

Product

BLAYCO® Face shield

Reference

PF-01

**Date**

March 2020

Specification N°

ETP/340/00

TECHNICAL SPECIFICATIONS

Materials

- Transparent shield: PET
- Headband: 50% Polyester and 50% Elastane
- Protector foam: Polyurethane
- Rivet: Acetal resin
- Individual packaging: PE zip pouch, re-sealable
- Secondary packaging: Cardboard box

Main dimensional properties

- Shield width: 325 mm
- Shield total length: 230 mm
- Visor length: 210 mm
- Visor thickness: 400 µm.
- Shield depth: 40 mm
- Protective foam length: 225 mm

Biocompatibility

- ISO 10993-5: Non cytotoxic
- ISO 10993-10: Non sensitizing
- ISO 10993-10: Negative intracutaneous irritation test

Made with hypoallergenic materials.

Sterilization

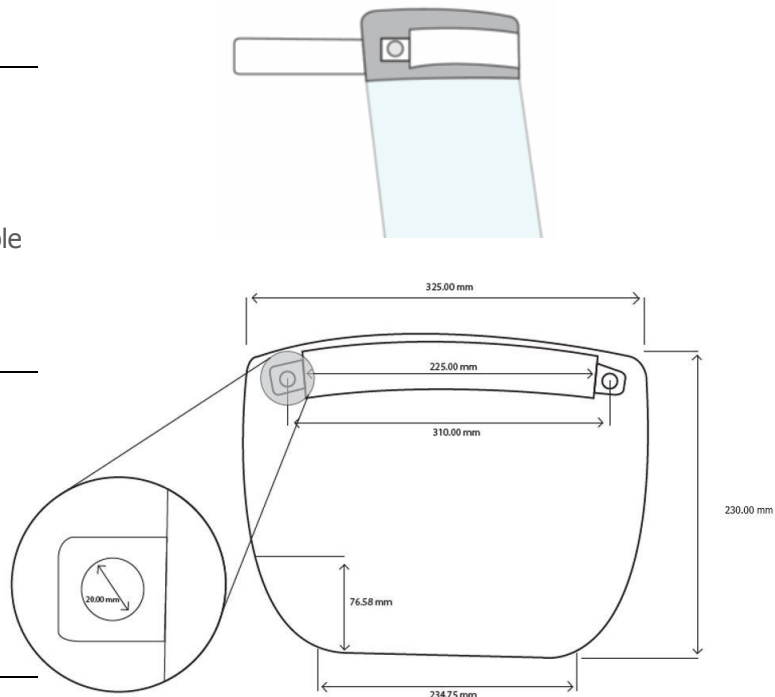
- Non sterile product.

Storage and maintenance

- Keep protected from direct sunlight / the outside.
- Keep in a dry place.
- Single use product. No maintenance required.
- Limitation of temperature: 5°C – 40°C

Packaging

- Unitary PE zip pouch.
- Card box with 50 units.



PRODUCT CHARACTERISTICS

- Offers protection for facial mucosae (eyes, nose and mouth).
- Contagion prevention of diseases produced by microorganisms which spread by droplets due to the lock of splashes of body fluids and / or aerosols.
- Headband for subjection of the shield.
- Manufactured with light materials. Comfortable for use.
- Shied protection is compatible with the use of additional glasses and / or complementary masks.

INSTRUCTIONS FOR USE

Prior to healthcare personnel is exposed to any possible contamination, they should:

- Place the Blayco® Face shield on the head, so that positioning the elastic headband in the rear and the screen on the front, covering the face.
- Adjust the position of Blayco® face shield until is conveniently adapted.

this product is recommended as single use. If disinfection is required, we recommend clean the face shield with soap and water, and disinfect with 70% Ethanol, 0,5% Hydrogen peroxide or 0,1% Sodium hypochlorite.

REGULATORY INFORMATION

This product is in conformity with Regulation (UE) 2016/425 about Personal Protective Equipment, and that it has been manufactured following the directives of the Quality Assurance System certifies as ISO 13485.

This product is classified as:

- Category I product according to Annex I of Regulation (UE) 2016/425, point e
 - GMDN code: 11961- Face splash shield, single-use
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