



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 31st 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/cm ²)	< 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

	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 heat (>40°)

Usage: Single Use

Product Classification: Medical Device according to Directive 93/42/EEC

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
Mask Body (Felt Material)	Outer: Non-woven fabric (100% polypropylene fiber) Inner: Melt Blown Outer: Non-woven fabric (100% polypropylene fiber)
Clear Panel	PET 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
- Visible Facial Expressions
- Allows Lip Reading
- Deeper Connection