OMNITEX®

TECHNICAL DATASHEET

Omnitex Type IIR Procedure Face Mask with Ear Loops

DESCRIPTION:

Pleated rectangular face mask with shapeable nosepiece and two ear loops, one 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 Methodlogy	Acceptable Limits & Results
Bacterial Filtration Efficiency (BFE)	EN14683:2019 Ann.B	Required: ≥ 98% Result: 99.49%
Differential Pressure	EN14682:2019 Ann.C	Required: <60 Pa/cm2 Result: 21.95 Pa/cm2
Microbial Cleanliness	EN14683:2019 Ann.D	Required: ≤30 CFU/g Result: 5.06 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

- **Ear Loops :** Polyester and Spandex

- **LATEX FREE**

OMNITEX®
Omnipresent Protection

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
60 Packs per carton
16 Cartons per pallet

PRODUCT CODES:

MK-OX-50DU   **MK-OX-50RL**   **MK-OX-50PK**

OMNITEX®

Omnipresent Protection