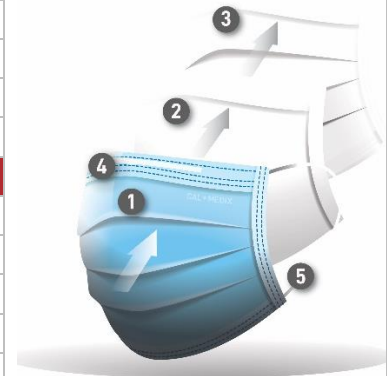


TECHNICAL DATA SHEET

ASTM LEVEL 2/ EN TYPE IIR

A 3-ply disposable medical mask manufactured in a clean room approved facility for the intended use by pharmaceutical, research and/or healthcare professionals. It is designed to prevent and spread infections and providing confidence in safety through relevant accreditations and test validations.

Key Features		
Country of Origin	Singapore	
Manufactured By	Calmedix Manufacturing Pte Ltd	
Description / Product Code	3 Ply Disposal Medical Mask	FF2-20-01
Brand / Model	Fortify	F2
Adult Size	175mm x 95mm (L x W)	
Features	Light blue / White ear loops	
	Hypoallergenic and Fluid resistant	
Specifications		
(1) Outer facial layer	Polypropylene Spunbond / Non-Woven	25 gsm
(2) Filter middle layer	Polypropylene Melt-blown / Non-woven	25 gsm
(3) Inner Facial layer	Polypropylene Spunbond / Non-Woven	25 gsm
(4) Nose Strip	Galvanized Iron, Polyethylene Covering	W (3mm)
		L (105mm)
		Ø (3mm)
(5) Ear Loop	Round / Polyester spandex blend	L (165mm)
		H (62.5mm)
Body Size	Length	L (175 mm)
	Width	W (95 mm)



Manufacturing and Safety Standards	
Product Standards Conformance	EN 14683:2019 & ASTM F2100-19
Manufacturing Standards	ISO 13485: 2016

Performance Characteristics	Testing Methodology	Acceptable Limits (Level 2 & Type IIR)	
		ASTM F2100-19	EN 14683:2019
Bacterial Filtration Efficiency (BFE)	ASTM F2101 & EN 14683	≥ 98 %	≥ 98 %
Particulate Filtration Efficiency (PFE)	ASTM F2299	≥ 98 % at 0.1 micron	Not Required
Fluid Penetration / Splash Resistance	ASTM F1862 & ISO 22609	120 mm Hg	≥ 16 kPa
Differential Pressure (ΔP) / Breathability	EN 14683	< 6.0 mmH ₂ O/cm ²	< 60 Pa/cm ²
Flammability	16 CFR Part 1610	Class 1 (≥ 3.5 seconds)	Not Required
Microbial Cleanliness	ISO 11737-1	Not Required	≤ 30 cfu/g

Usage Instructions



Blue side should be worn facing out



Loop the straps over the ear



Press metal wire down to fit the nose



Do not touch outer layer of the mask



Dispose mask in a closed bin.

Packaging	Description	Specification	Sample Image
Box (Mask)	50 pieces per box	Weight : 240 g Size : 20cm x10cm x11.5cm Color : Red	
Inner Package	10 pieces per packet	Weight : 38 g Size : 22.5cm x11.5cm Material : BOPP Film	
Carton A	20 boxes per carton (5 boxes x 2 rows x 2 layer)	Weight : 5700 g Size : 521mm x 416mm x 248mm Color : Brown	
Carton B	40 boxes per carton (5 boxes x 2 rows x 4 layer)	Weight : 10,850 g Size : 521mm x 416mm x 483mm Color : Brown	

Storage

The product has a shelf life of two (2) years. All masks boxes' shelf life is marked on the package of the product (lower bottom face). Users are encouraged to check product purchased and consumed within the appropriate shelf life. The mask should be stored in a clean, dry room temperature conditions.

Disposal

Used masks must be disposed in closed bin in accordance with local policies and procedures. Users must not touch the outer layer of the mask during time of disposal.

Limitations

Users have the obligation to ensure the mask is;

- Suitable for the objective of the use.
- Of proper fitting.
- Not reused when damp or when outer surfaced is touch.
- Not reused when in contact with other things/ exterior surfaces.
- Not reused to be worn when damaged.
- Worn at all times during exposure.

Other information

- Non-sterile and not a surgical mask.
- Not suitable for use as protection against toxic dusts, fumes, mists, gases, vapours or paints.
- For the use of adults only.