

L1 Medical Mask

Mask Type: Flat/Medical

Designed to meet: AS 4381:2015 –Single-use face masks for use in healthcare

- Bacterial Filtration Efficiency (BFE) =95%
- Differential Pressure, < 5mmH₂O/cm²
- Resistance to penetration by synthetic blood to 160mmHg

Summary Of Testing

Certificate	Description	Scope	Certificate No.	Date	Expire date	Who by
CE Certificate - Manufacturer Declaration of Conformity	N/A	Desposable Medical Mask (L 175*95mm; M 145*95mm; M 125*85mm)	N/A	5th JUN 2020	N/A	Manufacturer & EC Representative SUNGO Europe B.V.
CE CIGB Registration	EC Representative registration evidence	N/A	N/A	N/A	N/A	N/A
ISO 9001:2015 Certificate	N/A	Production non-woven fabric and face mask (products with licensing requirements are excluded)	USA17Q45496R0M	Initial Issuance: 26th Feb 2013; Issuance: 27th OCT 2017	26th OCT 2020	Beijing East Allreach Certification Center Co., Ltd
nqa Class I Certificate	N/A	Nonwoven Fabric; Face Mask; Surgical Gown; Surgical Instruments Wrapper; Surgical Drape; Isolation Gown	No.02486	26th FEB 2016	N/A	NQA
ISO 13485:2016 Certificate	N/A	Production and Distribution of Disposable Normal Medical Face Mask, Medical Bed Sheet, Surgical Gown, Wrapper, Medical Drape, Isolation Gown, Surgical Combination Package	Q60986220002Rev.00	8th JAN 2019	24th AUG 2020 (Annual Audit finished, certificate will renew on 24th AUG 2020)	TUV SUD Product Service GmbH - Certification Body - Ridlerstraße 65 - 80339 Munich - Germany
FDA	Searched via FDA web	Face Mask; Surgical Gown; Isolation Gown; Examination Gown (Tissue+Poly); SURGICAL CAP; Disposable Bed Sheets; Disposable Prophyl Cup; Air/Water Syringe Tip; Micro Applicator; Impression Mixing Tips	Registration Number: 3003071753	Current Registration Year 2020	N/A	FDA
ASTM F2100-19e1	Brand - The Complete Guardian	Disposable Medical Mask Level 1, Level 2 and Level 3	Issue at 24th Jul 2020	24th Jul 2020	N/A	BSI
AS4381:2015	Brand - The Complete Guardian	Disposable Medical Mask Level 1, Level 2 and Level 3	BMP 731192	22nd Jul 2020	N/A	BSI

Summary Completed Testing Reports and Certificates

- **TGA - ARTG Identifier 337636 - Medical Device Included Class 1**

- **FDA - Registration no. 3003071753**

- **Nelson Lab -**

Bacterial Filtration (BFE) at an Increased Challenge Level STP0009 Rev10

Viral Filtration Efficiency (VFE) STP0007 Rev15

Latex Particle Challenge STP0005 Rev05

- **CE - Medical Device Directive (93/42/EEC)**

- **TUV SUD - EN13485 - No. Q6 098622 0002 Rev.00 - 08, EN14683:2019 - 721654580**

Bacterial Filtration (BFE)

Differential Pressure Test (Pa/cm²)

Synthetic Blood Penetration Test (kPa)

Microbial Cleanliness Test (CFU/g)

Type IIR - EN13485

- **nqa - 02486**

Medical Device Directive (93/42/EEC) including (2007/47/EC)

- **Test Report - Vic Lab - 200654**

Differential Pressure Test (mm,H₂O/cm²)

Synthetic Blood Penetration Test (mm Hg)

- **China Patent**

- **BSI Certificate - BMP 731192**