

E C Declaration of Conformity



Medical Filtration Solutions Ltd,
72 Roman Way Industrial Estate,
Longridge Road,
Preston,
Lancashire
PR2 5BE
United Kingdom

Medical Filtration Solutions are solely responsible for this declaration of conformity. Declaring that the undernoted Medical Device(s) is/are in conformity with the essential requirements and provisions of the Medical Devices Regulations 2002, and Harmonised Standards and / or other Technical Standards listed below.

Medical Device(s)

Medical face mask. Indicated by product family prefix 'F13'.

The main intended use of medical face masks is to protect the patient from infective agents and, additionally, in certain circumstances to protect the wearer against splashes of potentially contaminated liquids. Medical face masks may also be intended to be worn by patients and other persons to reduce the risk of spread of infections, particularly in epidemic or pandemic situations.

Part codes of current 'F13' listed below:

Product code		
F13	1	001

Device Classification & criteria

Medical Devices Directive 93/42/EEC, Annex IX, Section 3:

Rule 1: Class I

Relevant Directives & Standards

Medical Devices Directive 93/42/EEC Annex VII Class I

Title	Ref number	Issue	Harmonised standard
Medical Devices Regulations	UK MDR	2002	Y
Medical Device Directive	93/42/EEC	2007	Y
Biological evaluation of Medical Devices. Part 1 Evaluation and Testing	ISO 10993-1	2009	Y
Medical devices – Quality management systems - Requirements for regulatory purposes.	BS EN ISO 13485	2016	Y
Medical face masks – Requirements and test methods	EN 14683	2019	Y
Personal eye-protection – Specifications (Section 7.3.2 – excluding conditioning)	EN 166	2002	Y
Medical devices- Application of risk management to medical devices	BS EN ISO 14971	2012	Y
Medical devices – symbols to be used with medical Device labels, labelling and information to be supplied. Part1: General requirements	ISO 15223-1	2016	Y

Company Director and/or Management Representative:

Name: KARL HOWARD

Position: DIRECTOR

Signed by: 

Place & Date of validity: PRESTON, UK

2nd March 2022