

C-Smile[®] T1

Medical grade transparent face mask

Compliant to the Transparent Face Mask Specification on www.gov.uk
Relevant clauses of BS EN14683:2019 & BS EN166:2002





Instructions for use

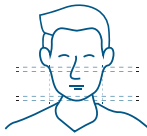
Intended use


The **C-Smile T1 transparent face mask** is a non-sterile medical device and recommended for single shift use. Its primary purpose is for healthcare professionals, healthcare workers, first responders and other personnel to protect the patient from infection via direct breath, vapour, liquid splashes, and droplets at the same time as letting their facial expressions being seen.

Donning the mask

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1 Wash hands thoroughly before removing the C-Smile T1 from packaging.
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2 Ensuring the Comfort Nose Band is at the top, pull the two elastic loops over your head. Adjust the bottom loop to be below your ears.
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3 Align the Comfort Nose Band two thirds down the bridge of your nose. Tie further knots in the elastic to tighten if necessary.
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4 Do not touch mask again unless you plan to remove it.

Removing the mask

1. Remove mask by pulling elastic over your head not touching the surface of the mask.
2. Dispose of the mask in a covered waste bin immediately after removing from your face.
3. Wash your hands thoroughly after disposing of your mask.

*The T1 should sit comfortably below your glasses, if you experience any interference lower the mask on the bridge of the nose and ensure it is central.

Cautions

- This is a disposable, single shift use product, do not use if packaging is damaged.
- Do not share product to prevent cross infection.
- Do not use the mask if it is damaged e.g. ripped or torn.
- Do not try to clean the mask as it is not a reusable product, it should be disposed of safely after each shift use
- Any adverse reaction or serious incident with the device should be reported to the manufacturer and competent authority.

C-Smile T1 is a single use device and should be disposed of safely, and according to medical waste disposal guidelines. It should not be re-used.



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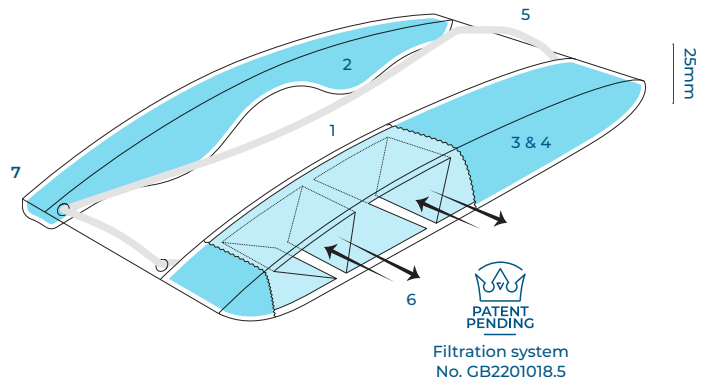
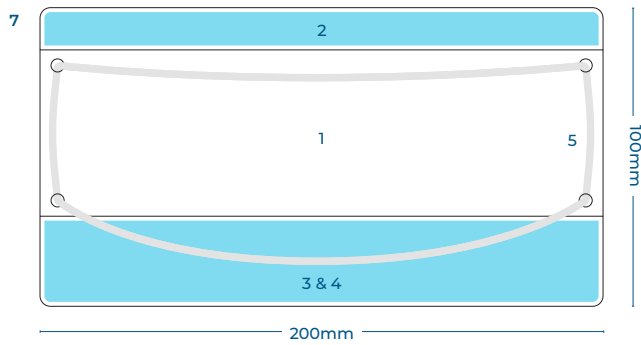
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ECTOVISE[®]

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C-Smile® T1 Technical details



Component/Device	Material
1 Transparent Plastic Shield	Anti Fog PET
2 Comfort Nose Band	PU Foam
3 Comfort Chin Filter Frame	
4 Filtration	Meltblown + Spunbond PP
5 Strap	Latex Free Elastic
6 Filtration System (3 + 4)	Meltblown + Spunbond PP + PU Foam
7 C-Smile T1 (Complete Mask)	All of above list



Do not use if package is damaged



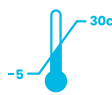
Not made with natural rubber latex



Single use



Keep dry



Store (and/or) use within temp range of -5 to 30c



Non sterile



Store out of sunlight



Ultra-clear PET protective shield



Anti-fog

Regulatory

- Meets the splash resistance performance requirements for type IIR surgical masks (EN14683:2019+AC:2019, chapter 5.2.7).
- Meets the microbial cleanliness (bioburden) performance requirements for type IIR surgical masks (EN14683:2019+AC:2019, chapter 5.2.7).
- The filter area meets the breathability performance requirements for type IIR surgical masks (EN14683:2019+AC:2019, chapter 5.2.7).
- The filter area meets the bacterial filtration efficiency performance requirements for type IIR surgical masks (EN14683:2019+AC:2019, chapter 5.2.7).
- The panoramic window meets the EN166:2002 resistance to fogging (anti-fog) performance requirements.
- Meets requirements of the MDR for medical devices 2017/745.
- In conformity with Directive 93/42/EEC on medical devices (Annex VII) as brought into UK law and amended 'Medical Devices Regulations 2002 (SI 2002 No 618)'



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