CE

DECLARATION OF CONFORMITY

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

Manufacturer: 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: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product Name: Disposable Medical Face Mask

Specification: 17.5cm*9.5cm, 14.5cm*9.5cm

Classification: Class I (MDD, Annex IX)

Conformity Assessment Procedure: Annex VII of Medical Device Directive(93/42/EEC)

We herewith declare that the above-mentioned products meet the requirements of Medical Device Directive (93/42/EEC) including Directive 2007/47/EC and the following harmonized standards.

EN ISO 14971:2012
EN 1041:2008+A1:2013
EN ISO 10993-5:2009
EN 14683:2019
EN ISO 15223-1:2016
ISO 10993-1:2018
EN ISO 10993-10:2013

Signature:

Name: Position: Xinrong Yan/ GM

Date: 2020.5.8

Place: Guangdong, China

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

Sungo

Authorized Signature (S)

Certificate CN20/42094

The management system of

Guangdong Winsun Personal Care Products Co., Ltd.

NO. 1 Guangxing Road, Xiqiao Sci-Tec Industrial Zone, Xiqiao Town, Nanhai District, Foshan City, Guangdong Province, 528211, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design and manufacture of single use non-sterile medical face mask

This certificate is valid from 17 June 2020 until 16 June 2023
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 2 June 2023
Issue 1. Certified since 17 June 2020

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

认 证 证 书

证书号：USA19Q42833R1M

兹证明

广东昱升个人护理用品股份有限公司

统一社会信用代码：91440600782011571O

注册地址：佛山市南海区西樵镇西樵科技工业园广兴路1号
生产地址：广东省佛山市南海区西樵镇西樵科技工业园广兴路1号车间一
办公地址：广东省佛山市南海区西樵镇西樵科技工业园广兴路1号

质量管理体系符合标准

ISO 9001:2015

质量管理体系适用范围

纸尿裤、纸尿片的生产（该公司许可证范围内）

初次发证日期　2010年04月22日
证书颁发日期　2019年07月17日
证书有效期至　2022年07月16日

签发：

北京东方纵横认证中心有限公司

获证组织必须定期接受监督审核并经审核合格此证书方继续有效。本证书信息可在北京东方纵横认证中心有限公司网站（www.eacc.com.cn）和国家认证认可监督管理委员会官方网站（www.cnca.gov.cn）上查询。也可扫描右下角的二维码查询。

认证机构地址：北京市通州区中关村科技园区通州园金桥科技产业基地景盛南四街1号121号楼一层101102

Certificate

Certificate No.: USA19Q42833R1M

This is to certify that the Quality Management System of

GUANGDONG YUSHENG PERSONAL NURSING SUPPLIES CO., LTD.

Unified Social Credit Code: 914406007820115710

Registered/Office Address: No. 1 Guangxing Road, Xiqiao Technology Industry Park, Xiqiao Town, Nanhai District, Foshan, Guangdong

Production Address: Workshop 1, No. 1 Guangxing Road, Xiqiao Technology Industry Park, Xiqiao Town, Nanhai District, Foshan, Guangdong

Has been audited to conform to the following Quality Management System standard

ISO 9001:2015

This Quality Management System is valid for the

Production of diapers and diapers
(within the scope of the company's license)

Date of initial issuance: Apr. 22, 2010
Date of issuance: Jul. 17, 2019
Date of expiry: Jul. 16, 2022

Issued by: Wu Fengru

Beijing East Allreach Certification Center Co., Ltd.

The certificate will remain valid only if the certified organization accepts surveillance audits at regular intervals and is audited to be qualified. The information of this certificate is available at EACC website (www.eacc.com.cn) and CNCA's official website (www.cnca.gov.cn), and it is also available by scanning the QR Code in the lower right corner.

EACC address: 1st Floor, No. 121 building, No. 17 Jingshengnanxi Street, Jinqiao Science & Technology Industrial Base Tongzhou Park of Zhongguancun Science & Technology Zone, Tongzhou District, Beijing 101102

GUANGDONG WINSUN PERSONAL CARE PRODUCTS CO., LTD
NO.1 GUANGXING ROAD, XIQIAO SCI-TEC INDUSTRIAL PARK, XIQIAO TOWN, NANHAI DISTRICT, FOSHAN CITY, GUANGDONG PROVINCE

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

Sample Description	:	(A)Disposable Medical Face Mask(Claimed Type IIR)
Composition	:	(A)Spunbond nonwoven, meltblown nonwoven, elastic earloop,nose strip etc
Sample Color	:	(A)Blue/White
Lot No./Batch No.	:	Not provided
Proposed Care Instruction	:	-
Sample Receiving Date	:	May 28, 2020
Testing Period	:	May 28, 2020 - Jun 19, 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).
Test Performed	:	Selected test(s) as requested by applicant

Comment:

EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods **Clause 5.2 Performance Requirement**	(A)
Clause 5.2.2 Bacterial filtration efficiency (BFE)	M
Clause 5.2.3 Breathability	M
Clause 5.2.4 Splash Resistance	M
Clause 5.2.5 Microbial Cleanliness	M
Clause 5.2.6 Biocompatibility	EXCLUDED

Remark: M=Meet EN 14683:2019+AC:2019 Performance Requirement (Type IIR)
F=Below EN 14683:2019+AC:2019 Performance Requirement (Type IIR)

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

Sara Guo (Account Executive)

Helen Xuan

Dongjing Liu / Hailian Xuan (Authorized Signatory)

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Test Result

EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods

Clause 5.2 Performance Requirement

Clause 5.2.2 Bacterial filtration efficiency (BFE)
(EN 14683:2019+AC:2019 Annex B)

Sample: A

Conditioning Parameters	:	Minimum of 4 hours at 21±5°C and 85±5% R.H.
Dimensions of test specimen	:	~172 mm x 152 mm
Test Area	:	~60 cm^2
Test Side	:	Inside
Flow Rate	:	28.3 l/min
Positive Control Average	:	2914.5 CFU
Negative Monitor Count	:	< 1 CFU

	1#	2#	3#	4#	5#
(BFE), %	99.9	99.9	99.9	99.9	99.9

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

Clause 5.2.3 Breathability
(EN 14683 :2019+AC:2019 Annex C)

Sample: A

Test number and location	:	5 random areas for each specimen (face mask)
Conditioning Parameters	:	Minimum of 4 hours at 21±5°C and 85±5% R.H.
Test Area	:	4.9 cm^2
Flow Rate	:	8 l/min

	1#	2#	3#	4#	5#
Differential pressure ΔP (Pa/cm^2)	31	31	32	33	32

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

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

Sample: A

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

Clause 5.2.5 Microbial Cleanliness
(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

Sample: A

	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