

TYPE I

3 PLY MASK

CERTIFICATE(S)

EC Declaration of Conformity
Regarding Medical Device Directive(93/42/EEC)
including Directive 2007/47/EC

Applicant

Name: Guangdong Winsun Personal Care Products Co.,Ltd
Address: NO.1 Guangxing Road,Xiqiao Sci-Tec Industrial Park,Xiqiao Town,Nanhai District,Foshan City,Guangdong Province, P.R.China

EC Representative

Name: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Disposable hygiene face mask

Type: 17.5cm*9.5cm, 14.5cm*9.5cm

Classification: Class I (MDD, Annex IX), Rule 1(All non-invasive devices are in class I)
Conformity Assessment Route: Annex VII

We confirm our product can meet the requirement of Medical Device Directive(93/42/EEC) and the following harmonized standards.

EN ISO 14971:2012
EN ISO 15223-1:2016
EN 1041:2013
EN ISO 10993-1:2009/AC:2010
EN ISO 10993-5:2009
EN ISO 10993-10:2013

Signature:



Date: 2020.3.13

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.





Authorized Signature (S)

TEST REPORTS



Test Report

No.: GZCPCH200300773

Report date: 3/24/2020

Customer Name: Guangdong Winsun Personal Care Products Co., Ltd.
 Address: No.1, Guangxing Road, Xiqiao Technology Industrial Park, Xiqiao Town, Nanhai District, Foshan, Guangdong Province
 Sample Name: Disposable face mask
 Lot number/date: GD200059A/2020-02-28
 Manufacturer: Guangdong Winsun Personal Care Products Co., Ltd.

The above samples and information are provided and confirmed by the customer. SGS does not assume the responsibility for verifying the accuracy, appropriateness and / or completeness of the information provided by the customer.

SGS Job No.: GZCPCH200300773
 SGS Ref. No.: GZHL2003005413OT, CANCPCH2002628501
 Sample receipt date: 3/9/2020
 Sample testing date: 3/9/2020~3/24/2020

Testing requirements:

According to the applicant's requirements:
See next page

Testing method:

See next page

Test result:

See next page

Unless otherwise stated, the inspection results are only responsible for the tested samples. Without the consent of the inspection agency, the client shall not use the inspection results for improper publicity. No test report or certificate (except full text copy) shall be copied without written approval.

SGS authorized signatory:



Denny Li



SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch

RAND: 8464116



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Testing method:

Method provided by the customer(Q/YS 4-2020 for Disposable Protective Mask)
YY 0469-2011 for Medical Surgical Mask

Test results:

Test items	Unit	Testing method (for reference)	Limit **	Test Results	Individual judgment		
Appearance	/	Method provided by the customer (Q/YS 4-2020)	The appearance of the mask should be neat, the shape is intact, and the surface must not be damaged or stained	Conformed	Conformed		
Structure and size	/		(17.5cm×9.5cm) ± 0.5cm	17.6cm×9.6cm	Conformed		
Mask straps	/		Mask straps should be easy to wear and take off	Conformed to the requirements of the standard	Conformed		
			The breaking strength of the connection point between each mask strap and mask body should not be less than 5N	#1: 14.96N #2: 15.00N #3: 18.48N			
Nose clip	/		The mask must be equipped with a nose clip, which is made of a flexible plastic material	Conformed	Conformed		
			The length of nose clip should not be less than 8cm	Conformed			
Breathing resistance*	Pa		Inspiratory resistance (Pa): ≤350 Expiratory resistance (Pa): ≤250	Inspiratory resistance	Without pretreatment	89.1	
					Pretreated	90.2	
					Expiratory resistance	Without pretreatment	89.6
						Pretreated	91.3
		Expiratory resistance			Without pretreatment	76.5	
					Pretreated	77.1	
					Conformed		

Test Items*△	Unit	Testing method (for reference)	Limit#	Test Results	Individual judgment
Bacterial filtration efficiency	/	YY 0469-2011	≥95.0%	98.2%	Conformed
				97.7%	
				97.8%	

Note:

- (1) ** = Limit values quoted from Q/YS 4-2020 for Disposable Protective Mask, adult type.
- (2) # = Limit values quoted from YY 0469-2011 for Medical Surgical Mask.
- (3) * Subcontracted test items are carried out by laboratories outside the SGS Group.



SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch

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B

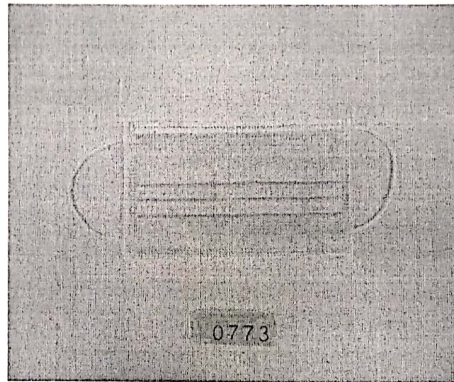
Test items	Unit	Testing method (for reference)	Limit**	Test Results	Individual judgment
Total bacterial colonies	CFU/g	Method provided by the customer (Q/YS 4-2020)	≤ 200	< 20	Conformed
Total fungal colonies	CFU/g		≤ 100	< 20	Conformed
Coliform	/0.25g		Not detectable	Not detected	Conformed
Staphylococcus aureus	/0.25g		Not detectable	Not detected	Conformed
Streptococcus hemolyticus	/0.25g		Not detectable	Not detected	Conformed
Pseudomonas aeruginosa	/0.25g		Not detectable	Not detected	Conformed

Note: ** = Limit values quoted from Q/YS 4-2020 for Disposable Protective Mask, ordinary level.

△ The test items are only used for purposes such as customer research, teaching, internal quality control and product development, and for internal reference only.

Sample description: Mask

Attached photo



*** End of report ***



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PRODUCT IMAGES



产品合格证
Quality Certificate

产品名称: 一次性防护口罩
Disposable Hygiene Face Mask

品牌: WINSUN

规格: 17.5cm*9.5cm

材质: 无纺布52%, 熔喷布25%, 耳带 13%, 鼻梁10%

Specification: Non woven 52%, Meltblown fabric 25%

材料成分: Material: Elastic strap 13%, Nose strip 10%

See on package.

生产批号: 见外包装
Batch No: See on package

生产日期: 见外包装
Production Date: See on package

保质期: 2年
Shelf Life: 2 years

标准号: QJ24-2020
Standard: QJ24-2020

检验员: 01
Inspector: 广东蓝升个人防护用品股份有限公司
Guangdong Winsun Personal Care Products Co., Ltd.

生产厂家: 广东佛山南海区西樵镇南边村科技工业园广环路1号
Manufacturer: Guangdong Winsun Personal Care Products Co., Ltd. Industrial Zone

地址: 广东省佛山市南海区西樵镇南边村科技工业园广环路1号
Address: No.1 Guangsheng Road, Xiqiao, South Sea District, Foshan City, Guangdong Province, China

本产品经检验合格, 准予出厂。
This product is qualified after inspection and is approved to deliver.

WINSUN
DISPOSABLE HYGIENE FACE MASK

CE MD BFE > 95%

50 PCS

DISPOSABLE HYGIENE FACE MASK

产品合格证

Quality Certificate

产品名称: 一次性防护口罩
Product Name Disposable Hygiene Face Mask
品牌: 昱升
Brand Name Winsun
规格: 17.5cm*9.5cm
Specification
材料成分: 无纺布52%, 熔喷布 25%, 耳带 13%, 鼻夹10%
Material Non woven 52%, Meltblown fabric 25%,
Elastic earloop 13%, Nose strip 10%
生产批号: See on package
Batch No. 见外包装
生产日期: See on package
Production Date 见外包装
保质期: 2年
Shelf Life 2 years
执行标准: Q/YS 4-2020
Standard
检验员: 01
Inspector
生产厂商: 广东昱升个人护理用品股份有限公司
Manufacturer Guangdong Winsun Personal Care Products Co., Ltd
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Xiqiao Town, Nanhai district, Foshan City, Guangdong
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This product is qualified after inspection and is approved to deliver.

