

TECHNICAL DATASHEET

Omnitex Type IIR Procedure Face Mask with Tie Backs

DESCRIPTION:

Pleated rectangular face mask with shapeable nosepiece and four ties, two on each side in order to hold the mask in place. Precise pleat positions and premium materials provide a comfortable fit and retention of shape around the face.

Non Toxic & Latex Free materials reduces the risk of allergic reactions & is kind to the user.

INTENDED USE:

Procedure Face Masks are intended to be worn by personnel during medical procedures to protect both the patient and the operating personnel from transfer of microorganisms, body fluids and particulate material transfer.

ANALYSIS:

Characteristic	Testing Methodology	Acceptable Limits & Results
Bacterial Filtration Efficiency (BFE)	EN14683:2019 Ann.B	Required: $\geq 98\%$ Result: 99.64%
Differential Pressure	EN14682:2019 Ann.C	Required: $<60 \text{ Pa/cm}^2$ Result: 21.04 Pa/cm ²
Microbial Cleanliness	EN14683:2019 Ann.D	Required: $\leq 30 \text{ CFU/g}$ Result: 1.21 CFU/g
Fluid Resistance	ISO22609:2004	Required: Resistant at 16kPa Result: Passed

MATERIALS AND CONSTRUCTION:

- **Mask Body:** 3 Layers
 - Outer Layer: Spunbond Polypropylene (SBPP)
 - Middle Layer: Meltblown Filter (MBPP)
 - Inner Layer: Spunbond Polypropylene (SBPP)
- **Nose Piece :** Plastic Covered Aluminium
- **Ties :** Spunbond Polypropylene
- **LATEX FREE**

CERTIFICATIONS:

UK MHRA Registered Product and Manufacturer

CE Certified

Registered as Class I Medical Device with MHRA

EN14683: 2019 Compliant

Produced in Class 10,000 Cleanrooms

Test Performed by Independent UKAS Certified Test Lab : 4ward testing, Surrey, UK

MARKINGS:

CE Mark, Latex Free, Single use, Pack Size, Barcode, Product Code, LOT, Expiry, Manufacturer

PACKING INFORMATION:

50 Masks per pack

40 Packs per carton

15 Cartons per pallet

PRODUCT CODES:



MK-OX-50TB



Manufacturer:

Omnitex is a Registered Trademark of Sharon Services (UK) Ltd.
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OMNITEX[®]
Omnipresent Protection