Shenzhen Shengshi Kanghua Industrial Group

Shenzhen Shengshi Kanghua Technology Co., Ltd

·Quality ·Professional ·Rigorous ·Reliable

GROUP INTRODUCTION

Shenzhen Shengshi Kanghua Industrial Group is a joint venture enterprise, which has many services such as real estate, finance, investment, and epidemic prevention products.
Shenzhen Shengshi Kanghua Technology Co., Ltd is a cooperative enterprise, which owned by China Sinopharm Group.

As a branch of the group，Shenzhen Shiyuan Technology Co., Ltd focuses on the industry of medical and epidemic prevention products. Products including cup-shaped KN95 protective mask, cup-shaped with breathing valve KN95 protective mask, medical disposable mask, medical surgical masks, protective gowns, protective gloves, virus testing kits, etc.

GROUP INTRODUCTION

Shenzhen ShiYuan Technology Ltd possesses a first-class production line, equipped with 10,000-level dust-free workshop. The monthly production of masks can be up to 50 million.

Shenzhen Shiyuan Trading Ltd is responsible for foreign market sales, which mainly sells to major government agencies, medical institutions and major social organizations in Europe, America and Southeast Asia. The Chinese market team is in charge of supermarkets, hospitals, pharmacies, convenience stores and other corporations in major cities.

REAL ESTATE PROJECTS

Hanking Center

Hanjing Group headquarters building, super-class landmark office building, located in Shennan Avenue, a nearly 80-story "new landmark building." The project is located in Nanshan High-tech Zone and covers a total area of 11017 square meters.

Hanking Peak Boulevard

Located in the middle of Xiaonanshan Mountain in the Qianhai Center,Pooling the expertise from the globe, Hanking Group has created the one-of-a-kind luxury hillside residence in Qianhai.

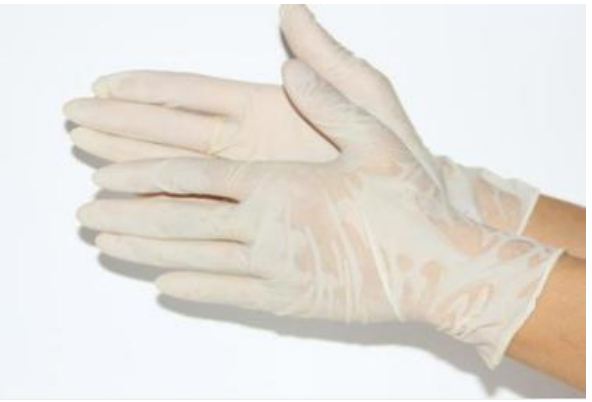
Shenzhen Shengshi Kanghua Industrial Group

Shenzhen Shengshi Kanghua Technology Co., Ltd

Shenzhen Shengshi Kanghua Technology Co., Ltd is a cooperative enterprise of China Sinopharm Group.

China Sinopharm Group is the largest pharmaceutical and health industry group in China with the most complete industrial chain and comprehensive strength under the direct management of the state-owned assets supervision and Administration Commission of the State Council. Its mainly focuses on the distribution, retail, R & D and industry of health-related products such as preventive treatment and diagnostic care.

Shenzhen Shengshi Kanghua Technology Co., Ltd. has always been concerned about the people’s daily lives, to improve the quality of people’s healthy life as its own responsibility. It is vital for Shengshi Kanghua to bring benefits to the society and country, which is the consistent tenet of the enterprise. It also committed to launch high-quality epidemic prevention products.



Shenzhen Shengshi Kanghua Industrial Group

Shenzhen Shengshi Kanghua Technology Co., Ltd

Shenzhen Shengshi Kanghua Technology Co.,Ltd. and Shenzhen Shiyuan Technology Co., Ltd. specializes in producing folding KN95 mask, Cup-shaped KN95 mask, Cup-shaped KN95 mask with breathing valve, medical disposable mask, medical surgical mask, protective gowns, protective gloves and other medical and epidemic prevention products.

Shenzhen Shengshi Kanghua Industrial Group

Shenzhen Shengshi KanghuaTechnology Co., Ltd

Commercial & Medical

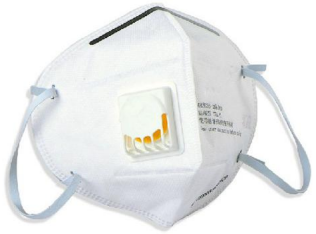
Disposable Protective Mask
Commercial（GB/T32610-2016）
Medical（YY/T0969-2013）
Surgical（YY0469-2011）

KN95 Protective Mask
Commercial（GB2626-2006）
Medical（GB19083-2010）

Cup-shaped Protective Mask
Commercial（GB2626-2006）
Medical（GB19083-2010）

flat-shaped Protective Mask
Commercial（GB2626-2006）
Medical（GB19083-2010）

Disposable Protective Mask for Children
Commercial（GB/T32610-2016）



KN95 Protective Mask with Valve
Commercial（GB2626-2006）
Medical（GB19083-2010）

Cup-shaped Protective Mask with breather valve
Commercial（GB2626-2006）
Medical（GB19083-2010）

Shenzhen Shengshi Kanghua Industrial Group

Shenzhen Shengshi KanghuaTechnology Co., Ltd

Non medical

Nitrile Gloves
（GB/T 25260.2-2018）

Latex Gloves
（GB/T 22845-2009）

PVC Gloves
（GB/T 22845-2009）

Medical

Nitrile Gloves
（GB 10213-2006）

Latex Gloves
（GB 10213-2006）

Latex Gloves (with powder)
（GB 10213-2006）

Shenzhen Shengshi Kanghua Industrial Group

Shenzhen Shengshi KanghuaTechnology Co., Ltd

Medical

Medical Isolation Eye Patches
（GB32166-2016）

Medical goggles
（GB32166-2016）

Medical protective face Shield
（GB14866-2006）

SARS-CoV-2 Nucleic Acid Test

Disposable Medical Protective Clothing(Strip)
（GB19082-2009）

Disposable Medical Protective Clothing
（GB19082-2009）

Disposable Medical isolation gown (one piece)

Disposable Medical isolation gown (hanging type)

OUR FACTORY

The factory is located in Shenzhen Xili Baiwangxin Industrial Zone. It has professional production equipments and technical team, equipped with first-class production lines and 1,000-grade dust-free workshops. Monthly production capacity of masks is up to 5 million.Production strictly implements GB2626-2006 standard, YY / T0969-2013 standard, YY0469-2011 standard. All products are delivered to SGS for testing on a daily basis.

Raw Material Storage

Product Warehouse

The factory is equipped with the special dust-proof suit, hand washing stations, air shower and a series of dust removal measures,constant temperature and humidity air conditioning system.

Shenzhen Shengshi Kanghua Industrial Group

Shenzhen Shengshi KanghuaTechnology Co., Ltd

Shenzhen Shiyuan Technology Co., Ltd.

统一社会信用代码
91440300MA5DLNB21F

营业执照

名　　称　深圳世圆科技有限公司
类　　型　有限责任公司
法定代表人　吴拓展
成立日期　2016年09月26日
住　　所　深圳市南山区粤海街道海岸城大厦东座1206

重要提示
1. 商事主体的经营范围由章程确定。经营范围中属于法律、法规规定应当经批准的项目，取得许可审批文件后方可开展相关经营活动。
2. 商事主体经营范围和许可审批项目等有关企业信用事项及年报信息和其他信用信息，请登录左下角的国家企业信用信息公示系统或扫描右上方的二维码查询。
3. 各类商事主体每年须于成立周年之日起两个月内，向商事登记机关提交上一自然年度的年度报告。企业应当按照《企业信息公示暂行条例》第十条的规定向社会公示企业信息。

登记机关
2019年 03月 28日

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn
国家市场监督管理总局监制

统一社会信用代码
91440300MA5G48BX4B

营业执照

名　　称　深圳盛世康华科技有限公司
类　　型　有限责任公司
法定代表人　吴拓展
成立日期　2020年03月31日
住　　所　深圳市南山区粤海街道海珠社区文心五路33号海岸大厦西座2205

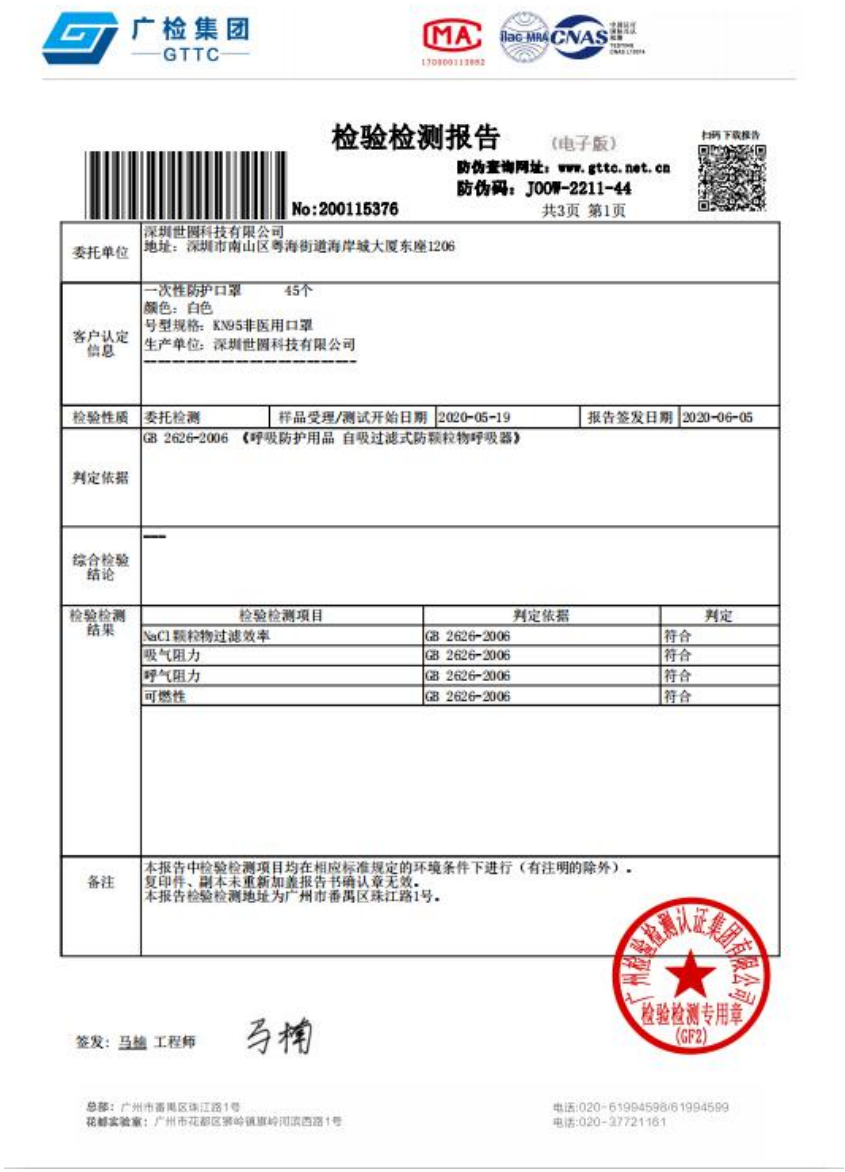
重要提示
1. 商事主体的经营范围由章程确定。经营范围中属于法律、法规规定应当经批准的项目，取得许可审批文件后方可开展相关经营活动。
2. 商事主体经营范围和许可审批项目等有关企业信用事项及年报信息和其他信用信息，请登录左下角的国家企业信用信息公示系统或扫描右上方的二维码查询。
3. 各类商事主体每年须于成立周年之日起两个月内，向商事登记机关提交上一自然年度的年度报告。企业应当按照《企业信息公示暂行条例》第十条的规定向社会公示企业信息。

登记机关
2020年 05月 19日

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn
国家市场监督管理总局监制

Shenzhen Shengshi Kanghua Industrial Group

Shenzhen Shengshi KanghuaTechnology Co., Ltd 国药集团 SINOPHARM Shenzhen Shiyuan Technology Co., Ltd.



广检集团 GTTC

检验检测报告 （电子版）

防伪查询网址：www.gttc.net.cn
防伪码：J00W-2211-44
No:200115376
共3页 第1页

委托单位	深圳世圆科技有限公司 地址：深圳市南山区粤海街道海岸城大厦东座1206				
客户认定信息	一次性防护口罩 45个 颜色：白色 号型规格：KN95非医用口罩 生产单位：深圳世圆科技有限公司 ----------				
检验性质	委托检测	样品受理/测试开始日期	2020-05-19	报告签发日期	2020-06-05
判定依据	GB 2626-2006 《呼吸防护用品 自吸过滤式防颗粒物呼吸器》				
综合检验结论	—				

检验检测结果

检验检测项目	判定依据	判定
NaCl颗粒物过滤效率	GB 2626-2006	符合
吸气阻力	GB 2626-2006	符合
呼气阻力	GB 2626-2006	符合
可燃性	GB 2626-2006	符合

备注：本报告中检验检测项目均在相应标准规定的环境条件下进行（有注明的除外）。
复印件、副本未重新加盖报告书确认章无效。
本报告检验检测地址为广州市番禺区珠江路1号。

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

签发：马楠 工程师

总部：广州市番禺区珠江路1号 电话:020-61994598/61994599
花都实验室：广州市花都区狮岭镇旗岭河滨西路1号 电话:020-37721161

广检集团 GTTC

检验检测报告 （电子版）

防伪查询网址：www.gttc.net.cn
防伪码：UQHM-8591-34
No:200115604
共3页 第1页

委托单位	深圳世圆科技有限公司 地址：深圳市南山区粤海街道海岸城大厦西座22楼2201				
客户认定信息	日常防护型口罩 40个 号型规格：一次性平面口罩（非医用） 生产单位：深圳世圆科技有限公司 ----------				
检验性质	委托检测	样品受理/测试开始日期	2020-05-25	报告签发日期	2020-06-03
判定依据	YY/T 0969-2013 《一次性使用医用口罩》				
综合检验结论	—				

检验检测结果

检验检测项目	判定依据	判定
细菌过滤效率	YY/T 0969-2013	符合
大肠菌群	YY/T 0969-2013	符合
细菌菌落总数	YY/T 0969-2013	符合
真菌菌落总数	YY/T 0969-2013	符合
绿脓杆菌	YY/T 0969-2013	符合
金黄色葡萄球菌	YY/T 0969-2013	符合
溶血性链球菌	YY/T 0969-2013	符合
通气阻力	YY/T 0969-2013	符合
鼻夹[3个]	YY/T 0969-2013	符合

备注：本报告中检验检测项目均在相应标准规定的环境条件下进行（有注明的除外）。
复印件、副本未重新加盖报告书确认章无效。
本报告检验检测地址为广州市番禺区珠江路1号。

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

签发：郭子山 高级工程师

总部：广州市番禺区珠江路1号 电话:020-61994598/61994599
花都实验室：广州市花都区狮岭镇旗岭河滨西路1号 电话:020-37721161

对外贸易经营者备案登记表

备案登记表编号：04956023　　统一社会信用代码：91440300MA5DLHP91N
进出口企业代码：

经营者中文名称	深圳世圆贸易有限公司		
经营者英文名称	Shenzhen Shiyuan Trading Co., Ltd.		
组织机构代码	----------	经营者类型（由备案登记机关填写）	私营有限责任公司
住　所	深圳市南山区粤海街道海岸城大厦东座1206		
经营场所（中文）	深圳市南山区粤海街道海岸城大厦东座1206		
经营场所（英文）	1206 East Block, Coastal City Building, Yuehai Street, Nanshan District, Shenzhen		
联系电话	0755-86325469	联系传真	0755-86325469
邮政编码	518000	电子邮箱	770923125@qq.com
工商登记注册日期	2016-9-23	工商登记注册号	----------

依法办理工商登记的企业还须填写以下内容

企业法定代表人姓名	吴拓展	有效证件号	440301199107276775
注册资金	伍拾万元		（折美元）

依法办理工商登记的外国（地区）企业或个体工商户（独资经营者）还须填写以下内容

企业法定代表人／个体工商负责人姓名		有效证件号	
企业资产／个人财产			（折美元）

备注	

填表前请认真阅读背面的条款，并由企业法定代表人或个体工商负责人签字、盖章。

备案登记机关
签　章
2020 年 03 月 31 日

第二类医疗器械经营备案凭证

备案编号：粤深食药监械经营备 202015898 号

企业名称	深圳世圆贸易有限公司
法定代表人	吴拓展
企业负责人	吴拓展
经营方式	批零兼营
住　所	深圳市南山区粤海街道海岸城大厦东座 1206
经营场所	深圳市南山区粤海街道海岸城大厦东座 1206
库房地址	深圳市南山区粤海街道海岸城大厦东座 1206
经营范围	2002 年分类目录（二类）：6801，6802，6803，6804，6805，6806，6807，6808，6809，6810，6812，6813，6815，6816，6820，6821，6822，6823，6824，6825，6826，6827，6828，6830，6831，6832，6833，6834，6840（体外诊断试剂除外），6841，6845，6846，6854，6855，6856，6857，6858，6863，6864，6865，6866，6870，6877，以上类别中包含的植入和介入类产品除外，以上类别中包含的角膜接触镜、助听器产品除外 2017 年分类目录（二类）：01，02，03，04，05，06，07，08，09，10，11，12，13，14，15，16，17，18，19，20，21，22，以上类别中包含的植入和介入类产品除外，以上类别中包含的角膜接触镜、助听器产品除外

备案部门（公章）
备案日期：2020 年 02 月 28 日

Our Partners

GUANGDONG WILLING TECHNOLOGY CORPORATION

Shenzhen Cathay Clean Science and Technology Co.,LTD

Mezorrison Health Science & Technology (Shenzhen) Co.,Ltd

Shenzhen Tianlong Century Technology Development Co., Ltd.

Shenzhen Da Sheng Yuan Medical Equipments Company Limited

EC&FDA

GUANGDONG WILLING TECHNOLOGY CORPORATION

Fiscal Year 2020
FDA REGISTRATION CERTIFICATE

Certificate Holder:
GUANGDONG WILLING TECHNOLOGY CORPORATION
Willing Industrial park, Dongjiang Industrial District Shuikou Town, Huicheng District, Huizhou, Guangdong, 516005, CHINA
has completed the FDA Establishment Registration (as manufacturer , foreign exporter, contract manufacturer) and Device Listing with the US Food & Drug Administration.

Registration Number: N

Owner/Operator Number: 10065753

Device Listing:

Device#	Product Codes	Device Name
D382189	QKR	Face mask (except N95 respirator) for general public/healthcare personnel per IIE guidance
D397302	LYU	ACCESSORY, SURGICAL APPAREL (N95 Face Mask /Mask MN-01/ Mask MM-02/Ear-hanging KN95-04)

Registration Expiration Date: 2020-12-31

UCL-REG SERVICE INC has verified and declares that the above stated facility is registered with the US Food & Drug Administration, Center for Drug Evaluation and Research, Office of Drug Registration and Listing pursuit to the Code of Federal Regulation 21 CFR 207, on the data state above, and makes no other representations and warranties, nor does this certificate makes other representations and warranties to other person or entity other than the name certificate holder, for whose sole benefit it is issued. UCL-REG SERVICE INC. assumes no liability to any person or entity in connection with the foregoing. UCL-REG SERVICE INC is a private registration agent and is not affiliated with the US Food and Drug Administration.

UCL-REG SERVICE INC.
3907 PRINCE STREET SUITE 6F
Flushing, New York, 11354,
UNITED STATES

EC Declaration of Conformity

according to the Medical Devices Directive 93/42/EEC
Class I Medical Device
(non-sterile, without measuring function)

Manufacturer: Guangdong Willing Technology Corporation
Address: Willing Industrial park, Dongjiang Industrial District, Shuikou Town, Huizhou city, Guang Dong, P.R.China

EC Representative: Share Info Consultant Service LLC Repräsentanzbüro
Heerdter Lohweg 83, 40549 Düsseldorf, Nordrhein-Westfalen, Deutschland

We, the manufacturer, declare under our sole responsibility that

	Product Name	Type/model, identification of product allowing traceability (Where applicable)
the medical device(s)	Disposable Medical Mask	MM-02
of class	according to annex IX of directive 93/42/EEC, Rule 1	**Class I** Medical Device (non-sterile)

is/are in conformity with the relevant provisions and requirements of directive 93/42/EEC, as amended by Directive 2007/47/EC.

Applied harmonised standards, national standards or other normative documents		
	EN ISO 13485:2016	EN ISO 15223-1:2016
	EN 1041:2008	EN 14683：2019+AC：2019
	EN ISO 14971:2012	EN ISO 10993-5:2009
	ISO 10993-1: 2018	EN ISO 10993-10:2013
	EN 62366-1：2015	

Conformity assessment procedure: Module A (EC Declaration of Conformity (Annex VII) + Technical Files)

Notified Body (name & number): **NOT applicable**

Certificate & number: **NOT applicable**

Signed on: June 05,2020. Place: Huizhou, Guangdong, China

Signature (on behalf of the manufacturer)

CE

Name of authorized signatory: Jingnong Ye
Position held in the company: General Manager

GUANGDONG WILLING TECHNOLOGY CORPORATION

CE

Module B EU Type-Examination Certificate

For the requirements of PPE Regulation 2016/425

Certificate No.: CE-PC-200506-335-01-9A

Certificate holder:	**Guangdong Willing Technology Corporation** Willing Industrial Park, Dongjiang Industrial District Shuikou Town, Huizhou City, Guangdong, P. R. China
Product:	**Particle Filtering Half Mask** Folding filtering half mask without valve fitted with ear loops with head harness clip, internal metal nose clip Classification: FFP2 NR
Model reference:	WL-01
Standard(s):	EN 149:2001+A1:2009
Test report No.:	2020(D) - 0789
Issue date:	2020-06-09
Expiry date:	2020-09-08

The product(s) on this certificate and the Technical File have been assessed and found to be in conformance with the Essential Health and Safety Requirements in Annex II of the PPE regulation 2016/425 and meeting the needs of WHO document dap-nbov.pdf and EU Commission Recommendation (EU) 2020/403.
Any changes to the design, manufacturing location or manufacture of the PPE product certified here must be advised to CCQS Certification Services Limited for review.
CE marking shall not be applied until the requirements of all the PPE Regulation 2016/425 and relevant EN Harmonised standards and/or Technical specifications have been met.
If the certified product is Category III then this certificate is only valid if used in conjunction with Conformity Assessment against Module C2 or Module D.
This certificate remains the property of CCQS and maybe withdrawn at any time if it is considered that the equipment is no longer in conformity with the requirements of the PPE Regulation 2016/425.

CE Approved by Ireland Government as a Notified Body for CE Marking No.2834

Approved by: Owen Blair, Director

CCQS Certification Services Limited
Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin15, D15 AKK1, Ireland
Tel: +00 353 1 588 6920 Website: www.ccqs.co.uk E-mail: info@ccqs.ie
If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.

Page 1 of 1 (Fm220-017, Rev.1)

Certificate of Module C2 production monitoring for equipment within the scope of Personal Protective Equipment Regulation (EU) 2016/425 Category III

FPC Certificate No.: CE-PC-200506-335-FPC-A

Certificate holder:	**Guangdong Willing Technology Corporation** Willing Industrial Park, Dongjiang Industrial District Shuikou Town, Huizhou City, Guangdong, P. R. China
The scope of the certification for:	**Respiratory Protective Equipment** Products covered by the certificate are described below.
Model:	Particle Filtering Half Mask WL-01
Standard:	EN 149:2001+A1:2009
Validity from:	2020-06-09
To:	2020-09-08

CCQS Certification Services Limited in its role as a Notified Body for PPE Regulation, is monitoring that the manufacturer is producing PPE in conformity with the type described in the EU type-examination certificate and associated technical file and which satisfies the Essential Health and Safety Requirements of the Regulation.
The manufacturer is hereby authorized to affix our Notified Body number, 2834, to each item of PPE as identified on this certificate whilst this certificate remains valid.
This certificate is the property of CCQS and maybe withdrawn or revised at any time if CCQS considers that the equipment is no longer in conformity with the requirements of the Regulation.

CE Approved by Ireland Government as a Notified Body for CE Marking No.2834

Approved by: Owen Blair, Director

CCQS Certification Services Limited
Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin15, D15 AKK1, Ireland
Tel: +00 353 1 588 6920 Website: www.ccqs.co.uk E-mail: info@ccqs.ie
If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.

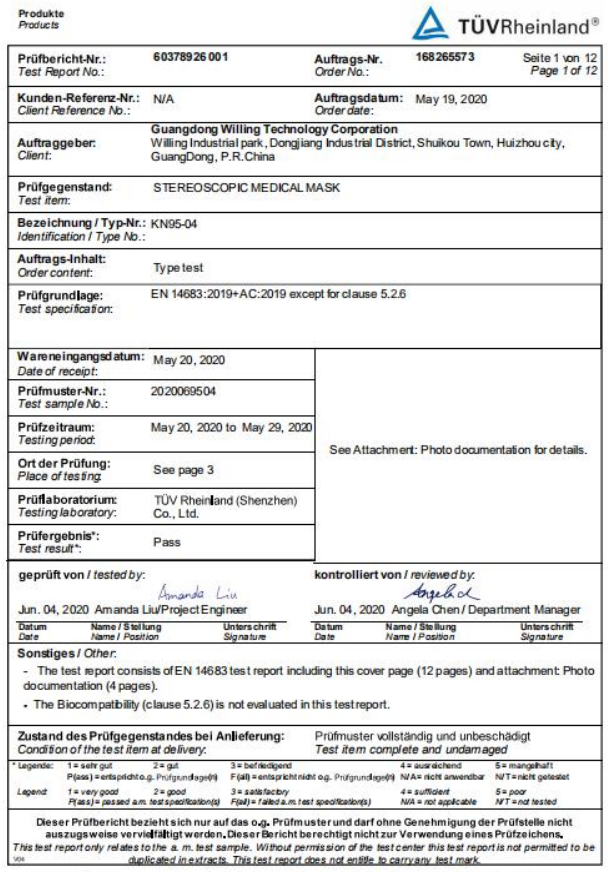
Page 1 of 1 (Fm220-016, Rev.1)

Shenzhen Shengshi Kanghua Industrial Group

Shenzhen Shengshi KanghuaTechnology Co., Ltd

GUANGDONG WILLING TECHNOLOGY CORPORATION

Test report



Produkte / Products — TÜVRheinland®

Prüfbericht-Nr.: / Test Report No.:	60378926 001	Auftrags-Nr. / Order No.:	168265573
Seite 1 von 12 / Page 1 of 12			
Kunden-Referenz-Nr.: / Client Reference No.:	N/A	Auftragsdatum: / Order date:	May 19, 2020
Auftraggeber: / Client:	Guangdong Willing Technology Corporation Willing Industrial park, Dongjiang Industrial District, Shuikou Town, Huizhou city, GuangDong, P.R.China		
Prüfgegenstand: / Test item:	STEREOSCOPIC MEDICAL MASK		
Bezeichnung / Typ-Nr.: / Identification / Type No.:	KN95-04		
Auftrags-Inhalt: / Order content:	Type test		
Prüfgrundlage: / Test specification:	EN 14683:2019+AC:2019 except for clause 5.2.6		
Wareneingangsdatum: / Date of receipt:	May 20, 2020		
Prüfmuster-Nr.: / Test sample No.:	2020069504		
Prüfzeitraum: / Testing period:	May 20, 2020 to May 29, 2020		
Ort der Prüfung: / Place of testing:	See page 3		
Prüflaboratorium: / Testing laboratory:	TÜV Rheinland (Shenzhen) Co., Ltd.		
Prüfergebnis*: / Test result*:	Pass		

See Attachment: Photo documentation for details.

geprüft von / tested by: Amanda Liu — Jun. 04, 2020 Amanda Liu/Project Engineer

kontrolliert von / reviewed by: Angela Chen — Jun. 04, 2020 Angela Chen / Department Manager

Datum / Date | Name / Stellung / Name / Position | Unterschrift / Signature

Sonstiges / Other:

- The test report consists of EN 14683 test report including this cover page (12 pages) and attachment: Photo documentation (4 pages).
- The Biocompatibility (clause 5.2.6) is not evaluated in this test report.

Zustand des Prüfgegenstandes bei Anlieferung: / Condition of the test item at delivery: Prüfmuster vollständig und unbeschädigt / Test item complete and undamaged

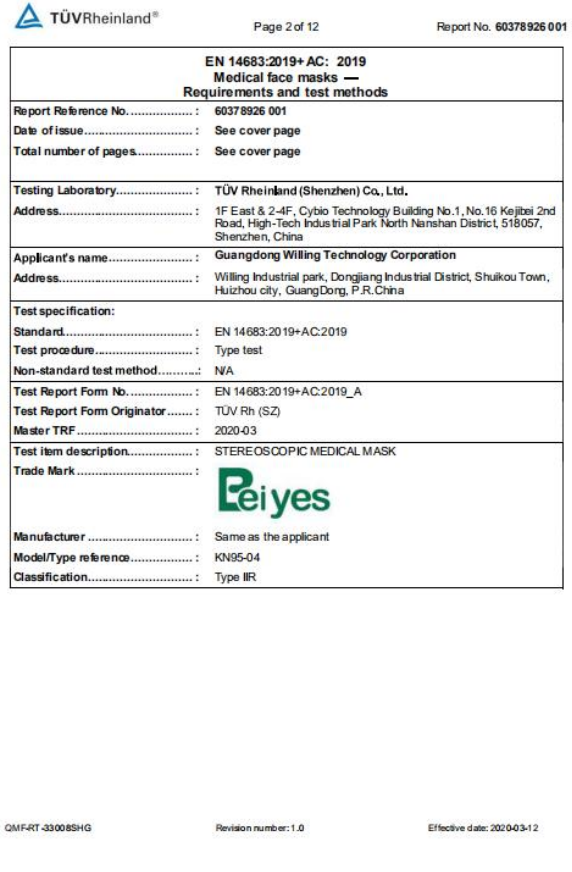
* Legende: 1 = sehr gut / P(ass) = entspricht o.g. Prüfgrundlage(n) / 2 = gut / 3 = befriedigend / F(ail) = entspricht nicht o.g. Prüfgrundlage(n) / 4 = ausreichend / N/A = nicht anwendbar / 5 = mangelhaft / N/T = nicht getestet

Legend: 1 = very good / P(ass) = passed a.m. test specification(s) / 2 = good / 3 = satisfactory / F(ail) = failed a.m. test specification(s) / 4 = sufficient / N/A = not applicable / 5 = poor / N/T = not tested

Dieser Prüfbericht bezieht sich nur auf das o.g. Prüfmuster und darf ohne Genehmigung der Prüfstelle nicht auszugsweise vervielfältigt werden. Dieser Bericht berechtigt nicht zur Verwendung eines Prüfzeichens.

This test report only relates to the a. m. test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any test mark.

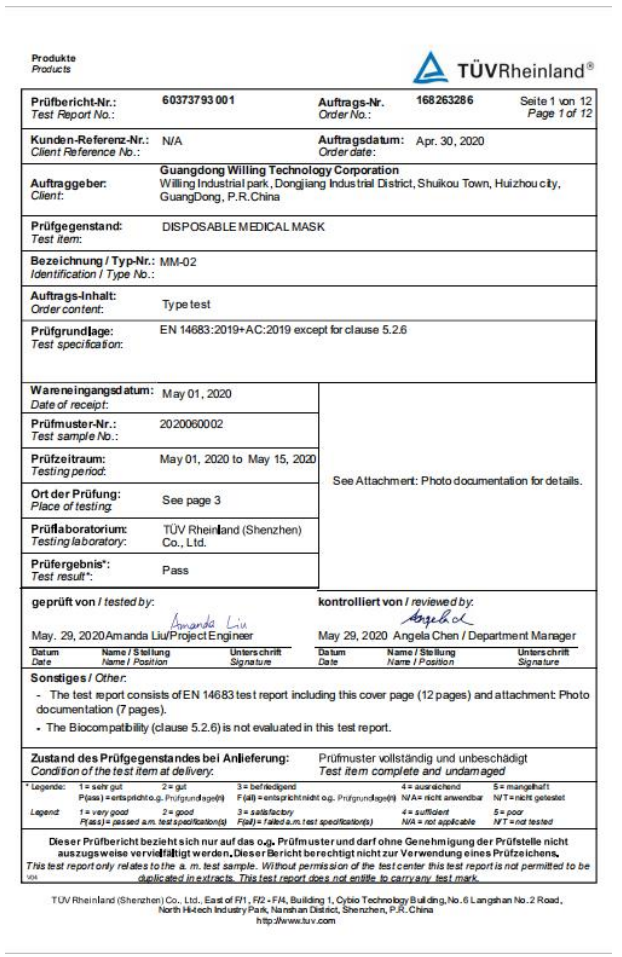
V04



TÜVRheinland®

EN 14683:2019+AC: 2019
Medical face masks —
Requirements and test methods

Report Reference No.	60378926 001
Date of issue	See cover page
Total number of pages	See cover page
Testing Laboratory	TÜV Rheinland (Shenzhen) Co., Ltd.
Address	1F East & 2-4F, Cybio Technology Building No.1, No.16 Kejibei 2nd Road, High-Tech Industrial Park North Nanshan District, 518057, Shenzhen, China
Applicant's name	Guangdong Willing Technology Corporation
Address	Willing Industrial park, Dongjiang Industrial District, Shuikou Town, Huizhou city, GuangDong, P.R.China
Test specification:	
Standard	EN 14683:2019+AC:2019
Test procedure	Type test
Non-standard test method	N/A
Test Report Form No.	EN 14683:2019+AC:2019_A
Test Report Form Originator	TÜV Rh (SZ)
Master TRF	2020-03
Test item description	STEREOSCOPIC MEDICAL MASK
Trade Mark	Peiyes
Manufacturer	Same as the applicant
Model/Type reference	KN95-04
Classification	Type IIR



Produkte / Products — TÜVRheinland®

Prüfbericht-Nr.: / Test Report No.:	60373793 001	Auftrags-Nr. / Order No.:	168263286
Seite 1 von 12 / Page 1 of 12			
Kunden-Referenz-Nr.: / Client Reference No.:	N/A	Auftragsdatum: / Order date:	Apr. 30, 2020
Auftraggeber: / Client:	Guangdong Willing Technology Corporation Willing Industrial park, Dongjiang Industrial District, Shuikou Town, Huizhou city, GuangDong, P.R.China		
Prüfgegenstand: / Test item:	DISPOSABLE MEDICAL MASK		
Bezeichnung / Typ-Nr.: / Identification / Type No.:	MM-02		
Auftrags-Inhalt: / Order content:	Type test		
Prüfgrundlage: / Test specification:	EN 14683:2019+AC:2019 except for clause 5.2.6		
Wareneingangsdatum: / Date of receipt:	May 01, 2020		
Prüfmuster-Nr.: / Test sample No.:	2020060002		
Prüfzeitraum: / Testing period:	May 01, 2020 to May 15, 2020		
Ort der Prüfung: / Place of testing:	See page 3		
Prüflaboratorium: / Testing laboratory:	TÜV Rheinland (Shenzhen) Co., Ltd.		
Prüfergebnis*: / Test result*:	Pass		

See Attachment: Photo documentation for details.

geprüft von / tested by: Amanda Liu — May. 29, 2020 Amanda Liu/Project Engineer

kontrolliert von / reviewed by: Angela Chen — May 29, 2020 Angela Chen / Department Manager

Datum / Date | Name / Stellung / Name / Position | Unterschrift / Signature

Sonstiges / Other:

- The test report consists of EN 14683 test report including this cover page (12 pages) and attachment: Photo documentation (7 pages).
- The Biocompatibility (clause 5.2.6) is not evaluated in this test report.

Zustand des Prüfgegenstandes bei Anlieferung: / Condition of the test item at delivery: Prüfmuster vollständig und unbeschädigt / Test item complete and undamaged

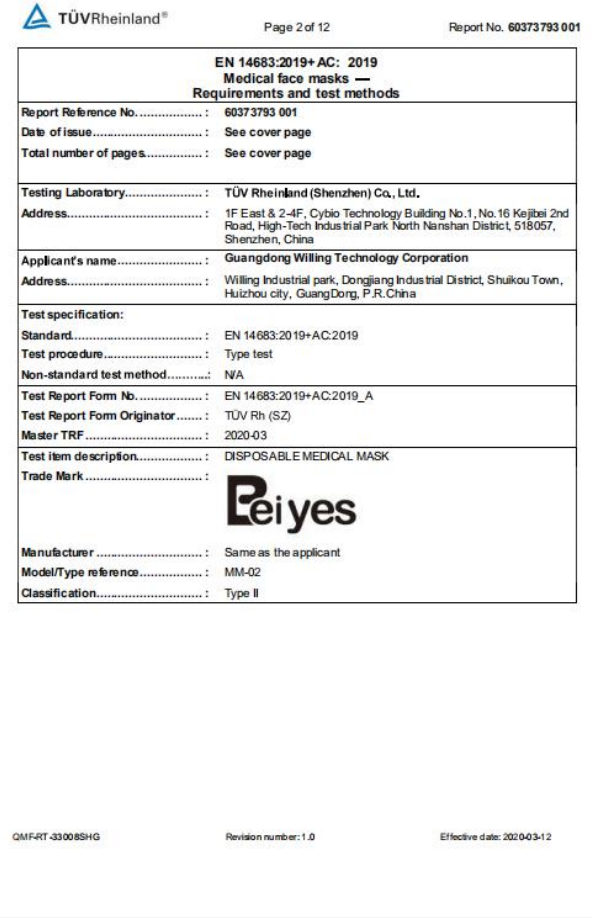
* Legende: 1 = sehr gut / P(ass) = entspricht o.g. Prüfgrundlage(n) / 2 = gut / 3 = befriedigend / F(ail) = entspricht nicht o.g. Prüfgrundlage(n) / 4 = ausreichend / N/A = nicht anwendbar / 5 = mangelhaft / N/T = nicht getestet

Legend: 1 = very good / P(ass) = passed a.m. test specification(s) / 2 = good / 3 = satisfactory / F(ail) = failed a.m. test specification(s) / 4 = sufficient / N/A = not applicable / 5 = poor / N/T = not tested

Dieser Prüfbericht bezieht sich nur auf das o.g. Prüfmuster und darf ohne Genehmigung der Prüfstelle nicht auszugsweise vervielfältigt werden. Dieser Bericht berechtigt nicht zur Verwendung eines Prüfzeichens.

This test report only relates to the a. m. test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any test mark.

V04



TÜVRheinland®

EN 14683:2019+AC: 2019
Medical face masks —
Requirements and test methods

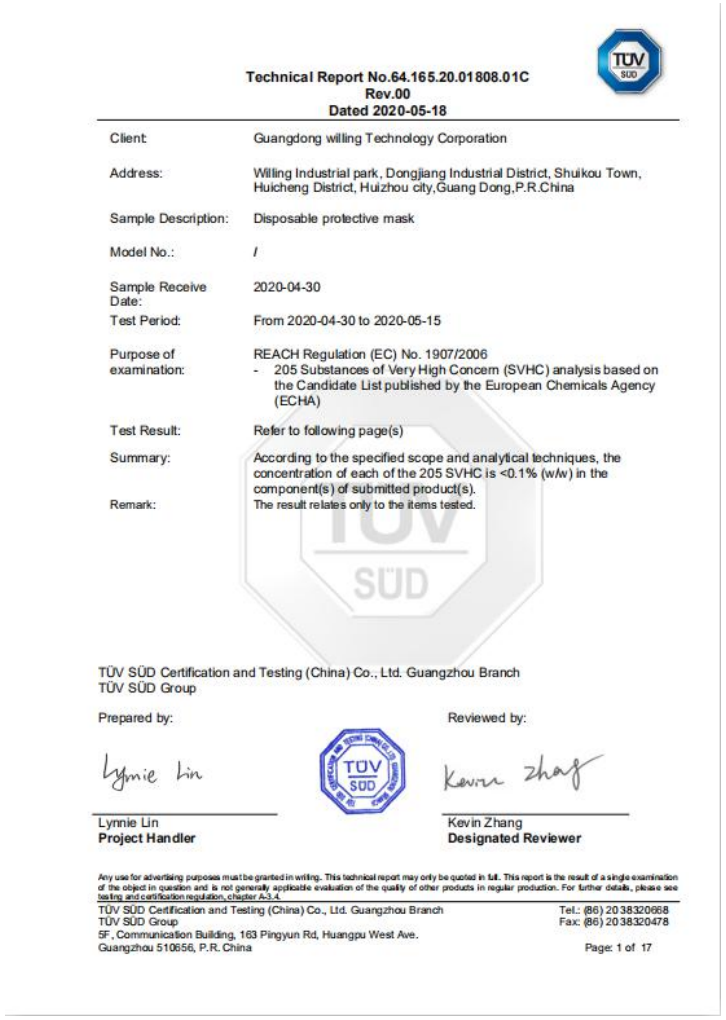
Report Reference No.	60373793 001
Date of issue	See cover page
Total number of pages	See cover page
Testing Laboratory	TÜV Rheinland (Shenzhen) Co., Ltd.
Address	1F East & 2-4F, Cybio Technology Building No.1, No.16 Kejibei 2nd Road, High-Tech Industrial Park North Nanshan District, 518057, Shenzhen, China
Applicant's name	Guangdong Willing Technology Corporation
Address	Willing Industrial park, Dongjiang Industrial District, Shuikou Town, Huizhou city, GuangDong, P.R.China
Test specification:	
Standard	EN 14683:2019+AC:2019
Test procedure	Type test
Non-standard test method	N/A
Test Report Form No.	EN 14683:2019+AC:2019_A
Test Report Form Originator	TÜV Rh (SZ)
Master TRF	2020-03
Test item description	DISPOSABLE MEDICAL MASK
Trade Mark	Peiyes
Manufacturer	Same as the applicant
Model/Type reference	MM-02
Classification	Type II

Shenzhen Shengshi Kanghua Industrial Group

Shenzhen Shengshi KanghuaTechnology Co., Ltd

GUANGDONG WILLING TECHNOLOGY CORPORATION

Test report



Technical Report No.64.165.20.01808.01C
Rev.00
Dated 2020-05-18

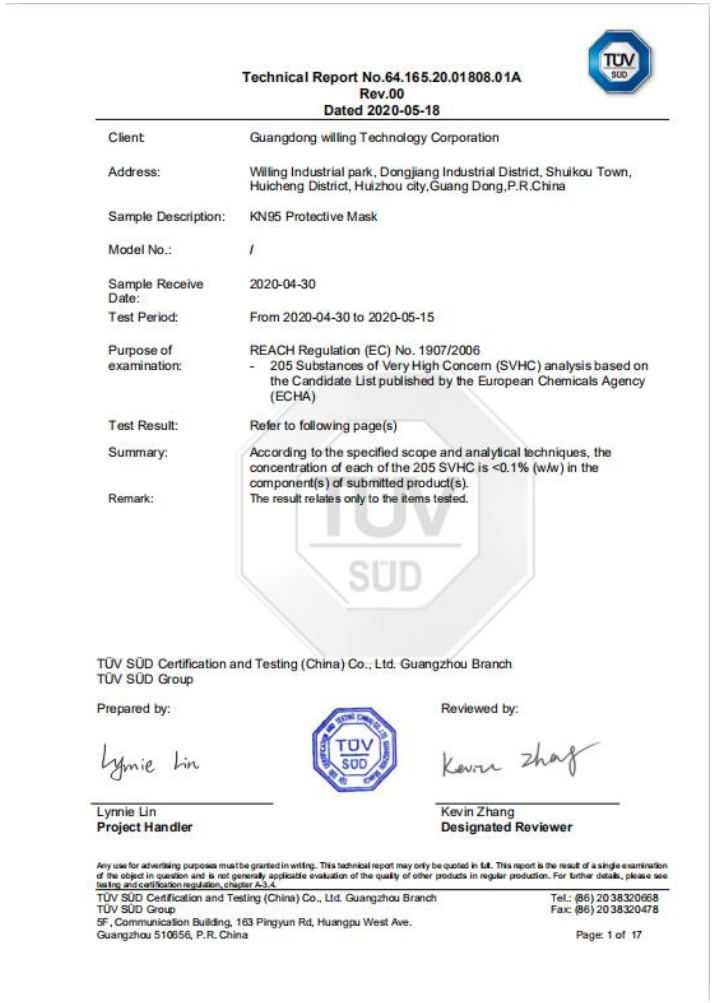
Client:	Guangdong willing Technology Corporation
Address:	Willing Industrial park, Dongjiang Industrial District, Shuikou Town, Huicheng District, Huizhou city,Guang Dong,P.R.China
Sample Description:	Disposable protective mask
Model No.:	/
Sample Receive Date:	2020-04-30
Test Period:	From 2020-04-30 to 2020-05-15
Purpose of examination:	REACH Regulation (EC) No. 1907/2006 - 205 Substances of Very High Concern (SVHC) analysis based on the Candidate List published by the European Chemicals Agency (ECHA)
Test Result:	Refer to following page(s)
Summary:	According to the specified scope and analytical techniques, the concentration of each of the 205 SVHC is <0.1% (w/w) in the component(s) of submitted product(s).
Remark:	The result relates only to the items tested.

TÜV SÜD Certification and Testing (China) Co., Ltd. Guangzhou Branch
TÜV SÜD Group

Prepared by: Lynnie Lin
Project Handler

Reviewed by: Kevin Zhang
Designated Reviewer

TÜV SÜD Certification and Testing (China) Co., Ltd. Guangzhou Branch
TÜV SÜD Group
5F, Communication Building, 163 Pingyun Rd, Huangpu West Ave.
Guangzhou 510656, P.R. China
Tel.: (86) 20 38320668
Fax: (86) 20 38320478



Technical Report No.64.165.20.01808.01A
Rev.00
Dated 2020-05-18

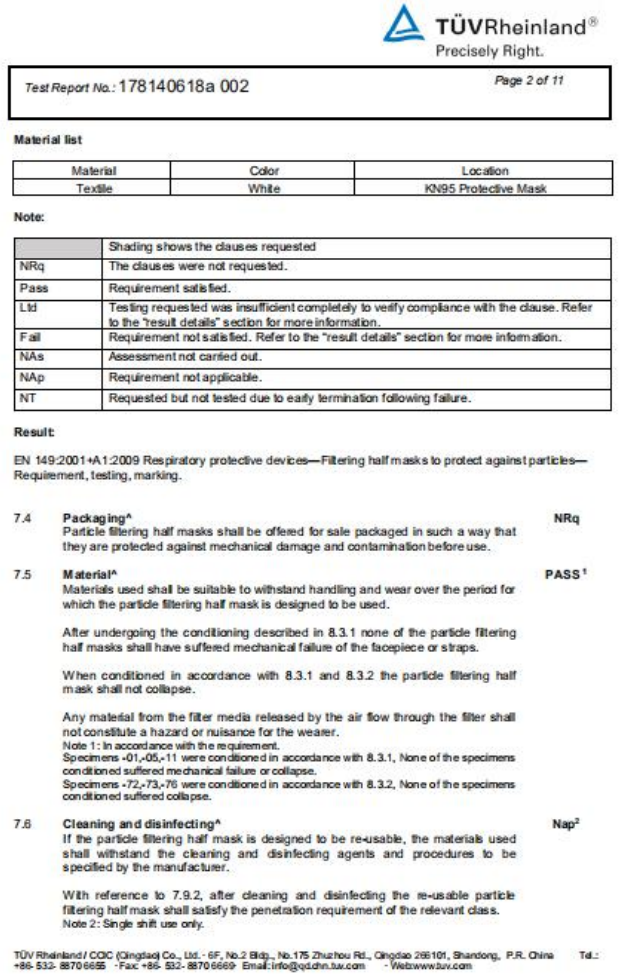
Client:	Guangdong willing Technology Corporation
Address:	Willing Industrial park, Dongjiang Industrial District, Shuikou Town, Huicheng District, Huizhou city,Guang Dong,P.R.China
Sample Description:	KN95 Protective Mask
Model No.:	/
Sample Receive Date:	2020-04-30
Test Period:	From 2020-04-30 to 2020-05-15
Purpose of examination:	REACH Regulation (EC) No. 1907/2006 - 205 Substances of Very High Concern (SVHC) analysis based on the Candidate List published by the European Chemicals Agency (ECHA)
Test Result:	Refer to following page(s)
Summary:	According to the specified scope and analytical techniques, the concentration of each of the 205 SVHC is <0.1% (w/w) in the component(s) of submitted product(s).
Remark:	The result relates only to the items tested.

TÜV SÜD Certification and Testing (China) Co., Ltd. Guangzhou Branch
TÜV SÜD Group

Prepared by: Lynnie Lin
Project Handler

Reviewed by: Kevin Zhang
Designated Reviewer

TÜV SÜD Certification and Testing (China) Co., Ltd. Guangzhou Branch
TÜV SÜD Group
5F, Communication Building, 163 Pingyun Rd, Huangpu West Ave.
Guangzhou 510656, P.R. China
Tel.: (86) 20 38320668
Fax: (86) 20 38320478



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Precisely Right.

Test Report No.: 178140618a 002 *Page 2 of 11*

Material list

Material	Color	Location
Textile	White	KN95 Protective Mask

Note:

	Shading shows the clauses requested
NRq	The clauses were not requested.
Pass	Requirement satisfied.
Ltd	Testing requested was insufficient completely to verify compliance with the clause. Refer to the "result details" section for more information.
Fail	Requirement not satisfied. Refer to the "result details" section for more information.
NAs	Assessment not carried out.
NAp	Requirement not applicable.
NT	Requested but not tested due to early termination following failure.

Result:

EN 149:2001+A1:2009 Respiratory protective devices—Filtering half masks to protect against particles—Requirement, testing, marking.

7.4 **Packaging^** — **NRq**
Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.

7.5 **Material^** — **PASS[1]**
Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.

After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.

When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.

Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.
Note 1: In accordance with the requirement.
Specimens -01,-05,-11 were conditioned in accordance with 8.3.1, None of the specimens conditioned suffered mechanical failure or collapse.
Specimens -72,-73,-76 were conditioned in accordance with 8.3.2, None of the specimens conditioned suffered collapse.

7.6 **Cleaning and disinfecting^** — **Nap[2]**
If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer.

With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.
Note 2: Single shift use only.

GUANGDONG WILLING TECHNOLOGY CORPORATION

Packaging instruction

◆ KN95 PROTECTIVE MASK-PACKAGE 包装简介

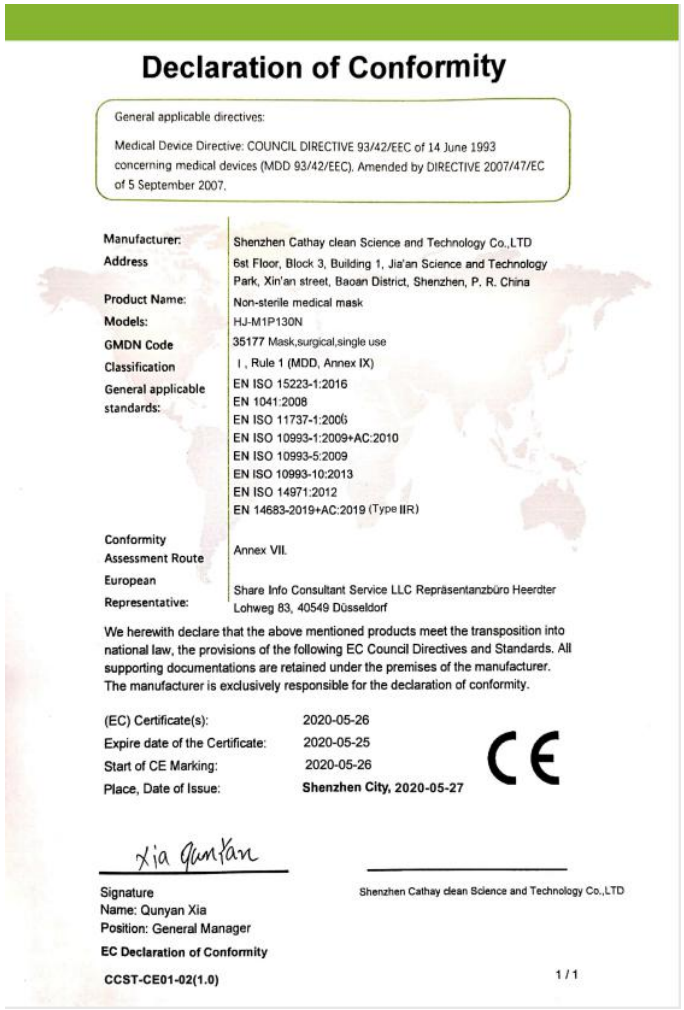
Gift box size：180X120X40mm（10 pcs/box ）　　G.W：0.076Kg
Master Carton size：510X380X440mm（80 pack/CTN）　　G.W：6.8Kg

◆ DISPOSABLE PROTECTIVE MASK-PACKAGE 包装简介

Gift box size：190X100X85mm（50 pcs/box ）　　G.W：0.187Kg
Master Carton size：530X400X380mm（40 pack/CTN）　　G.W：8.7Kg

CE&FDA

Shenzhen Cathay Clean Science and Technology Co.,LTD



Declaration of Conformity

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007.

Manufacturer:	Shenzhen Cathay clean Science and Technology Co.,LTD
Address	6st Floor, Block 3, Building 1, Jia'an Science and Technology Park, Xin'an street, Baoan District, Shenzhen, P. R. China
Product Name:	Non-sterile medical mask
Models:	HJ-M1P130N
GMDN Code	35177 Mask,surgical,single use
Classification	I , Rule 1 (MDD, Annex IX)
General applicable standards:	EN ISO 15223-1:2016 EN 1041:2008 EN ISO 11737-1:2006 EN ISO 10993-1:2009+AC:2010 EN ISO 10993-5:2009 EN ISO 10993-10:2013 EN ISO 14971:2012 EN 14683-2019+AC:2019 (Type IIR)
Conformity Assessment Route	Annex VII.
European Representative:	Share Info Consultant Service LLC Repräsentanzbüro Heerdter Lohweg 83, 40549 Düsseldorf

We herewith declare 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. The manufacturer is exclusively responsible for the declaration of conformity.

(EC) Certificate(s):	2020-05-26
Expire date of the Certificate:	2020-05-25
Start of CE Marking:	2020-05-26
Place, Date of Issue:	**Shenzhen City, 2020-05-27**

CE

Xia Qunyan

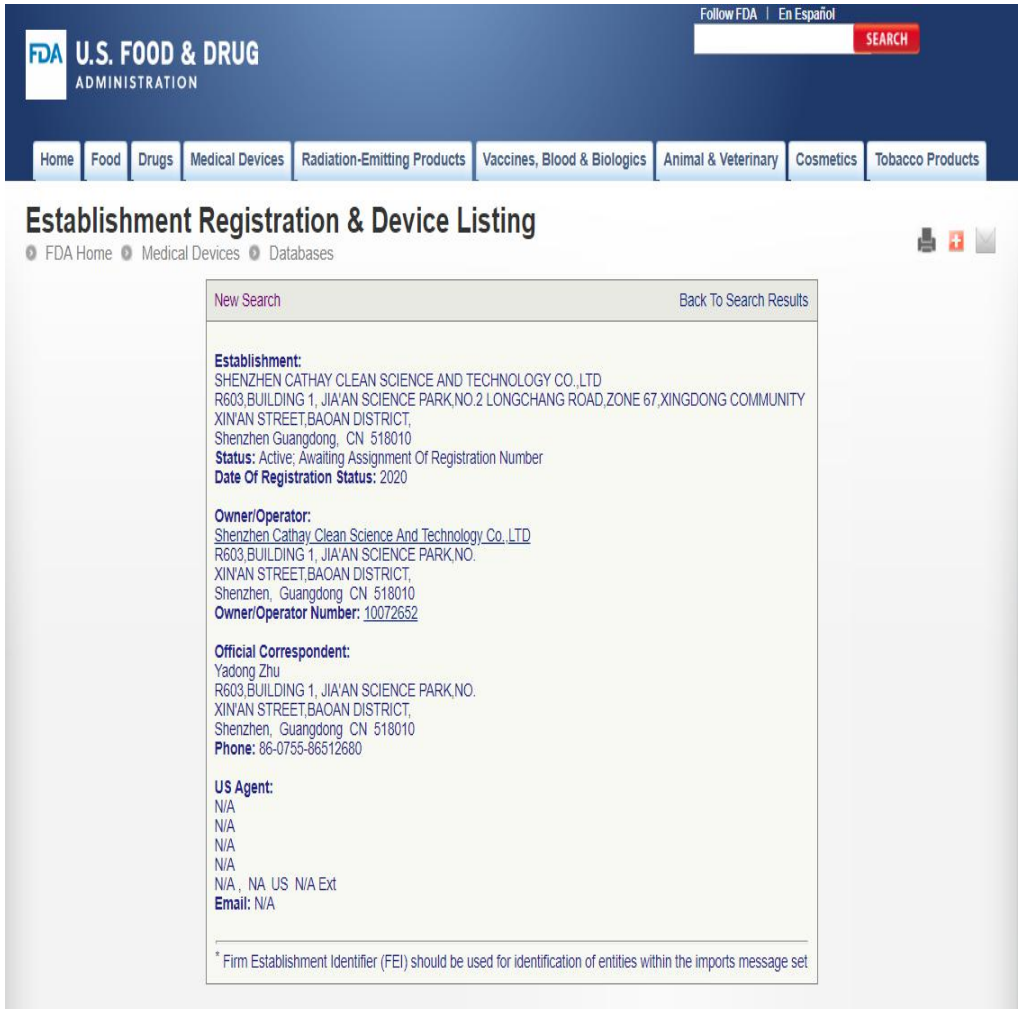
Signature
Name: Qunyan Xia
Position: General Manager

Shenzhen Cathay clean Science and Technology Co.,LTD

EC Declaration of Conformity

CCST-CE01-02(1.0)

1 / 1



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Establishment Registration & Device Listing

FDA Home ▸ Medical Devices ▸ Databases

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Establishment:
SHENZHEN CATHAY CLEAN SCIENCE AND TECHNOLOGY CO.,LTD
R603,BUILDING 1, JIA'AN SCIENCE PARK,NO.2 LONGCHANG ROAD,ZONE 67,XINGDONG COMMUNITY
XIN'AN STREET,BAOAN DISTRICT,
Shenzhen Guangdong, CN 518010
Status: Active; Awaiting Assignment Of Registration Number
Date Of Registration Status: 2020

Owner/Operator:
Shenzhen Cathay Clean Science And Technology Co. LTD
R603,BUILDING 1, JIA'AN SCIENCE PARK,NO.
XIN'AN STREET,BAOAN DISTRICT,
Shenzhen, Guangdong CN 518010
Owner/Operator Number: 10072652

Official Correspondent:
Yadong Zhu
R603,BUILDING 1, JIA'AN SCIENCE PARK,NO.
XIN'AN STREET,BAOAN DISTRICT,
Shenzhen, Guangdong CN 518010
Phone: 86-0755-86512680

US Agent:
N/A
N/A
N/A
N/A
N/A , NA US N/A Ext
Email: N/A

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Shenzhen Shengshi Kanghua Industrial Group

Shenzhen Shengshi KanghuaTechnology Co., Ltd

Disposable medical mask test report

Shenzhen Cathay Clean Science and Technology Co.,LTD

Test Report No. 66.441.20.5815.01
Dated 2020-05-27

Applicant	:	Shenzhen Cathay Clean Science and Technology Co.,LTD
Address	:	R603, Building 1, Jia'an Science Park, No.2 Longchang Road, Zone 67, Xingdong Community, Xin'an Street, Baoan District, Shenzhen P.R.China
Contact Person	:	Yadong Zhu
Sample Description	:	Non-sterile medical mask
Color	:	White
Style No	:	HJ-M1P130N
Order No	:	362119882038
End Use	:	Defense The Virs
Lot No	:	20200408
Size	:	17.5*9.5
Manufacturer / Supplier	:	Shenzhen Cathay Clean Science and Technology Co.,LTD
Country of Origin	:	China
Country of Destination	:	America,EU
Sample Received Date	:	2020-05-20
Date of Testing	:	2020-05-21 to 2020-05-26
Sample Submitted	:	The sample(s) was (were) submitted by applicant and identified.
Test Result(s)	:	Refer to the Section 3
Restricted Substance List (RSL) test conclusion(s) is/are based on	:	REACH Regulation (EC) No. 1907/2006 Annex XVII Restrictions On The Manufacture, Placing On The Market And Use Of Certain Dangerous Substances, Mixtures And Articles; REGULATION (EU) 2019/1021 on Persistent Organic Pollutants, Annex I
SVHC Examination Purpose	:	Analysis of the 205 substances of very high concern (SVHC) on the Candidate List for authorization, concerning Regulation (EC) No. 1907/2006 as published on the European Chemicals Agency (ECHA) website in October 2008, January 2010, March 2010, June 2010, December 2010, June 2011, December 2011, June 2012, December 2012, June 2013, December 2013 ,June 2014, December 2014, June 2015, December 2015, June 2016, January 2017, July 2017, January 2018,June 2018, January 2019, July 2019 and January 2020

Remark: The result relates only to the items tested.
Any use for advertising purposes must be granted in writing. This technical report may only be quoted in full. This report is the result of a single examination of the object in question and is not generally applicable evaluation of the quality of other products in regular production. For further details, please see testing and certification regulation, chapter A-3.4.

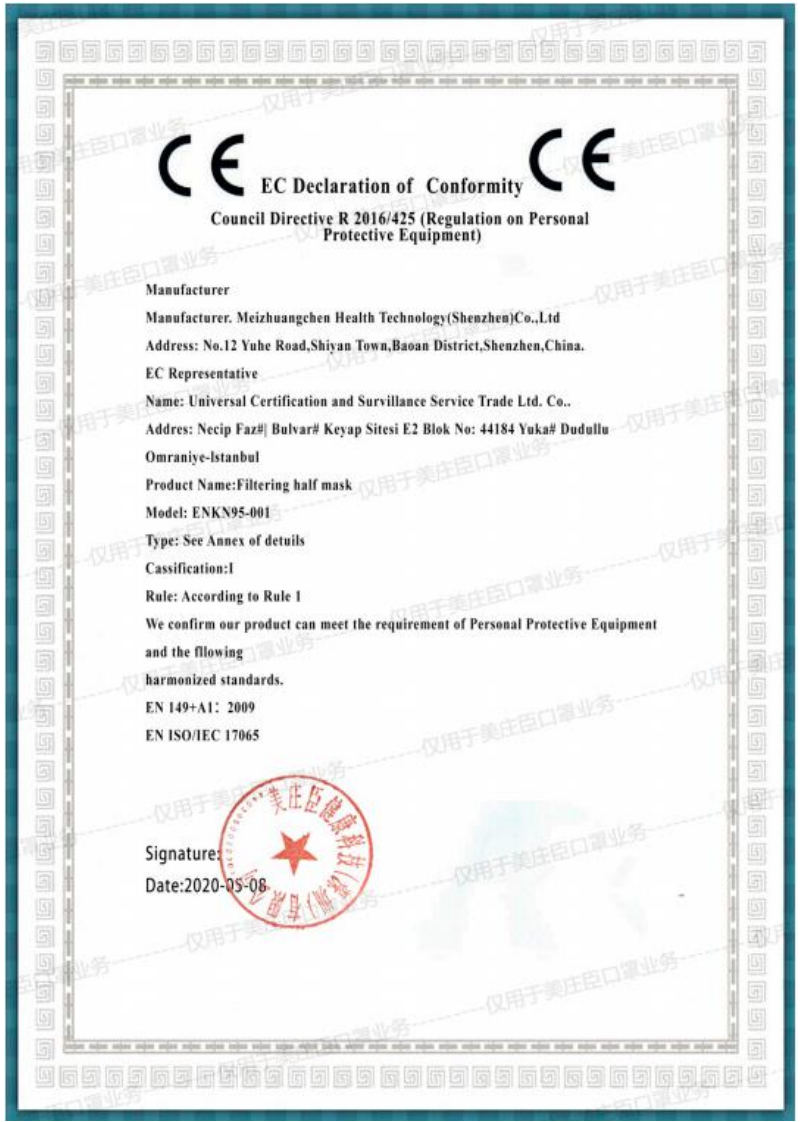
Test Report No. 66.441.20.5815.01
Dated 2020-05-27

1. Description of the test subject:

1.	Light Blue/White face mask
2.	Light Blue nonwoven fabric (upper)
3.	White nonwoven fabric (lining)
4.	White melt-blown fabric (interlining)
5.	White fabric rope (ear hook)
6.	White plastic (nasal splint)
7.	Silver metal wire of plastic strip (nasal splint)

Mezorrison Health Science & Technology (Shenzhen) Co.,Ltd

CE&FDA



CE EC Declaration of Conformity CE

Council Directive R 2016/425 (Regulation on Personal Protective Equipment)

Manufacturer

Manufacturer. Meizhuangchen Health Technology(Shenzhen)Co.,Ltd

Address: No.12 Yuhe Road,Shiyan Town,Baoan District,Shenzhen,China.

EC Representative

Name: Universal Certification and Survillance Service Trade Ltd. Co..

Addres: Necip Faz#| Bulvar# Keyap Sitesi E2 Blok No: 44184 Yuka# Dudullu Omraniye-Istanbul

Product Name:Filtering half mask

Model: ENKN95-001

Type: See Annex of detuils

Cassification:I

Rule: According to Rule 1

We confirm our product can meet the requirement of Personal Protective Equipment and the fllowing harmonized standards.

EN 149+A1：2009

EN ISO/IEC 17065

Signature:

Date:2020-05-08

CERTIFICATION OF REGISTRATION

This certifies that:

Mezorrison Health Science &Technology(Shenzhen) Co., Ltd

No.12 Yuhe Road, Shiyan Town, Bao'an District, Shenzhen, Guangdong, 518000, CHINA

is registered and has listed the following medical device with the U.S. Food and Drug Administration :

Owner/Operator Number : 10064314

Listing Number: D378809

Product Code : MSH

Product : Respirator filter

Model(s) : MZC-KZ-06

Date Of Registration Status: 2020

Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holderd's device or establishment by the U.S. Food and Drug Administration. Registrar Corp assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Registrar Corp is not affiliated with the U.S. Food and Drug Administration

Chief Engineer: Zaochao Lee

Issued: Mar. 25, 2020

Validity Period:2020-12-31

Web rep/www.fda.gov Tel 1-888-INF0-FDA(1-888-0332) E-mal vcrp@fda.gov

Mezorrison Health Science & Technology (Shenzhen) Co.,Ltd

CE

UNIVERSAL
CERTIFICATION
NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163 - PPE - 667

Respiratory protective devices, filtering half masks to protect against particles manufactured for

DISTRIBUZIONE JUNIOR SRL
Via Pace, 25/26 - 80047 San Giuseppe Vesuviano (Na) ITALY
manufactured at
MEIZHUANGCHEN HEALTH TECHNOLOGY (SHENZHEN) CO., LTD
Meizhuangchen Health Technology (Shenzhen) Co. Ltd
No.12, Yuhe Road, Shiyan Town, Baoan District, Shenzhen, China.

are tested and evaluated according to

EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

Product Definition

Branda : ENHANCE **Model:** ENKN95-001
Filtering half mask
Total Inwards Leakage: Class – FFP2

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.**
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective **Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on **08 / 05 /2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

CE 2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR

Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Ümraniye - İSTANBUL - TURKEY T:+90 216 455 80 80
UNIVERSALCERT.COM

UNIVERSAL
CERTIFICATION
NB 2163

CERTIFICATE OF CONFORMANCE

Certificate Nr: 2163 - PPE – 667/01

Respiratory protective devices, filtering half masks to protect against particles manufactured for

DISTRIBUZIONE JUNIOR SRL
Via Pace, 25/26 - 80047 San Giuseppe Vesuviano (Na) ITALY
manufactured at
MEIZHUANGCHEN HEALTH TECHNOLOGY (SHENZHEN) CO., LTD
Meizhuangchen Health Technology (Shenzhen) Co. Ltd
No.12, Yuhe Road, Shiyan Town, Baoan District, Shenzhen, China.

Continues to fulfil the requirements of

EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Based on the evaluation of test reports and internal quality control audit reports according to EN 149+A1:2009 and Personal Protective Equipment Regulation (EU) 2016/425 Annex VII (Module C2). This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation.

Product Definition

Model	Class	EU Type Examination Certificate		
		Serial Nr.	Date	Issuing NB Nr.
ENKN95-001	FFP2	2163-PPE-667	08.05.2020	2163

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.**
- Taking all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type examination certificate.

This certificate is issued on **08/05/2020** and will be valid for one year, until **07/05/2021** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.

CE 2163

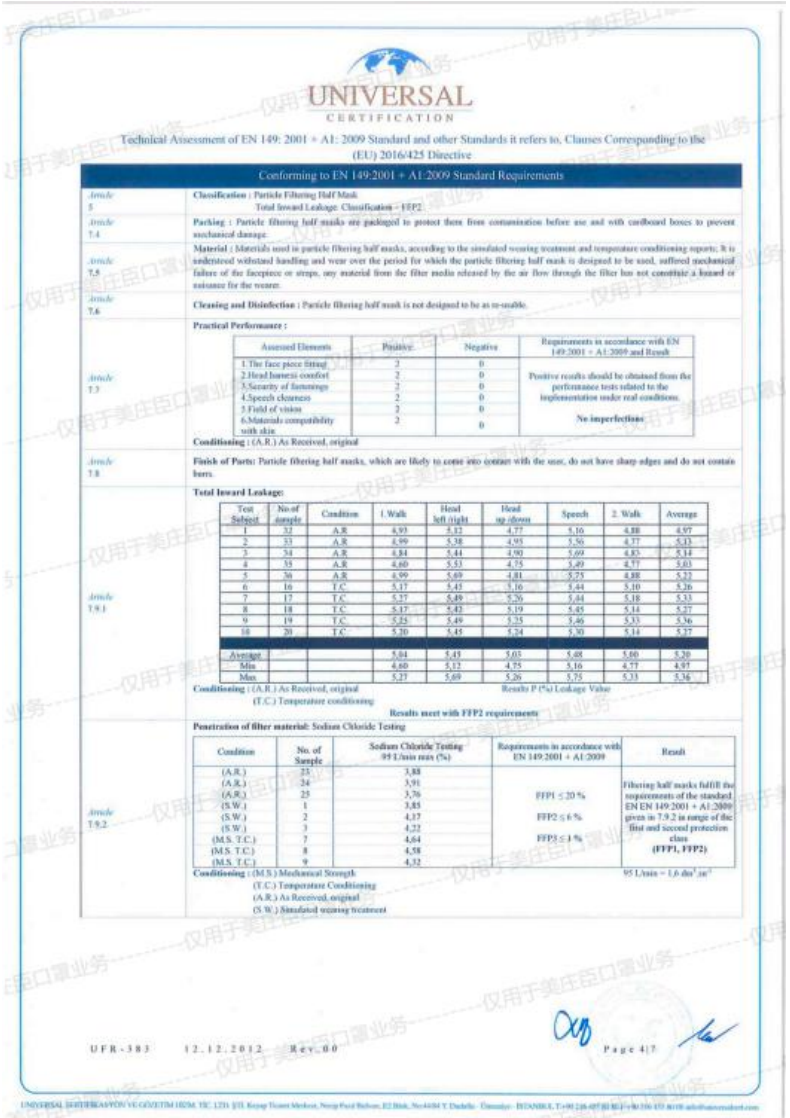
Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR

Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Ümraniye - İSTANBUL - TURKEY T:+90 216 455 80 80
UNIVERSALCERT.COM

Test report

Mezorrison Health Science & Technology (Shenzhen) Co.,Ltd



UNIVERSAL
CERTIFICATION

Technical Assessment of EN 149: 2001 + A1: 2009 Standard and other Standards it refers to, Clauses Corresponding to the (EU) 2016/425 Directive

Conforming to EN 149:2001 + A1:2009 Standard Requirements

Article 5 — **Classification :** Particle Filtering Half Mask
Total Inward Leakage Classification – FFP2

Article 7.4 — **Packing :** Particle filtering half masks are packaged to protect them from contamination before use and with cardboard boxes to prevent mechanical damage.

Article 7.5 — **Material :** Materials used in particle filtering half masks, according to the simulated wearing treatment and temperature conditioning reports; It is understood withstand handling and wear over the period for which the particle filtering half mask is designed to be used, suffered mechanical failure of the facepiece or straps, any material from the filter media released by the air flow through the filter has not constitute a hazard or nuisance for the wearer.

Article 7.6 — **Cleaning and Disinfection :** Particle filtering half mask is not designed to be as re-usable.

Article 7.3 — **Practical Performance :**

Assessed Elements	Positive	Negative	Requirements in accordance with EN 149:2001 + A1:2009 and Result
1.The face piece fitting	2	0	Positive results should be obtained from the performance tests related to the implementation under real conditions. No imperfections
2.Head harness comfort	2	0	
3.Security of fastenings	2	0	
4.Speech clearness	2	0	
5.Field of vision	2	0	
6.Materials compatibility with skin	2	0	

Conditioning : (A.R.) As Received, original

Article 7.8 — **Finish of Parts:** Particle filtering half masks, which are likely to come into contact with the user, do not have sharp edges and do not contain burrs.

Article 7.9.1 — **Total Inward Leakage:**

Test Subject	No.of sample	Condition	1.Walk	Head left /right	Head up /down	Speech	2. Walk	Average
1	32	A.R	4,93	4,32	4,77	5,16	4,88	4,97
2	33	A.R	4,99	5,38	4,95	5,56	4,77	5,13
3	34	A.R	4,84	5,44	4,90	5,69	4,85	5,14
4	35	A.R	4,60	5,53	4,75	5,49	4,77	5,03
5	36	A.R	4,99	5,69	4,81	5,75	4,88	5,22
6	16	T.C	5,17	5,45	5,16	5,44	5,10	5,26
7	17	T.C	5,37	5,49	5,26	5,64	5,18	5,33
8	18	T.C	5,17	5,42	5,19	5,45	5,14	5,27
9	19	T.C	5,25	5,49	5,25	5,46	5,33	5,36
10	20	T.C	5,20	5,45	5,24	5,30	5,14	5,27
Average			5,04	5,45	5,03	5,48	5,00	5,20
Min			4,60	5,12	4,75	5,16	4,77	4,97
Max			5,37	5,69	5,26	5,75	5,33	5,36

Conditioning : (A.R.) As Received, original — Results P (%) Leakage Value
(T.C.) Temperature conditioning
Results meet with FFP2 requirements

Article 7.9.2 — **Penetration of filter material:** Sodium Chloride Testing

Condition	No. of Sample	Sodium Chloride Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	23	3,88	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Filtering half masks fulfil the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the first and second protection class (FFP1, FFP2)
(A.R.)	24	3,91		
(A.R.)	25	3,76		
(S.W.)	1	3,85		
(S.W.)	2	4,17		
(S.W.)	3	4,22		
(M.S. T.C.)	7	4,64		
(M.S. T.C.)	8	4,58		
(M.S. T.C.)	9	4,32		

Conditioning : (M.S.) Mechanical Strength — 95 L/min = 1,6 dm³/sn
(T.C.) Temperature Conditioning
(A.R.) As Received, original
(S.W.) Simulated wearing treatment

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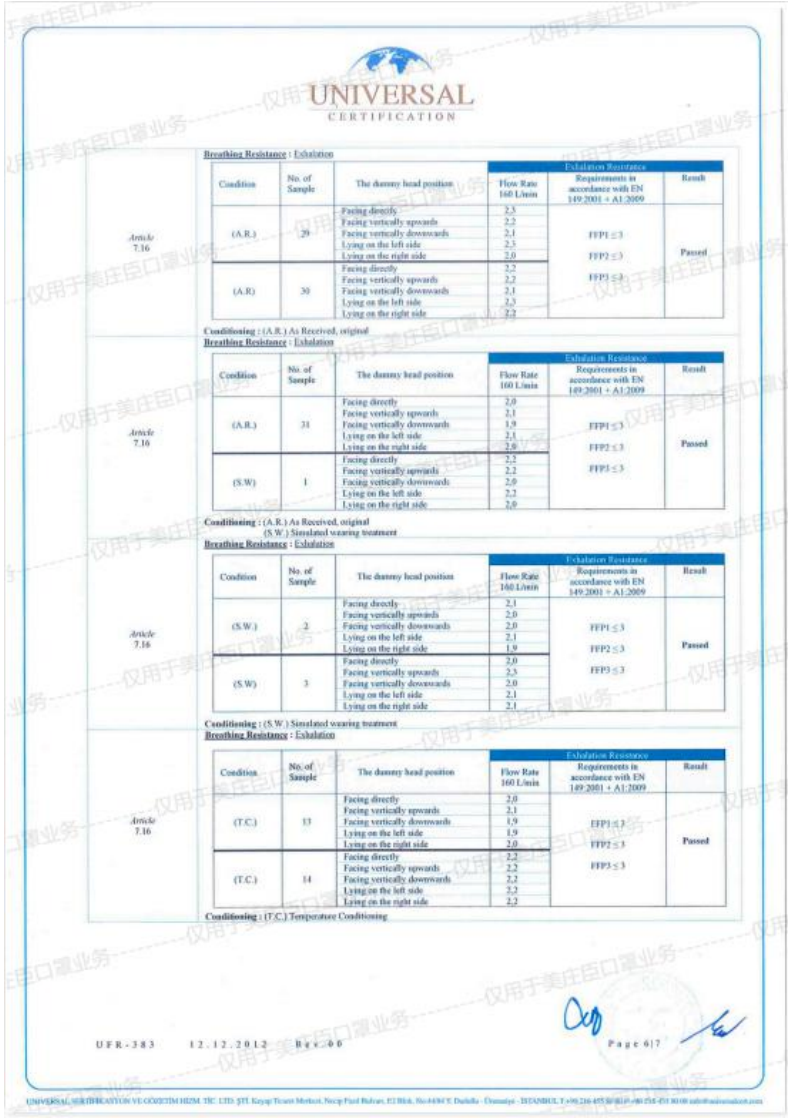

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CERTIFICATION

Article 7.16 — **Breathing Resistance :** Exhalation

Condition	No. of Sample	The dummy head position	Exhalation Resistance: Flow Rate 160 L/min	Exhalation Resistance: Requirements in accordance with EN 149:2001 + A1:2009	Exhalation Resistance: Result
(A.R.)	29	Facing directly	2,3	FFP1 ≤ 3 FFP2 ≤ 3 FFP3 ≤ 4	Passed
		Facing vertically upwards	2,2		
		Facing vertically downwards	2,1		
		Lying on the left side	2,3		
		Lying on the right side	2,0		
(A.R)	30	Facing directly	2,2		
		Facing vertically upwards	2,2		
		Facing vertically downwards	2,1		
		Lying on the left side	2,3		
		Lying on the right side	2,2		

Conditioning : (A.R.) As Received, original

Article 7.16 — **Breathing Resistance :** Exhalation

Condition	No. of Sample	The dummy head position	Exhalation Resistance: Flow Rate 160 L/min	Exhalation Resistance: Requirements in accordance with EN 149:2001 + A1:2009	Exhalation Resistance: Result
(A.R.)	31	Facing directly	2,0	FFP1 ≤ 3 FFP2 ≤ 3 FFP3 ≤ 3	Passed
		Facing vertically upwards	2,1		
		Facing vertically downwards	1,9		
		Lying on the left side	2,1		
		Lying on the right side	2,0		
(S.W)	1	Facing directly	2,2		
		Facing vertically upwards	2,2		
		Facing vertically downwards	2,0		
		Lying on the left side	2,2		
		Lying on the right side	2,0		

Conditioning : (A.R.) As Received, original
(S.W.) Simulated wearing treatment

Article 7.16 — **Breathing Resistance :** Exhalation

Condition	No. of Sample	The dummy head position	Exhalation Resistance: Flow Rate 160 L/min	Exhalation Resistance: Requirements in accordance with EN 149:2001 + A1:2009	Exhalation Resistance: Result
(S.W.)	2	Facing directly	2,1	FFP1 ≤ 3 FFP2 ≤ 3 FFP3 ≤ 3	Passed
		Facing vertically upwards	2,0		
		Facing vertically downwards	2,0		
		Lying on the left side	2,1		
		Lying on the right side	1,9		
(S.W)	3	Facing directly	2,0		
		Facing vertically upwards	2,3		
		Facing vertically downwards	2,0		
		Lying on the left side	2,1		
		Lying on the right side	2,1		

Conditioning : (S.W.) Simulated wearing treatment

Article 7.16 — **Breathing Resistance :** Exhalation

Condition	No. of Sample	The dummy head position	Exhalation Resistance: Flow Rate 160 L/min	Exhalation Resistance: Requirements in accordance with EN 149:2001 + A1:2009	Exhalation Resistance: Result
(T.C.)	13	Facing directly	2,0	FFP1 ≤ 3 FFP2 ≤ 3 FFP3 ≤ 3	Passed
		Facing vertically upwards	2,1		
		Facing vertically downwards	1,9		
		Lying on the left side	1,9		
		Lying on the right side	2,0		
(T.C.)	14	Facing directly	2,2		
		Facing vertically upwards	2,2		
		Facing vertically downwards	2,2		
		Lying on the left side	2,2		
		Lying on the right side	2,2		

Conditioning : (T.C.) Temperature Conditioning

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Test report

Mezorrison Health Science & Technology (Shenzhen) Co.,Ltd

Test Report No.: 68.431.20.02240.01
Dated: 2020-05-14

Applicant	:	Mezorrison Health Science & Technology (shenzhen) Co., Ltd No.12 Yuhe Road, Shiyan Town, Baoan District, Shenzhen
Sample Description	:	mezorison mask
Supplier	:	Mezorrison
Test Sample Receipt Date, Location	:	2020-05-06, Shenzhen
Test Period, Location	:	From 2020-05-06 to 2020-05-12, Shenzhen
Test Result(s)	:	Refer to Section 3

907/2006 Entry 23

Test Report No.: 68.431.20.02240.01
Dated: 2020-05-14

Purpose Of Examination / Conclusion:

No.	Test Item(s)	Conclusion
1.	**Total Lead** Regulation (EC) No.1907/2006 Annex XVII, Entry 63 and its amendment Regulation (EU) 2015/628	Pass
2.	**Polycyclic Aromatic Hydrocarbons (PAHs)** Regulation (EC) No.1907/2006 and its amendment (EU) No. 1272/2013 Regulation (EC) No. 552/2009 Annex XVII, Entry 50	Pass
3.	**Phthalates** Regulation (EC) No.1907/2006 and its amendment Regulation (EC) No. 2018/2005 Annex XVII, Entry 51 and 52.	Pass
4.	**Total Cadmium** Regulation (EU) 2016/217, amending Annex XVII to Regulation (EC) No. 1907/2006 Entry 23.	Pass

Remarks:
(1) The results relate only to the items tested.
(2) Samples are tested as received.
(3) "Pass" means the measured result is within a limit, even when extended by expanded uncertainty. "Fail" means the measured result is beyond a limit, even when extended by expanded uncertainty. "Inconclusive" means the measured result can be within or beyond a limit when extended by expanded uncertainty. The confidence level of the expanded uncertainty for "Pass", "Fail" and "Inconclusive" is 95%.

TÜV SÜD Certification and Testing (China) Co., Ltd. Shenzhen Branch
TÜV SÜD Group

Prepared by: Cara Xiang, Senior Project Coordinator

Reviewed by: Ken Chen, Project Manager

Any use for advertising purposes must be granted in writing. This technical report may only be quoted in full. This report is the result of a single examination of the object in question and is not generally applicable evaluation of the quality of other products in regular production. For further details, please see testing and certification regulation, chapter A-3.4.

Shenzhen Tianlong Century Technology Development Co., Ltd.

FDA

Fiscal Year 2020
CERTIFICATION OF REGISTRATION

This certifies that:

SHENZHEN TIANLONG CENTURY TECHNOLOGY

DEVELOPMENT CO.,LTD.

3&5th Floor, Building 1, Quanxinyuan Industrial zone,Tongsheng community,Dalang street, Longhua District, Shenzhen, GUANGDONG, 518000, CHINA

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through

HEALREG SERVICE INC

Owner/Operator Number: 10064253

Device Listing#: See annex

HEALREG SERVICE INC will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. HEALREG SERVICE INC makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. HEALREG SERVICE INC assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, HEALREG SERVICE INC is not affiliated with the U.S. Food and Drug Administration.

FDA

Chief engineer
Issued: March 25, 2020
Expiration Date: December 31, 2020

Fiscal Year 2020
CERTIFICATION OF REGISTRATION

Annex to Device Listing# for Owner/Operator Number: 10064253

Listing No.	Code	Device Name	Proprietary Names	Activities
D378655	MSH	Respirator, surgical	Disposable protective mask TL-M01, TL-M02 KN95 protective mask TL-KN95-01	Manufacturer Repackager/Relabeler

END OF THE ANNEX

Chief engineer
Issued: March 25, 2020
Expiration Date: December 31, 2020

Shenzhen Shengshi Kanghua Industrial Group

Shenzhen Shengshi KanghuaTechnology Co., Ltd

Shenzhen Tianlong Century Technology Development Co., Ltd.

CE

bsi.

EU Type Examination Certificate

This is to certify that: Shenzhen Tianlong Century Technology Development Co.,Ltd. 3 & 5th Floor, Building 1 Quanxinyuan Industrial zone Tongsheng community, Dalang street Longhua District, Shenzhen Guangdong 518000 China

Holds Certificate Number: CE 728603

In respect of:

Model TL-KN95-01 Face mask.
To technical specification Annex II (EHSR) of the PPE Regulation (EU) 2016/425
PPE for use by healthcare professionals as per Commission recommendation 2020/403

on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):
Drs. Dave Hagenaars, Managing Director

Previous Notified Body: BSI 0086
First Issued: 2020-05-26
Latest Issue: 2020-05-26
Effective Date: 2020-05-26
Expiry Date: 2021-05-26

Page: 1 of 3

...making excellence a habit.™

This certificate has been issued by and remains the property of BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands and should be returned immediately upon request.
To check its validity telephone +31 20 3460780. An electronic certificate can be authenticated online.

BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
A member of BSI Group of Companies.

bsi.

Conformity to Type based on Internal Production Control plus supervised product checks at random intervals

This is to certify that: Shenzhen Tianlong Century Technology Development Co.,Ltd. 3 & 5th Floor, Building 1 Quanxinyuan Industrial zone Tongsheng community, Dalang street Longhua District, Shenzhen Guangdong 518000 China

Holds Certificate Number: CE 728605

In respect of:

Model TL-KN95-01 Face mask.
To technical specification Annex II (EHSR) of the PPE Regulation (EU) 2016/425
PPE for use by healthcare professionals as per Commission recommendation 2020/403

on the basis that BSI carried out the supervised production checks at random intervals under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex VII (Module C2)

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):
Drs. Dave Hagenaars, Managing Director

Previous Notified Body: BSI 0086
First Issued: 2020-05-26
Latest Issue: 2020-05-26
Effective Date: 2020-05-26
Expiry Date: 2021-05-26

Page: 1 of 3

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To check its validity telephone +31 20 3460780. An electronic certificate can be authenticated online.

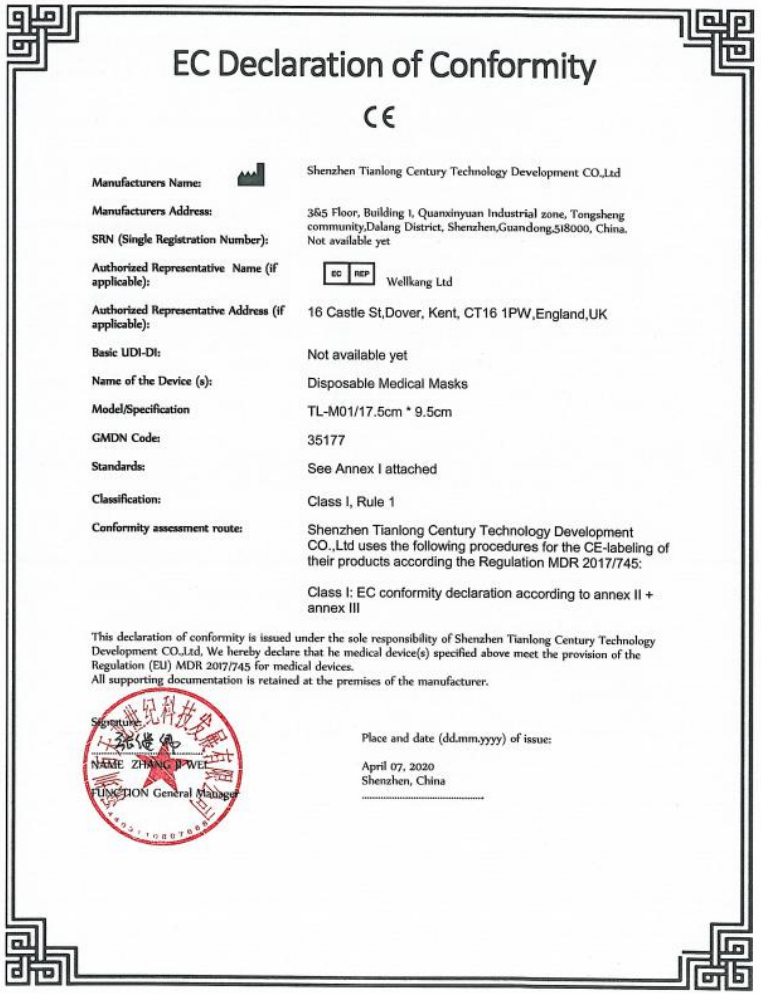
BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
A member of BSI Group of Companies.

Shenzhen Shengshi Kanghua Industrial Group

Shenzhen Shengshi KanghuaTechnology Co., Ltd

Test report

Shenzhen Tianlong Century Technology Development Co., Ltd.



EC Declaration of Conformity

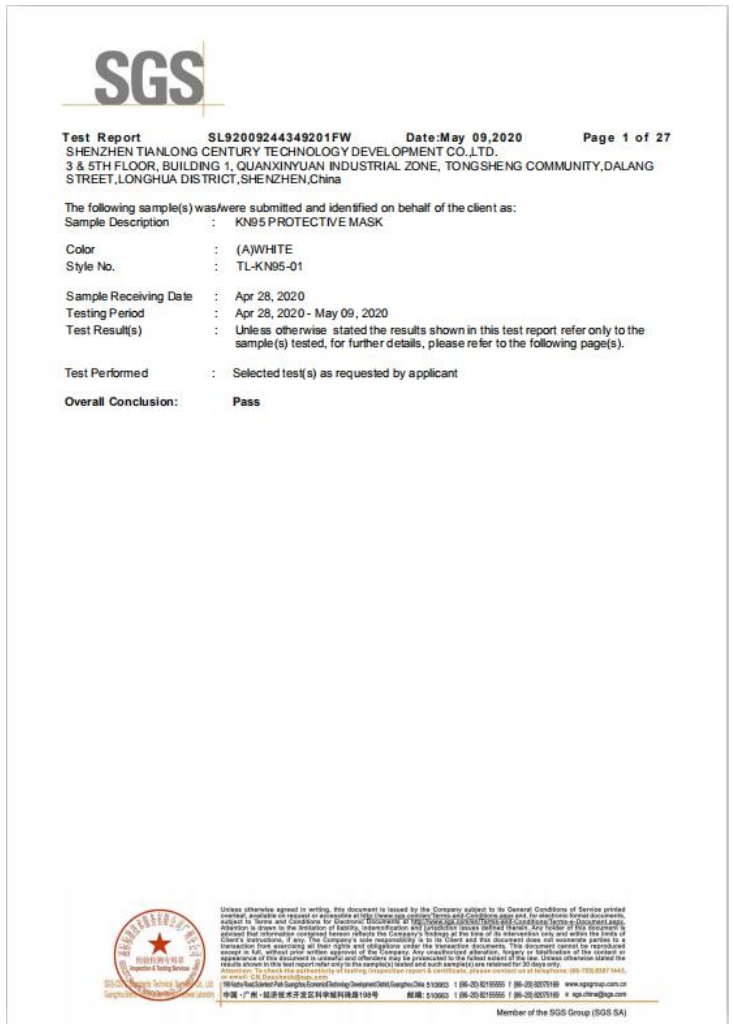
CE

Manufacturers Name:	Shenzhen Tianlong Century Technology Development CO.,Ltd
Manufacturers Address:	3&5 Floor, Building 1, Quanxinyuan Industrial zone, Tongsheng community,Dalang District, Shenzhen,Guandong,518000, China.
SRN (Single Registration Number):	Not available yet
Authorized Representative Name (if applicable):	Wellkang Ltd
Authorized Representative Address (if applicable):	16 Castle St,Dover, Kent, CT16 1PW,England,UK
Basic UDI-DI:	Not available yet
Name of the Device (s):	Disposable Medical Masks
Model/Specification	TL-M01/17.5cm * 9.5cm
GMDN Code:	35177
Standards:	See Annex I attached
Classification:	Class I, Rule 1
Conformity assessment route:	Shenzhen Tianlong Century Technology Development CO.,Ltd uses the following procedures for the CE-labeling of their products according the Regulation MDR 2017/745: Class I: EC conformity declaration according to annex II + annex III

This declaration of conformity is issued under the sole responsibility of Shenzhen Tianlong Century Technology Development CO.,Ltd, We hereby declare that he medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices.
All supporting documentation is retained at the premises of the manufacturer.

Signature:
NAME ZHANG P WEI
FUNCTION General Manager

Place and date (dd.mm.yyyy) of issue:
April 07, 2020
Shenzhen, China



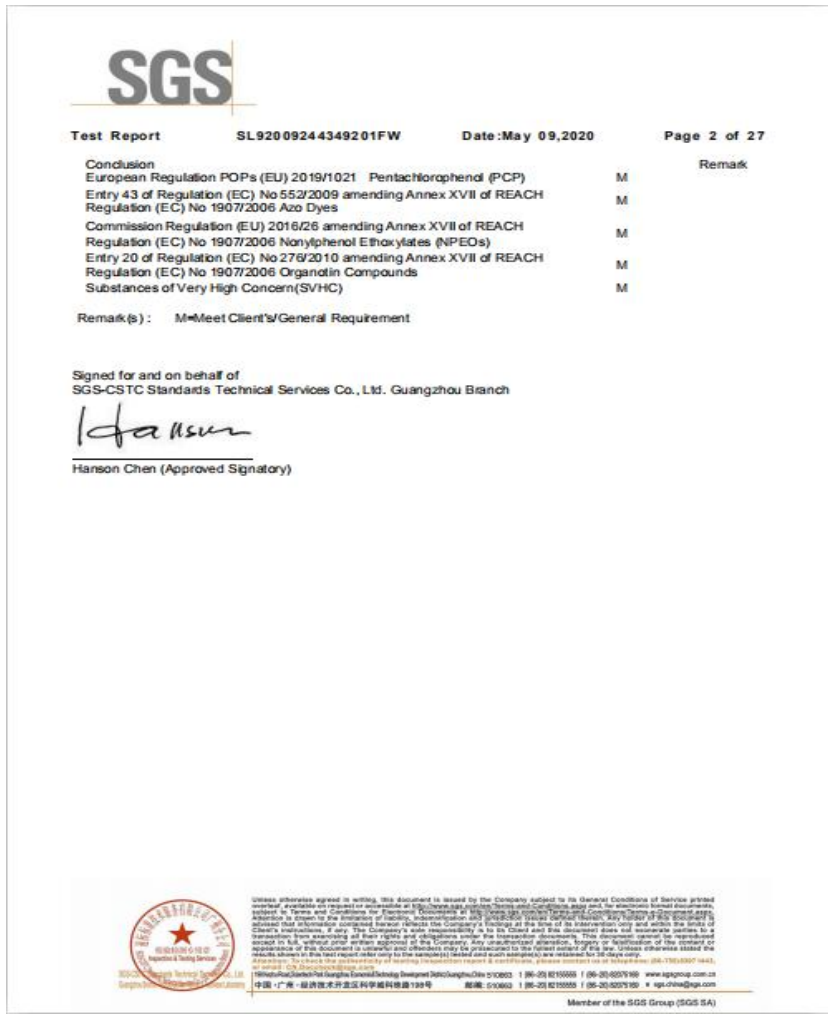
SGS

Test Report SL92009244349201FW Date:May 09,2020 Page 1 of 27

SHENZHEN TIANLONG CENTURY TECHNOLOGY DEVELOPMENT CO.,LTD.
3 & 5TH FLOOR, BUILDING 1, QUANXINYUAN INDUSTRIAL ZONE, TONGSHENG COMMUNITY,DALANG STREET,LONGHUA DISTRICT,SHENZHEN,China

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

Sample Description	:	KN95 PROTECTIVE MASK
Color	:	(A)WHITE
Style No.	:	TL-KN95-01
Sample Receiving Date	:	Apr 28, 2020
Testing Period	:	Apr 28, 2020 - May 09, 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
Overall Conclusion:		**Pass**



SGS

Test Report SL92009244349201FW Date:May 09,2020 Page 2 of 27

Conclusion		Remark
European Regulation POPs (EU) 2019/1021 Pentachlorophenol (PCP)	M	
Entry 43 of Regulation (EC) No 552/2009 amending Annex XVII of REACH Regulation (EC) No 1907/2006 Azo Dyes	M	
Commission Regulation (EU) 2016/26 amending Annex XVII of REACH Regulation (EC) No 1907/2006 Nonylphenol Ethoxylates (NPEOs)	M	
Entry 20 of Regulation (EC) No 276/2010 amending Annex XVII of REACH Regulation (EC) No 1907/2006 Organotin Compounds	M	
Substances of Very High Concern(SVHC)	M	

Remark(s): M=Meet Client's/General Requirement

Signed for and on behalf of
SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch

Hanson Chen (Approved Signatory)

Shenzhen Da Sheng Yuan Medical Equipments Company Limited

FDA

FDA

Fiscal Year 2020

CERTIFICATION OF REGISTRATION

This certifies that:
Name: Shenzhen Da Sheng Yuan Medical Equipments Company Limited
Add: 301, Building 9, Nangang No.2 Industrial Park, No.1026 Songbai Road, Yangguang community, Xili street, Nanshan District, Shenzhen

has completed the FDA Establishment Registration (as manufacturer and foreign exporter) and Device Listing with the US Food & Drug Administration, through
The Owner/ Operator Number for this Registration is: 10070139

Listing No	Code	Premarket Submission NO.	Device Name
D392351	QKR	Enforcement	Particulate Respirator (KN95) and Protective Mask, Q/DSY 001-2020, Q/DSY 002-2020, Q/DSY 003-2020, Q/DSY 005-2020, Q/DSY 006-2020

ABmed will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. ABmed makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate - holder's device or establishment by the U.S Food and Drug Administration.
ABmed assumes no liability to any person or entity in connection with foregoing.

Date of verification: Apr. 16, 2020
Date of expiration: Dec. 31,2020

SH OFFICE
TEL:0086-21-50313932 Boyle Wang Phone:0086-18930777676 info@truthful.com.cn
ABMED SERVICE INC.
36 South 18th Avenue, Suite A Brighton USA 80601
TEL:213-375-3998 FAX:213-375-3998 info@abmed.com.cn

FDA

Fiscal Year 2020

CERTIFICATION OF REGISTRATION

This certifies that:
Name: Shenzhen Da Sheng Face Mask Factory
Add: 301, Building 9, Nangang No.2 Industrial Park, No.1026 Songbai Road, Yangguang community, Xili street, Nanshan District, Shenzhen

has completed the FDA Establishment Registration (as manufacturer and foreign exporter) and Device Listing with the US Food & Drug Administration, through
The Owner/ Operator Number for this Registration is: 10063515

Listing No	Code	Premarket Submission NO.	Device Name
D392351	QKR	Enforcement	Particulate Respirator (KN95) and Protective Mask, Q/DST 001-2020, Q/DSY 002-2020, Q/DST 003-2020, Q/DSY 005-2020, Q/DST 006-2020
D376646	KHA	Enforcement	Daily Protective mask, N95 mask, KN95, Q/DST 001-2020, Q/DSY 002-2020, Q/DST 003-2020, Q/DSY 005-2020, Q/DST 006-2020

ABmed will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. ABmed makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate - holder's device or establishment by the U.S Food and Drug Administration.
ABmed assumes no liability to any person or entity in connection with foregoing.

Date of verification: Apr. 30, 2020
Date of expiration: Dec. 31,2020

SH OFFICE
TEL:0086-21-50313932 Boyle Wang Phone:0086-18930777676 info@truthful.com.cn
ABMED SERVICE INC.
36 South 18th Avenue, Suite A Brighton USA 80601
TEL:213-375-3998 FAX:213-375-3998 info@abmed.com.cn

CE

Shenzhen Da Sheng Yuan Medical Equipments Company Limited

EC REP CERTIFICATE

CMC MEDICAL DEVICES & DRUGS SL
NO. CMC/CE/2020/07052020.5

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of

Shenzhen Dasheng Yuan Medical Equipments Co.,Ltd.
301, Building 9, Nangang No.2 Industrial Park, No.1026 Songbai Road, Yangguang community, Xili street, Nanshan District, Shenzhen,China

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.
The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 93/42/EEC on medical devices as amended.

The products in Annex I was registered in Spanish MOH with number **RPS/697/2020**

CE

Issued on: 07/05/2020 Valid until: 08/05/2021

Authorized Signatory
CMC Medical Devices & Drugs SL

www.cmcmedicaldevices.com

EC REP CERTIFICATE

CMC MEDICAL DEVICES & DRUGS SL
NO. CMC/CE/2020/30062020.2

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of

Shenzhen Da Sheng Face Mask Factory
301, Building 9, Nangang No.2 Industrial Park, No.1026 Songbai Road, Yangguang community, Xili street, Nanshan District, Shenzhen, China

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.
The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 93/42/EEC on medical devices as amended.

The products in Annex I was registered in Spanish MOH with number **RPS/1576/2020**

CE

Issued on: 30/06/2020 Valid until: 29/06/2021

Authorized Signatory
CMC Medical Devices & Drugs SL

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Shenzhen Da Sheng Yuan Medical Equipments Company Limited

Europ DC

EU Declaration of Conformity

Company Manufacturer:	Shenzhen Da Sheng Yuan Medical Equipments Co. ,Ltd. 501, Building 11, Nangang No.2 Industrial Park, No.1026 Songbai Road, Yangguang community, Xili street, Nanshan District, Shenzhen Tel:+86-18926031197
SRN:	/
European Representative:	CMC Medical Devices & Drugs S.L.
SRN:	Horacio Lego Nº 18, CP 29006, Málaga, Spain
Product Name:	Disposable Medical Mask
Specification:	17.5cm×9.5cm
UMDN Code:	12-458

Classification (MDR, Annex VIII): Class I, Rule 1.

Conformity Assessment Route: EU DECLARATION OF CONFORMITY following the Annex II + Annex III + Article 19 of MDR (EU) 2017/745.

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EU Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer.
Shenzhen Da Sheng Yuan Medical Equipments Co. ,Ltd.is exclusively responsible for the declaration of conformity.

General applicable regulations, directives:
Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Applied standards, common specification, guidance:
EN 14683:2019+AC:2019, EN ISO 15223-1:2016, EN 1041:2008, EN ISO 14971:2012, EN 62366-1:2015+AC:2015, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010, ASTM D4169-2016, MDCG 2019-15.

Signature:	
Name:	YINGYING LI
Position:	General Manager
Place/date	Shenzhen, China / May 6,2020

EU Declaration of Conformity

Manufacturer:	Shenzhen Da Sheng Face Mask Factory 301, Building 9, Nangang No.2 Industrial Park, No.1026 Songbai Road, Yangguang community, Xili street, Nanshan District, Shenzhen, China Tel:+86-18926031197
SRN:	/
European Representative:	CMC Medical Devices & Drugs S.L.
SRN:	Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Product Name:	Disposable Medical Mask
Model:	DS003-2020
Specification:	17.5*9.5cm
UMDN Code:	12-458

Classification (MDR, Annex VIII): Class I, Rule 1.

Conformity Assessment Route: EU DECLARATION OF CONFORMITY following the Annex II + Annex III + Article 19 of MDR (EU) 2017/745.

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General applicable regulations, directives:
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Signature:	
Name:	LI YINGYING
Position:	General Manager
Place/date	China / June 21, 2020

Shenzhen Da Sheng Yuan Medical Equipments Company Limited

Test report

TÜVRheinland®

EN 14683:2019+AC: 2019
Medical face masks —
Requirements and test methods

Report Reference No.	60378934 001
Date of issue	See cover page
Total number of pages	See cover page
Testing Laboratory	TÜV Rheinland (Shenzhen) Co., Ltd.
Address	1F East & 2-4F, Cybio Technology Building No.1, No.16 Kejibei 2nd Road, High-Tech Industrial Park North Nanshan District, 518057, Shenzhen, China
Applicant's name	Shenzhen Da Sheng Yuan Medical Equipments Company Limited
Address	501, Building 11, Nangang No.2 Industrial Park, No.1026 Songbai Road, Yangguang community, Xili Street, Nanshan District, Shenzhen, 518000, China
Test specification:	
Standard	EN 14683:2019+AC:2019
Test procedure	Type test
Non-standard test method	N/A
Test Report Form No.	EN 14683:2019+AC:2019_A
Test Report Form Originator	TÜV Rh (SZ)
Master TRF	2020-03
Test item description	MEDICAL MASK
Trade Mark	DA SHENG
Manufacturer	Same as the applicant
Model/Type reference	17.5cmx9.5cm
Classification	Type II

Produkte
Products

TÜVRheinland®

Prüfbericht-Nr.: *Test Report No.:*	60378934 001	**Auftrags-Nr.** *Order No.:*	168264178 Seite 1 von 12 *Page 1 of 12*
Kunden-Referenz-Nr.: *Client Reference No.:*	N/A	**Auftragsdatum:** *Order date:*	May 09, 2020
Auftraggeber: *Client:*	Shenzhen Da Sheng Yuan Medical Equipments Company Limited 501, Building 11, Nangang No.2 Industrial Park, No.1026 Songbai Road, Yangguang community, Xili Street, Nanshan District, Shenzhen, 518000, China		
Prüfgegenstand: *Test item:*	MEDICAL MASK		
Bezeichnung / Typ-Nr.: *Identification / Type No.:*	17.5cmx9.5cm		
Auftrags-Inhalt: *Order content:*	Type test		
Prüfgrundlage: *Test specification:*	EN 14683:2019+AC:2019 except for clause 5.2.6& clause 6		
Wareneingangsdatum: *Date of receipt:*	May 13, 2020		
Prüfmuster-Nr.: *Test sample No.:*	20200408		
Prüfzeitraum: *Testing period:*	May 14, 2020 to May 26, 2020		
Ort der Prüfung: *Place of testing:*	See page 3		
Prüflaboratorium: *Testing laboratory:*	TÜV Rheinland (Shenzhen) Co., Ltd.		
Prüfergebnis*: *Test result *:*	Pass		

See Attachment: Photo documentation for details.

geprüft von / *tested by:* Amanda Liu
Jun. 24, 2020 Amanda Liu/Project Engineer
Datum / *Date* | Name / Stellung / *Name / Position* | Unterschrift / *Signature*

kontrolliert von / *reviewed by:* Angela Chen
Jun. 24, 2020 Angela Chen / Department Manager
Datum / *Date* | Name / Stellung / *Name / Position* | Unterschrift / *Signature*

Sonstiges / *Other:*
- The test report consists of EN 14683 test report including this cover page (12 pages) and attachment: Photo documentation (3 pages).
- The clause 5.2.6 (Biocompatibility) and clause 6 (Marking, labelling and packaging) are not evaluated in this test report.

Zustand des Prüfgegenstandes bei Anlieferung: Prüfmuster vollständig und unbeschädigt
Condition of the test item at delivery: *Test item complete and undamaged*

* Legende:	1 = sehr gut	2 = gut	3 = befriedigend	4 = ausreichend	5 = mangelhaft
	P(ass) = entspricht o.g. Prüfgrundlage(n)		F(ail) = entspricht nicht o.g. Prüfgrundlage(n)	N/A = nicht anwendbar	NT = nicht getestet
Legend:	*1 = very good*	*2 = good*	*3 = satisfactory*	*4 = sufficient*	*5 = poor*
	P(ass) = passed a.m. test specification(s)		*F(ail) = failed a.m. test specification(s)*	*N/A = not applicable*	*NT = not tested*

Dieser Prüfbericht bezieht sich nur auf das o.g. Prüfmuster und darf ohne Genehmigung der Prüfstelle nicht auszugsweise vervielfältigt werden. Dieser Bericht berechtigt nicht zur Verwendung eines Prüfzeichens.
This test report only relates to the a. m. test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any test mark.

Shenzhen Shengshi Kanghua Industrial Group

Pursuing the perfect quality

Advanced Technology
Adopt the world's leading fully automated production equipment.

Superior Quality
We strictly control quality, focusing on quality of product and implementing brand.

Continuous breakthrough
Introduce the latest equipment to improve the product quality and style, and the product continues to follow the new iteration.

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