

Face mask

Country of origin | United Kingdom of Great Britain and Northern Ireland

Primary function | Prevention

Category | Medical device

Commercial information

List price (USD): 2.5

Year of commercialization: 2021

Number of units distributed: Unknown

Currently marketed in: United Kingdom

Brand: Triple 1 Group LTD UK

Model: Transparent Face Mask



Product description

A certified medical transparent face mask for adults and children conforming to the standard EN14683 medical device. Approved by the Medical Health Regulatory Agency [MHRA].

Product details

Facility requirements: Healthcare waste disposal facilities (disposal of face mask), disposal guidance provided by the manufacturer

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NOTE: Information reported by manufacturer before 17 December 2021

WHO ASSESSMENT

Clinical assessment

In community settings where SARS-CoV-2 transmission is known or suspected, WHO advises that the general population use a non-medical mask indoors or outdoors if physical distancing of at least one meter cannot be maintained. Unless appropriate ventilation is ensured, WHO also advises that the general public wear a non-medical mask indoors, regardless of whether physical distancing can be maintained.

In healthcare settings, WHO recommends that healthcare practitioners that provide care to suspected or confirmed COVID-19 patients wear a medical mask in the absence of aerosol-generating procedures (AGPs). In contrast, respirators (N95 or FFP2 or FFP3 standards) are recommended where AGPs are performed if they are widely available.

This transparent face mask could be utilized best as a non-medical mask in community settings, where it may represent a single-use option for facilitating communication between mask wearers and patients with disabilities or special needs. Its use in resource-limited environments would be contingent upon non-clinical factors, including costs and ease of distribution.

WHO specification comparison







This device is a "Face mask" that can be used by nurses, physicians, and other health staff. The most similar WHO technical specifications that could be used for any compliance evaluation could be the "Medical mask" and/or the "Surgical Face mask".

This device complies with the "Medical Mask" (fluid resistant) and the "Surgical Face Mask" WHO technical specifications. It is restricted for community and emergency use. The product is not a respirator and should not be worn for extended use.

Compliance: Medical mask, good breathability, internal and external faces clearly identified, Bacterial Filtration Efficiency (BEF) higher than 98%, fluid resistance, and EN 14683 Type IIR compliant (test report provided).

Non-compliance: To EN 149 or NIOSH 42 CFR Part 84.

Regulatory assessment

 Pre-market assessment	 Proceed with caution
 Post-market assessment	 Not acceptable
 Quality system assessment	 Proceed with caution

Pre-maket - The validation report is not comprehensive for the medical-grade mask.; conforms to the standard EN14683 medical device and is approved by MHRA.

WHO specification: compliance: Bacterial Filtration Efficiency (BFE):

Fluid resistant masks (surgical masks):

- EN 14683 Type IIR
- ASTM F2100 Level 1, 2 or 3
- YY 0469, with at least 98% bacterial droplet filtration

Non-fluid resistant mask:

- EN 14683 Type II
- YY/T 0969, with at least 98% bacterial droplet filtration USFDA; 6-406 ASTM F1862/F1862M-17

Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)

























- 6-425 ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks
- 6-427 ASTM F2101-19 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus

Non-compliance: to EN 149 or NIOSH 42 CFR Part 84.

Post-maket - documentation not provided

QMS - Is based on ISO 9001 Adequate documentation was not provided to perform a medical device Regulatory or Quality System review.

Technology evidence assessment

Domains	Evidence assessment		Summary
	Risk/benefit ratio	Impact	
 Medical			<p>The device is commercially available. According to the information provided, it is intended for use in community and hospital settings. The test results indicate a protective potency in the community. There is a lack of evidence on clinical settings, particularly in high contagious areas, so sufficient effectiveness in this area is uncertain. From a social standpoint, it should be noted that the device appears to be useful for gathering information about facial expressions in social interactions as well as in the treatment of mental illness due to the mask design. Given that the mask is intended for single use only, the intended price per mask appears to be quite high for low-resource settings. As a result, affordability and environmental friendliness are both questioned. To summarize, the device should be included but only for community use.</p> <hr/> <p>Innovation</p> <p>Technology evidence assessment</p> <p>Technology readiness level 9</p> <p>Recommend with caution</p>
 Safety			
 Economy			
 Organizational			
 Legal			
 Social			
 Ethical			
 Green environment			

Health technology and engineering management

Domains	Appropriateness	Domains	Appropriateness	Target settings: Rural, Urban, Outdoors & Home
Durability		Ease of cleaning		<p>The transparent mask properties are difficult to evaluate due to the limited information available for this product. More data is needed to determine the product's disposition and effectiveness in prevention. Although the submission claims to have a fog-resistance clear window to facilitate better communications, evidence for its effectiveness and durability was not provided. Currently, disposable masks are available on the market at a reasonable price.</p>
Ease of Use		Ease of maintenance		
Positive impact on clinical outcomes		Infrastructure requirements		
Affordability		Local access to sales support		
Engineering resources minimization		Local access to technical support		
Cultural and social acceptability		Local access to training		
Environmental conditions		Local access to spare parts		
Aesthetics		Locations of use within target setting		

Intellectual property and local production

Technology transferability		Intellectual property - Protected by trade secret. Clearance to use this technology is required.
Openly access intellectual property		Local production - Local production will reduce costs, but regional product demand has to be high enough to justify the business case.
Local production		

WHO related guidance material

- Mask use in the context of COVID-19 - [https://www.who.int/publications/i/item/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-\(2019-ncov\)-outbreak](https://www.who.int/publications/i/item/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-(2019-ncov)-outbreak)
- Rational use of personal protective equipment for coronavirus disease (COVID-19) and considerations during severe shortages: interim guidance, 23 December 2020 - [https://www.who.int/publications/i/item/rational-use-of-personal-protective-equipment-for-coronavirus-disease-\(covid-19\)-and-considerations-during-severe-shortages](https://www.who.int/publications/i/item/rational-use-of-personal-protective-equipment-for-coronavirus-disease-(covid-19)-and-considerations-during-severe-shortages)
- Infection prevention and control during health care when coronavirus disease (COVID-19) is suspected or confirmed: interim guidance, 12 July 2021 - <https://apps.who.int/iris/handle/10665/342620>
- WHO Standard precautions in health care - <https://www.who.int/publications/m/item/standard-precautions-in-health-care>
- WHO Coronavirus (COVID-19) Dashboard - <https://covid19.who.int/>