Face mask Country of origin | Unit

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



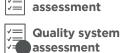
Pre-market assessment

Post-market



Proceed with caution







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 Risk/benefit Impact ratio



Medical

Safety

Economy

Organizational



























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 guite 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.

The device is commercially available. According to the information



Legal

Social









Summary



Ethical





Innovation

Technology evidence assessment **Recommend with** caution



Green environment









Health technology and engineering management

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