

TECHNICAL DATA SHEET

H300 Fluidshield

Fog-Free Surgical Mask with SO SOFT* Lining with WrapAround Visor

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Description

Reference 48247 H300 FluidShield Fog-Free Surgical Mask with SO SOFT* Lining, with WrapAround Visor, Orange

H300 Procedure and Surgical are designed for Moderate and Heavy Amounts of Fluid, Spray, and Aerosols. With Ties.

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: <49 Pa. Splash Resistance of 160 mmHg. EN14683 classification: Type IIR facemasks. ASTM F2100-11 classification: Level 3 facemasks.

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.

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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 93/42/EEC Directive on Medical Devices. Class of the device: I. Product compliant with EN14683 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 box.

Shelf life

5 years, from the date of manufacture.