

# MEDICAL FACE MASK







# SAFE, CLEAR COMMUNICATION

The **Smile Shield™** has changed the way people connect. Offering **Protection**, yet allowing **clear communication**.

The mask is perfect for areas where facial expression, lip reading or greater connection is required.

CARE HOMES | HOSPITALS | DISABLED CARE | EDUCATION

# **COMPLIANT TO UK TRANSPARENT MASK SPECIFICATION**



ANTI FOG CLEAR PANEL



HYPO-ALLERGENIC

50's Pack

Box Code: SSMIIR50 50 p/Box (15x7x7cm)



COMFORTABLE EAR LOOPS



>98% BFE



ADJUSTABLE NOSE STRIP





8.8kg p/Case

Box Code: SSMIIR10 10 p/Box (13.5x23x2cm) 2,000 p/Case (40x40x60cm)

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\*Clauses 5.2.2 | 5.2.3 | 5.2.4 | 5.2.5 | 5.2.7

\*\*Clauses 7.1.3 & 7.3.2







## SMILE SHIELD™ PRODUCT INFORMATION

Smile Shield™ felt material is compliant to EN14683:2019+AC+2019 (Clause 5.2.2, Clause 5.2.3, Clause 5.2.4, Clause 5.2.5 & Clause 5.2.7) and transparent area to EN166 (7.1.3 & 7.3.2) in accordance with The UK Transparent Face Mask Specification (Updated 31<sup>st</sup> July 2021).

EN14683:2019+AC:2019 (Felt Material)	Requirement	Smile Shield™
5.2.2 Bacterial Filtration Efficiency (BFE) (%)	≥ 98%	Pass
5.2.3 Breathability (Pa/cm2)	< 60,0	Pass
5.2.4 Splash Resistance (kPa)	≥ 29 @ 16k Pa	Pass
5.2.5 Microbial Cleanliness (cfu/g)	≤ 30	Pass

EN166 (7.1.3 & 7.3.2) (Clear Panel)	Requirement	Smile Shield™
7.1.3 Quality of material and surface	Free of Defects likely to impair vision	Pass
7.3.2 Resistance to Fogging	Free from fogging (8s)	Pass

## PACKAGING DETAILS (50's Box)

	Unit	Code	Quantity Per Unit	Dimensions (L X W X H cm)	Net Weight (kg)	Gross Weight( kg)
50's Pack	Box	SSMIIR50	50	19 x 9.7 x 7	0.190	0.215
	Case	SSMIIR2000	2,000 (40 Boxes)	52 x 41 x 33	7.6	8.8
Mask	Mask	N/A	N/A	17.5 x 9.5 x 0.2	0.0039	0.0039

Storage: Store under cool, clean dry conditions. Avoid storage in excessive hear (>40°)

Usage: Single Use

Product Classification: Medical Device according to Regulation (EU) 2017/745 on Medical Devices (MDR)

Marking: The product is CE Marked

### **FEATURES**

- Felt Material Compliant to EN14683 (Clause 5.2.2, Clause 5.2.3, Clause 5.2.4, Clause 5.2.5 & Clause 5.2.7)
- Anti Fog Clear Panel Compliant to EN166 7.1.3 & 7.3.2
- Fluid Resistant

- Hypoallergenic
- Latex Free
- Comfortable Ear Loops
- Adjustable Nose Strip
- Compliant to UK Transparent Mask Specification (Updated 31 July 21)



#### **PRODUCT MATERIALS**

The **Smile Shield™** is made from the materials detailed below.

Mask Area	Requirement
	Outer: Non-woven fabric (100% polypropylene fiber)
Mask Body (Felt Material)	Inner: Melt Blown
	Outer: Non-woven fabric (100% polypropylene fiber)
Clear Panel	CPP Film
Nose Bridge	Aluminium & Plastic
Ear Loops	Spandex

The Smile Shield is free from Glass Fibres, Latex and Additives.

The Smile Shield is Hypoallergenic and has passed the tests detailed below:

Test items	Standard	Result	Report No.:
Test for in vitro cytotoxicity (MTT cytotoxicity test)	ISO10993-5:2009	Pass	SSMT-R-2020-03682-01A
Test for in irritation (Animal skin irritation test)	ISO10993-10:2010	Pass	SSMT-R-2020-03682-02A
Test for skin sensitization (Closed- patch test)	ISO10993-10:2010	Pass	SSMT-R-2020-03682-03A

#### **BENEFITS**

Human connection is built on clear communication. The benefits of **Smile Shield™** include:

- Clear Communication
- Allows Lip Reading

- Visible Facial Expressions
- Deeper Connection

## **END USERS**

The Smile Shield™ is used across multiple areas such as:

- Hospitals
- Care Homes
- Domiciliary Care
- Schools / Universities / Colleges

- Business & Industry
- Retail
- Hospitality
- Police & Prisons



