| Article          | Size (mm) | Code    |
|------------------|-----------|---------|
| ORTOLUX          |           |         |
| 1 pcs Small      | 96x68     | 105.01  |
| 1 pcs Large      | 114x80    | 105.03  |
| 20 pcs Small     | 96x68     | D105.05 |
| 20 pcs Large     | 114x80    | D105.07 |
| ORTOLUX AIR      |           |         |
| 1 pcs Air Small  | 96x68     | 105.20  |
| 1 pcs Air Large  | 114x80    | 105.22  |
| 20 pcs Air Small | 96x68     | D105.27 |
| 20 pcs Air Large | 114x80    | D105.30 |

**INDICATIONS FOR USE**

Applications after surgery for ptosis, blepharochalasis of the upper and lower eyelid and all cases of lagophthalmos, and during the postoperative period after operations on the eye.

**INSTRUCTIONS FOR USE**

Patch on dry skin. Take care that the narrow end is patched towards the nose. Replace when necessary.  
*Important:* single use; use only if wrapper is undamaged.  
*Preservation and storage:* keep in a cool dry place, away from direct heat.

**MATERIALS / COMPONENTS**

The product consists of:  
- Adhesive tape  
- Transparent shield  
- Protective siliconised paper.

**PACKAGING**

Primary packaging: single in sealed pouches made of PP.  
Secondary packaging: in fully coated boxboard boxes.  
Transport pack: boxes made of corrugated cardboard.

**STERILISATION**

By ionising radiation (gamma rays Co-60).  
The process is validated according to standard UNI EN ISO 11137.

**MANUFACTURING PROCESS**

The manufacturing process can be briefly described in 7 steps:  
- Application of dye on the support tape  
- Adhesive coating of the support tape with slot-die coater (full coating).  
- Unwinding/cutting/rewinding of the components in smaller rolls  
- Assembly of the components to finished product and packaging in pouches with printing of the production information (step made in clean rooms belonging to Class ISO 8 according to standard UNI EN ISO 14644)  
- Sterilisation  
- Packaging in boxes  
- Packaging in transport pack/shipment

**TECHNICAL DATA OF THE FINISHED PRODUCT**

Adhesiveness (peel at 180°): > 1 N/cm  
Sterility: Sterile  
Shelf life: 5 years (if correctly stored, in undamaged wrappers).

**TECHNICAL DATA OF THE COMPONENTS**

| SUPPORT TAPE   |                               |
|--|-------------------------------|
| <b>Description</b><br>Medical-grade, extensible non woven (fibers: 100% PES), patterned with organic dyes in water dispersion. |                               |
| <b>Properties</b>  | <b>Standard value</b>         |
| Colour   | Beige                         |
| Weight   | 46,5 g/m <sup>2</sup>         |
| Thickness  | 0,47 mm                       |
| Tensile strength   | 123 N/5cm (MD), 36 N/5cm (CD) |
| Elongation at peak   | 27% (MD), 134 % (CD)          |

| SHIELD  |  |
|---|--|
| <b>Description</b><br>Film 100% PETG.<br>In the air article with holes (7 holes, Ø 4 - 4,5mm) |  |
| <b>Properties</b>   | <b>Standard value</b>                              |
| Colour  | Transparent<br>(85% according to ASTM D 1746)      |
| Density   | 1,27 g/cm <sup>3</sup>                             |
| Thickness   | 250 µm   |
| Elastic modulus   | 2,5 GPa  |
| Softening point   | 70°C   |
| MVTA  | 6g/m <sup>2</sup> • 24 h                           |
| Oxygen permeability   | 10cm <sup>3</sup> • mm/m <sup>2</sup> • 24 h • atm |

| PROTECTIVE PAPER FOR THE ADHESIVE           |   |
|---|---|
| <b>Description</b><br>Monosiliconised paper |   |
| <b>Properties</b>                           | <b>Standard value</b>                   |
| Colour                                      | White background + printing of 1 colour |
| Weight                                      | 80 g/m <sup>2</sup>                     |
| Thickness                                   | 68 µm                                   |

| ADHESIVE  |   |
|---|---|
| <b>Description</b><br>Hot melt pressure sensitive adhesive based on thermoplastic rubber.<br>The ingredients of the adhesive meet the compositional requirements of the FDA regulations 21 CFR 175.105. |   |
| <b>Properties</b>   | <b>Standard value</b>                   |
| Viscosity   | 7500 mPa.s (170°C), 35000 mPa.s (130°C) |
| Softening point   | 93°C                                    |

**Notes**

- This document is a guide for the best use of the product but does not constitute a specification.
- The values shown in the document are "typical" values.
- This "Product data sheet" substitutes any previous one and is property of Pietrasanta Pharma S.p.A. with the subject to change without notice.