MASQUE MEDICAL TYPE II R

Masque Chirurgical Jetable EN14683:2019 + AC:2019 TYPE II R

【Modèle et spécification】
Modèle : MSYCYY-01 spécification : 175x95mm non stérile

【Précautions】
1. Ce produit est à usage unique et la durée d'utilisation recommandée est de 4 heures.
2.Veuillez vérifier l'emballage et la date de production avant utilisation. N'utilisez pas si l'emballage ou le masque endommagé. En cas de dyspnée, d'endommagement et de pollution du masque (tache de sang, gouttelettes et autres corps étrangers) etc, changez votre masque.
3.Le masque est un moyen de protection complémentaire, qui ne remplace pas les gestes de barrières.

【Instructions d'utilisation】
1. Lavez vous les mains puis ouvrez le masque, orientez le côté avec barrette nasale vers le haut, la face blanche vers l'intérieur et la face colorée vers l'extérieur.
2. Placez les élastiques du masque sur les deux oreilles.
3. Appuyez légèrement sur la barrette nasale pour l'adapter à l'arrête du nez, puis ajuster l'éxtrémité inférieure du masque sur le menton.
4. Pour le retirer vous ne touchez que les élastiques.
5. Jetez votre masque usé dans une poubelle fermée puis lavez vous les mains.

【Méthode de stockage】
Le produit doit être stocké à température ambiante entre -20°C/+40°C bien aéré à l'abri du soleil avec une humidité relative non supérieure à 75%.

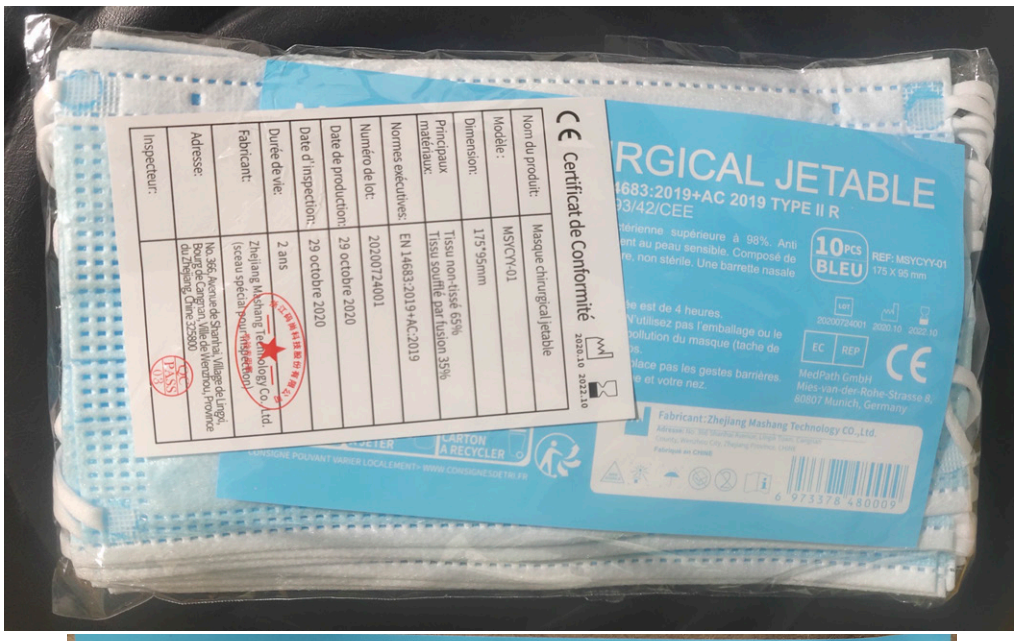
【Période de validité】
2ANS après production

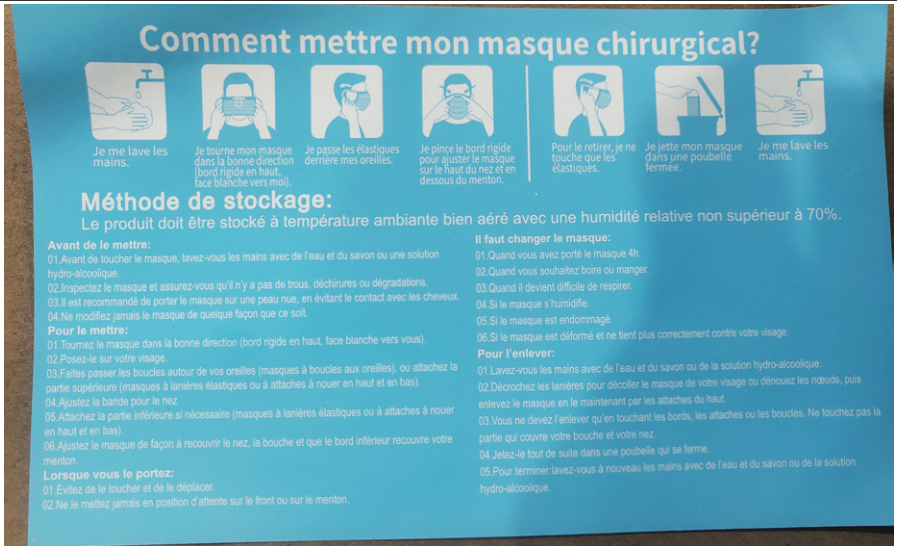
【Principaux matériaux】
Tissu non-tissé 65%, Tissu soufflé par fusion 35%

Fabriqué en CHINE

Les côtés de la boîte

A l'intérieur de la bôite Sachets de 10pcs X 5 Peut être vendu séparément





CE

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:	**MSYCYY-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

EC Declaration of Conformity
EC Declaration of Conformity
EC Declaration of Conformity
EC Declaration of Conformity

中国认可
国际互认
检测
TESTING
CNAS L0599

Test Report **SL52025257421601TX** **Date:June 10,2020**

ZHEJIANG MASHANG TECHNOLOGY CO.,LTD.
NO.366 SHANHAI AVENUE, LINGXI TOWN, CANGNAN 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.	:	MSYCYY-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)

3rd Building,No.889,Yishan Road,Xuhui District,Shanghai,China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgsgroup.com.cn
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64958763 e sgs.china@sgs.com

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 △P (Pa/cm^2)	38	37	38	38	37

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

Clause 5.2.4 Splash Resistance
(ISO 22609 :2004, Pressure 16.0 kPa)

Penetration on inside surface							
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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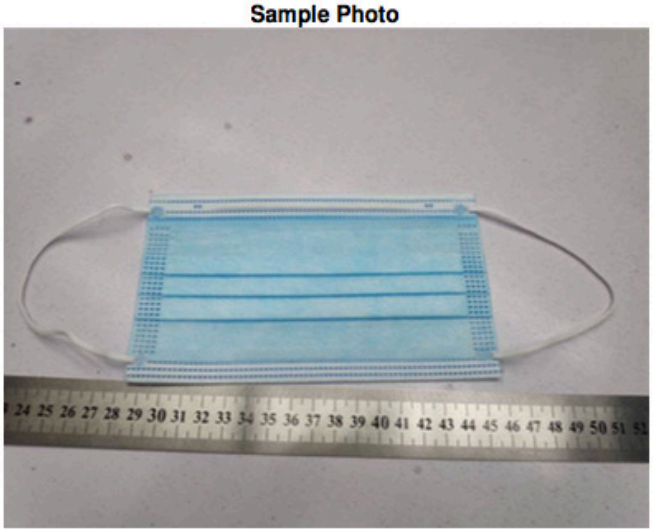
Clause 5.2.5 Microbial Cleanliness

(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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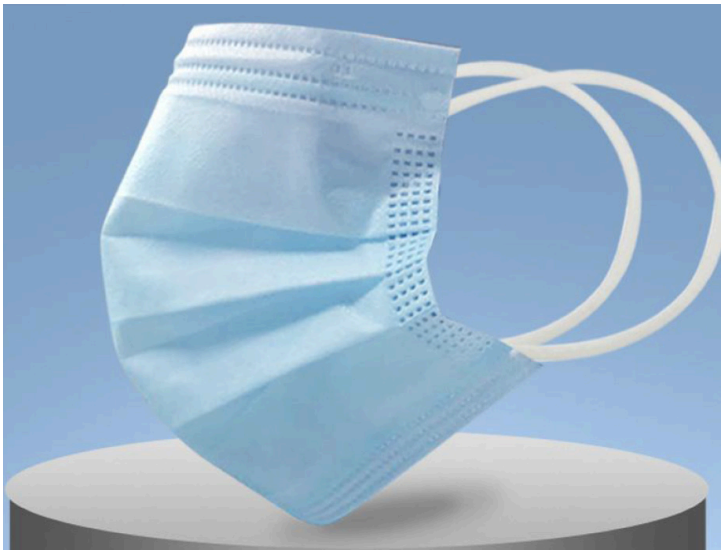
CONDITIONNEMENT

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**



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