



Technical Data Sheet

Comfort+ IIR Earloop Mask Orange

Item # MED-GMK211794

SAP Material Code & Color	SAP Material Code	Product Reference Code	Color
	MED-GMK211794	GMK211794	Orange Stripes

Country of Origin Japan

Intended Use The procedure masks are intended to be worn by personnel during surgical or other medical procedures to protect both the patient and the operating personnel from transfer of microorganisms, body fluids and particulate material transfer.

Material

- Body Composition Outer material: Cellulose Paper
Middle Layer: Spunbond Polypropylene
Filter media: Melt-blown Polypropylene
Inner material: Cellulose Paper

- Elastic Band Composition Polyurethane; Polyester

- Nose-piece Composition Polyethylene covered metal strip

Dimensions

- Body Size Length: 175 mm; Width: 90 mm

- Length of Nose-piece 118 mm

- Pleat Depth 15 mm

Complied Standard	EN 14683: 2019 Type IIR	ASTM F2100-19 Level 2
Bacterial Filtration Efficiency (BFE)	BFE @ 3.0 μm Bacteria $\geq 98\%$	BFE @ 3.0 μm Bacteria $\geq 98\%$
Differential Pressure (ΔP)	$\Delta P < 60 \text{ Pa/cm}^2$	$\Delta P < 6 \text{ mm H}_2\text{O/cm}^2$
Fluid Resistance	Resistance @ 16 kPa	Resistance @ 120 mmHg
Particulate Filtration Efficiency (PFE)	Not Required	PFE @ 0.1 μm large Latex particles $\geq 98\%$
Textile Flammability	Not Required	Class I flame spread
Microbial cleanliness	$\leq 30 \text{ cfu/g}$	Not Required

Sterility Non-sterile

Usage Disposable, single-use only

Packaging 50 masks per box, 12 boxes per case

Recommended Storage Conditions Store under cool, clean, and dry conditions. Avoid excessive heat (over 40°C or 104°F)