Fluidshield* 3 Fog-Free Surgical Mask with SO SOFT* Lining

Orange, Anti-Glare WrapAround Visor

CE

TECHNICAL DATA SHEET



Description

Reference: 48247
HIGH FLUID EXPOSURE
Dimensions
Length: 17.8 cm
Width: 9.5 cm
Visor Length: 30.5 cm
Properties:
Bacterial Filtration Efficiency (BFE): >98%.
Breathing resistance: <60 Pa.
Splash Resistance of 160 mmHg.
EN 14683:2019+AC:2019 classification: Type IIR facemasks.
ASTM F2100-11 classification: Level 3 facemasks.
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Indication

To minimise the direct transmission of infective agents between the
healthcare staff and the patient. Single use product

Counter Indication

none in particular.

Main Materials

Outside Layer: Cellulose/Polyester Facing, Orange.
Middle Layer: Spunbond (Polypropylene).
Third Layer: High Efficiency Filter (Polypropylene).
Inner Layer: PET/Polyester Bicomponent, White.
Nose piece: Aluminum Wire.
Foam: Polyester, Blue.
Visor: Clear Polyester Film, anti-glare, anti-fog.
Ties: Polyester, White.
Does not contain Natural Rubber Latex.
Does not contain DEHP.

Sterilisation

These products are non-sterile.
These products cannot be sterilised.

Shelf Life

5 years, from the date of manufacture.

Packaging

Shipping case of 100 units.
25 units are placed within 1 dispenser and 4 dispensers are placed within a shipping case.
Bar coding: GS1-128 symbology, linear, on shipping case and dispenser
boxes.

Manufacturing

Processed in Mexico of U.S. Materials.
The manufacturing site has ISO 13485 certified quality system.

Regulatory Information

Product CE marked as per Regulation (EU) 2017/745 on Medical Devices.
Class of the device: I.
Product compliant with EN 14683:2019+AC:2019 and ASTM F2100-11.

Storage

Store in a dry and cool place, away from intense sources of heat.
Keep the masks as much as practicably possible in their dispenser box.
Keep dispenser boxes as much as practicably possible in their shipper

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