



CLASS 1: DISPOSABLE 3 PLY MEDICAL FACE MASK WITH EAR LOOP

This is for use in the medical industry and has been manufactured under the guidance outlined in the medical devices directive 93/42/EEC (MDD)

This is not PPE and is not certified under the PPE Regulation (EU) 2016/42.

The product is manufactured :

- Following the requirements outlined in EN14683 - our manufacturer has provided evidence to show the product meets EN14683, and we are further testing the product with ITS as additional due diligence.
- Under an approved quality management system which meets ISO 13485, this has been performed and issued by SGS.
- The product is single use only & is non sterile.
- The item is a Type I mask which means it is suitable to reduce the risk of spread of infections.

In terms of performance the type I mask meets the below:

Bacteria filtering effectiveness	> 95%.
Differential pressure	< 40
Splash resistance (not tested)	Not applicable to type I
Microbial cleanliness	< 30