



## EC Declaration Of Conformity

**Manufacturer**      **Zhejiang Mashang Technology Co.,Ltd.**  
**Address**            **No. 366 Shanhai Avenue, Lingxi Town, Cangnan County, Wenzhou City, Zhejiang Province, China 325800**  
**EC Representative**    **MedPath GmbH**  
                               **Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany**  
                               **0049-89 189174474**  
**Product:**            **Disposable Medical Mask**  
**Model:**             **MSYCY-01**  
**Umdns:**             **12447**  
**Classification (MDD, Annex IX):**    **Class I      Rule 1**

We herewith declare under sole responsibility that the above mentioned products meet the transposition into national law. The provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are sole responsible for the DOC.

### DIRECTIVES

General applicable directives:

Medical Device Directive : COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC), amended by 2007/47/EC.

Applied Standards:

EN 14683:2019+AC:2019;

Place, Date: **Wenzhou, 02.06.2020**

Signature: 

Name/Position: **Wei Qian / General Manager**





中国认可  
国际互认  
检测  
TESTING  
CNAS L0599

**Test Report**                      **SL52025257421601TX**                      **Date: June 10, 2020**                      **Page 1 of 3**  
 ZHEJIANG MASHANG TECHNOLOGY CO.,LTD.  
 NO.366 SHANHAI AVENUE, LINGXI TOWN, GANGNAN COUNTY, WENZHOU CITY, ZHEJIANG PROVINCE,  
 CHINA 325800

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description : Disposable Medical Mask

Style No. : MSYCY-01  
 Composition : 65%non-woven fabric,35%melt-blown fabric  
 Sample Color : blue  
 Manufacturer : ZHEJIANG MASHANG TECHNOLOGY CO.,LTD.

Proposed Care Instruction : /

Test Performed : Selected test(s) as requested by applicant

Sample Receiving Date : May 13, 2020  
 Testing Period : May 13, 2020 - Jun 10, 2020  
 Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Signed for and on behalf of  
 SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

Dongjing Liu (Authorized Signatory)



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Member of the SGS Group (SGS SA)

Test Result

**Medical Face Masks-Requirements and Test Methods**

(EN 14683:2019+AC:2019)

**Clause 5.2.2 Bacterial filtration efficiency (BFE)**

(EN 14683:2019+AC:2019 Annex B)

|          | 1#   | 2#   | 3#   | 4#   | 5#   |
|----------|------|------|------|------|------|
| (BFE), % | 99.8 | 99.7 | 99.8 | 99.8 | 99.7 |

Remark: Performance Requirement: Type I ≥95%, Type II ≥98%, Type IIR ≥98%

\* This test standard is not within the accredited scope in SGS Shanghai testing centre, it is carried out by external laboratory accredited by CMA (China Metrology Accreditation).

**Clause 5.2.3 Breathability (Differential Pressure)**

(EN 14683 :2019+AC:2019 Annex C, Flow rate 8 l/min)

|  | 1# | 2# | 3# | 4# | 5# |
|--|----|----|----|----|----|
| Differential pressure ΔP (Pa/cm <sup>2</sup> ) | 38 | 37 | 38 | 38 | 37 |

Remark: Performance Requirement: Type I <40 Pa/cm<sup>2</sup>, Type II <40 Pa/cm<sup>2</sup>, Type IIR <60 Pa/cm<sup>2</sup>

**Clause 5.2.4 Splash Resistance**

(ISO 22609 :2004, Pressure 16.0 kPa)

| <b>Penetration on inside surface</b> |      |      |            |      |      |      |      |
|--------------------------------------|------|------|------------|------|------|------|------|
| 1#                                   | 2#   | 3#   | 4#         | 5#   | 6#   | 7#   | 8#   |
| Pass                                 | Pass | Pass | Pass       | Pass | Pass | Pass | Pass |
| 9#                                   | 10#  | 11#  | 12#        | 13#  | 14#  | 15#  | 16#  |
| Pass                                 | Pass | Pass | Pass       | Pass | Pass | Pass | Pass |
| 17#                                  | 18#  | 19#  | 20#        | 21#  | 22#  | 23#  | 24#  |
| Pass                                 | Pass | Pass | Pass       | Pass | Pass | Pass | Pass |
| 25#                                  | 26#  | 27#  | 28#        | 29#  | 30#  | 31#  | 32#  |
| Pass                                 | Pass | Pass | Pass       | Pass | Pass | Pass | Pass |
| Number of Pass:                      |      |      | 32         |      |      |      |      |
| Overall result:                      |      |      | Acceptable |      |      |      |      |

Remark:

- 1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR: ≥16.0kPa
- 2) Distance of the medical face mask target area surface to the tip of cannula is 300±10mm.
- 3) Condition and Test temperature (21±5)° C, relative humidity (85±10)%
- 4) An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show pass results



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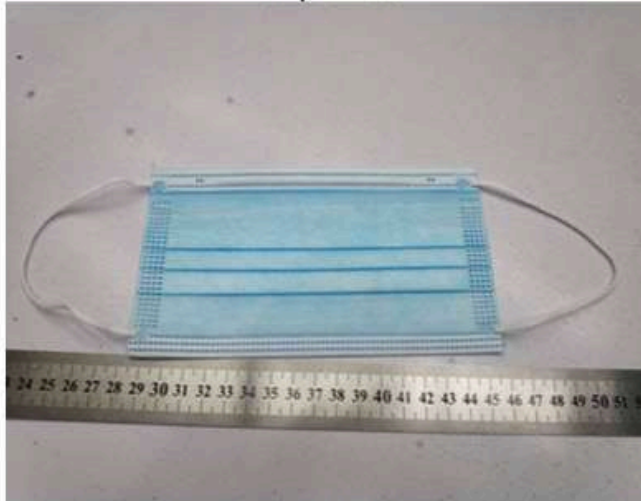
**Clause 5.2.5 Microbial Cleanliness**

(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

|       | 1# | 2# | 3# | 4# | 5# |
|-------|----|----|----|----|----|
| CFU/g | <1 | <1 | <1 | <1 | <1 |

Remark: Performance Requirement: Type I ≤ 30 CFU/g, Type II ≤ 30 CFU/g, Type IIR ≤ 30 CFU/g

**Sample Photo**



The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

\*\*\*End of Report\*\*\*



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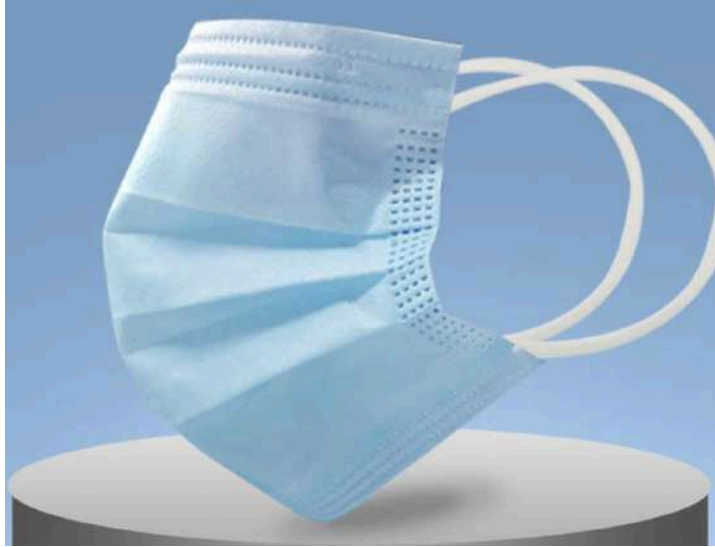
## CONDITIONNEMENT



| Dimension (cm) | Poids net(kg) | Poids brut (kg) | Quantité/Carton |
|----------------|---------------|-----------------|-----------------|
| 52 X 40 X 38   | 8.7           | 9,7             | 2000            |

5sachets de 10pcs dont 50pcs/Boîte

40boites/Carton

Palette de 30colis



|  |  |
|--|--|
| <p><b>Masque chirurgical jetable</b><br/>Standard:EN14683:2019+AC 2019 TYPE II R</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p>175X95mm</p> </div> <div style="border: 1px solid white; padding: 5px; font-size: small;">             50pcs/boite<br/>40boites/carton<br/>2000pcs/carton<br/>Couleur:BLEU         </div> </div> <div style="margin-top: 20px;">  </div> | <p><b>QTY: 2000 PCS</b><br/><b>G.W: 9.7 KGS</b><br/><b>N.W: 8.7 KGS</b><br/><b>MEAS: 52*40*38 CM</b><br/><b>MADE IN CHINA</b></p> <p style="font-size: x-small; margin-top: 10px;"> <b>Manufacturer: Zhejiang Mashang Technology Co.,Ltd.</b><br/>             Add.No. 268 Shantai Avenue, Lingqi Town, Cangnan County, Wenzhou City, Zhejiang Province, China 325900         </p> |
|--|--|

520X400X380MM