常美医疗
Changmei Medtech

Particle Filtering Half Mask

(EN149:2001+A1:2009 FFP2 NR)

Jiangsu ChangMei Medtech Co., Ltd.

DIRECTORY

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Version:20200619

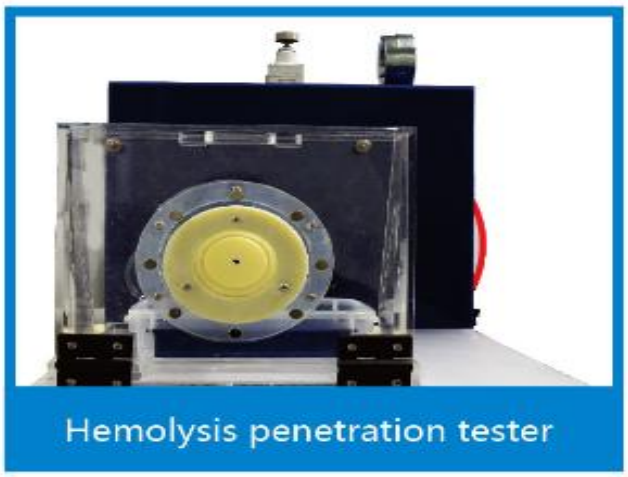
1. Company Profile

Jiangsu ChangMei Medtech Co., Ltd. specializes in the development and design of medical devices, with a particular focus on medical balloon research and production. We can provide integrated solutions of balloon and catheter related products as well as full-set production equipment according to customer requirements. Technology transfer, production drawings and related data are also available.

Our innovative technology, production equipment and fully integrated manufacturing closely follow the trend of the world, committing to domestically localize the balloon catheter solutions so as to provide quality service for medical device companies and patients both at home and abroad. The timely delivery and excellent service have already been well received in medical industry. We will maintain and continually improve our quality management system to ensure its effectiveness and comply with all applicable requirements.

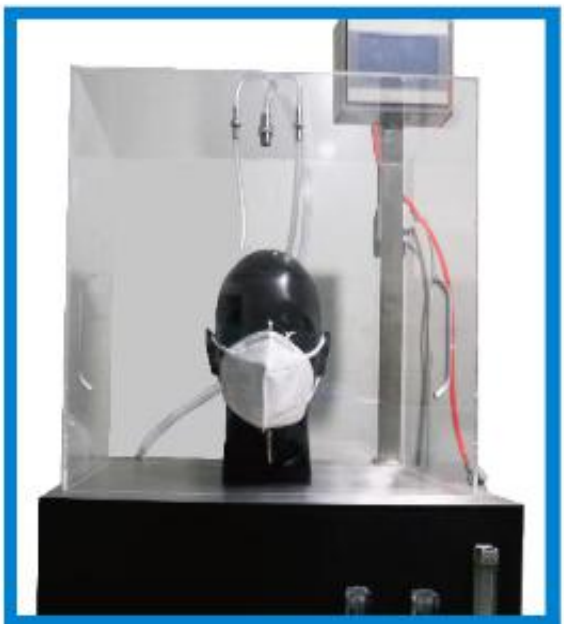
1.1 Production environment

1.2 Testing equipment



Tensile testing machine

High and low temperature humid heat test chamber



Face mask protection module

1.3 Business license

统一社会信用代码
91320412072779017U (1/1)

营业执照
(副本)

编号 320483666202004100117

扫描二维码登录"国家企业信用信息公示系统"了解更多登记、备案、许可、监管信息。

名称	江苏常美医疗器械有限公司	注册资本	1000万元整
类型	有限责任公司	成立日期	2013年07月17日
法定代表人	袁禄新	营业期限	2013年07月17日至2033年07月16日
经营范围	医疗器械制造（Ⅲ类产品按《医疗器械生产企业许可证》核定的范围生产）；机电设备及配件、计算机软硬件的研发，制造，销售；自营或代理各类商品及技术的进出口业务，但国家限定企业经营或禁止进出口的商品及技术除外。第一类医疗器械生产；第二类医疗器械生产；日用口罩（非医用）生产；日用口罩（非医用）销售；劳动保护用品生产；劳动保护用品销售；产业用纺织制成品销售（依法须经批准的项目，经相关部门批准后方可开展经营活动）	住所	武进区洛阳镇新科西路27号

登记机关 常州市武进区行政审批局

2020 年04 月10 日

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn

市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示年度报告。

国家市场监督管理总局监制

1.4 Production license

医疗器械生产许可证

许可证编号：苏食药监械生产许20140044号

企业名称：江苏常美医疗器械有限公司

生产地址：常州市武进区洛阳镇新科西路27号

法定代表人：袁禄新

生产范围：见医疗器械生产产品登记表

企业负责人：袁禄新

住　　所：武进区洛阳镇新科西路27号

发证部门：江苏省药品监督管理局

有效期限：至 2024 年 03 月 04 日

发证日期：2019 年 03 月 05 日

国家食品药品监督管理总局制

1.5 ISO13485 certificate

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 088875 0008 Rev. 01

Holder of Certificate: **Jiangsu Changmei Medtech Co., Ltd.**
No. 27, Xinke West Road, Luoyang
213104 Changzhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design, Development, Production and Distribution of Dilation Balloon Catheter, Kyphoplasty Balloon Catheter, Disposable Polypectomy Snare, Kyphoplasty Tool Kit, Balloon Inflator, Disposable Endoscopic Hose-type Biopsy Forceps, Disposable Endoscopic Cytology Brush, Endoscopic Foreign Body Forceps, 3-stage Dilation Balloon Catheter, Guide Wire other than Intravascular, Disposable Endoscopic Stone Retrieval Basket, Bougie Dilator Sets, Wireguided Balloon Dilatation Catheter and Disposable Stone Extraction Balloon**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1889305

Valid from: 2019-03-30
Valid until: 2021-01-07

Date, 2019-03-30

Stefan Preiß

A4 / 07.17

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 088875 0008 Rev. 01

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): Jiangsu Changmei Medtech Co., Ltd.
No. 27, Xinke West Road, Luoyang, 213104 Changzhou, Jiangsu,
PEOPLE'S REPUBLIC OF CHINA

Parameters:

.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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1.6 ISO9001 certificate

CICC CERTIFICATION
嘉泰认证

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate No:18120Q11155R0M

We hereby certify that

Jiangsu Changmei Medtech Co.,Ltd.

Credit No: 91320412072779017U

Registration Add:No.27, Xinke West Road, Luoyang Town, Wujin District

Business Add/Production Add:No.27, Xinke West Road, Luoyang, 213104 Changzhou City, Jiangsu Province, P. R. China

Has implemented and maintains a **Quality Management System**

Which fulfils the requirements of the following standards

GB/T19001-2016 idt ISO9001:2015

Scope of certification

Production of Particle Filtering Half Mask, Disposable Protective Face Mask (Non medical)

Initial issuance date: May 23, 2020

This certificate is valid during: May 23, 2020 ~ May 22, 2023

This certificate is invalid without CICC qualified label in the following period

First supervision and audit	Qualified mark

Second supervision and audit	Qualified mark

The certification registration scope doesn't include those product/service scopes which fail to be covered by the relevant effective administration permission and qualification permission regulated by the state;
The effectiveness of this certificate shall be validated by annual surveillance audit of CICC the certificate shall be valid when used together with the surveillance audit conclusion;
The related information of this certification can be searched on the portal of CNCA www.cnca.gov.cn
Or the site of company www.cicc-int.com.

CICC CERTIFICATION IAF CNAS 中国认可 国际互认 管理体系 MANAGEMENT SYSTEM CNAS C181-M

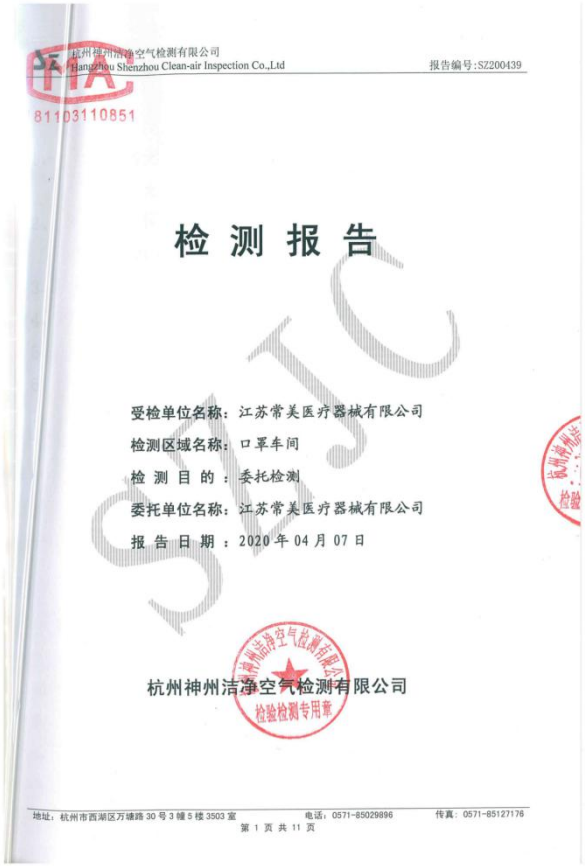
1.7 White list from CCCMHPIE

首页 关于商会 新闻中心 行业服务 权威发布 商会会刊

43	安庆市日新卫生材料有限公司 Anqing Rixin Sanitary Material Co., Ltd	91340822MA2UJ60F0Q	欧盟CE
44	安徽中科都菱商用电器股份有限公司 Anhui Zhongke Duling Commercial Appliance Co.,Ltd	91340100584599810H	欧盟CE
45	北京联合康力医疗器械有限公司 Uhealth Medical (Beijing) Products Co., Ltd.	91110111051360081K	欧盟CE
46	北京迈迪斯医疗技术有限公司 BeiJing Medis Medical Technology Co.,Ltd	91110113MA00EQD90E	欧盟CE
47	武汉中森医疗用品有限公司 Wuhan Zonsen Medical Products Co., Ltd	91420117303440396B	欧盟CE
48	茶陵县飞鹏竹木业有限公司 Chaling Feipeng Bamboo Industry Limited	914302245975555423	欧盟CE
49	湖南三瑞生物科技有限责任公司 Hunan SanRui Biotechnology Co., Ltd	91430122066350820B	欧盟CE
50	长沙比亚迪电子有限公司 Changsha BYD Electronic Co., Ltd. (持证公司：BYD Precision Manufacture Co. , Ltd.)	91430112MA4QJE2J8D	欧盟CE
51	江苏常美医疗器械有限公司 Jiangsu Changmei Medtech Co., Ltd.	91320412072779017U	欧盟CE
52	江苏金鹿集团医疗器械有限公司 Jiangsu Jinlu Group Medical Device CO.,LTD	913205827140763730	欧盟CE
53	江阴市鸿萌橡塑制品有限公司 Jiangyin Hongmeng Rubber Plastic Product Co., Ltd.	91320281765897358B	欧盟CE
54	腾飞科技股份有限公司 Tengfei Technology Co., LTd	913205007961117171	欧盟CE
55	昆山金富杰精密模具有限公司 Kunshan Jinfujie Precision Mould CO.,LTD	913205830694804017	欧盟CE

Official website: http://www.cccmhpie.org.cn/Pub/6325/176269.shtml

1.8 Clean room certificate

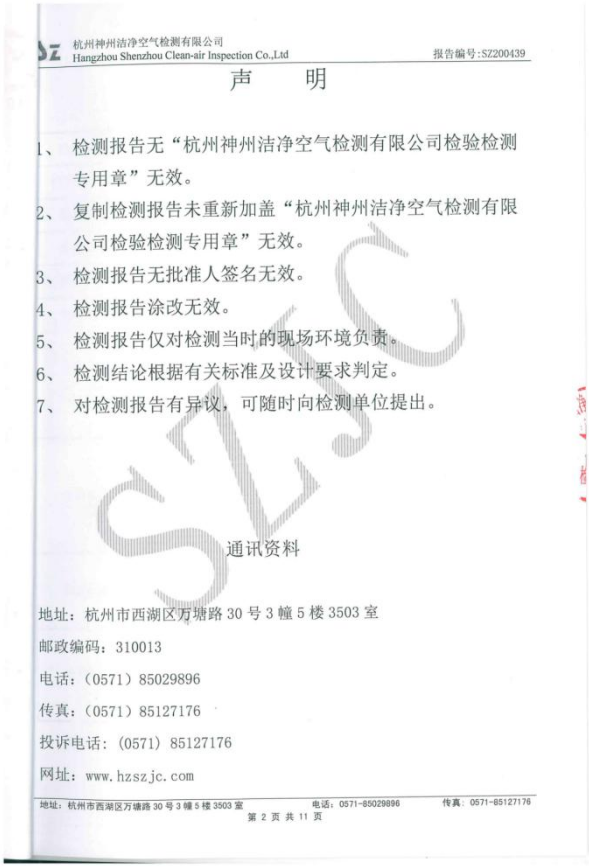


81103110851

检 测 报 告

受检单位名称：江苏常美医疗器械有限公司
检测区域名称：口罩车间
检 测 目 的 ：委托检测
委托单位名称：江苏常美医疗器械有限公司
报 告 日 期 ：2020 年 04 月 07 日

杭州神州洁净空气检测有限公司

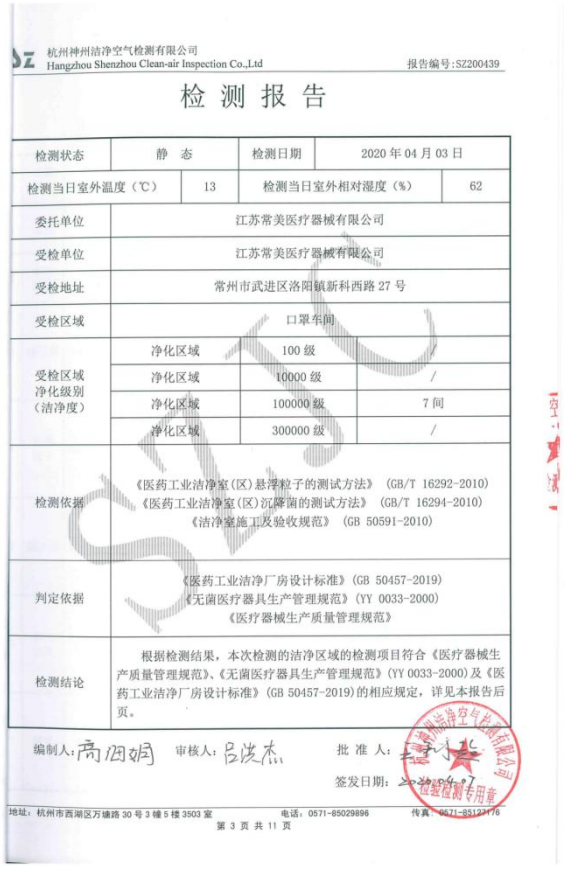


声 明

1、 检测报告无“杭州神州洁净空气检测有限公司检验检测专用章”无效。
2、 复制检测报告未重新加盖“杭州神州洁净空气检测有限公司检验检测专用章”无效。
3、 检测报告无批准人签名无效。
4、 检测报告涂改无效。
5、 检测报告仅对检测当时的现场环境负责。
6、 检测结论根据有关标准及设计要求判定。
7、 对检测报告有异议，可随时向检测单位提出。

通讯资料

地址：杭州市西湖区万塘路 30 号 3 幢 5 楼 3503 室
邮政编码：310013
电话：(0571) 85029896
传真：(0571) 85127176
投诉电话：(0571) 85127176
网址：www.hzszjc.com



检 测 报 告

检测状态	静 态	检测日期	2020 年 04 月 03 日
检测当日室外温度（℃）	13	检测当日室外相对湿度（%）	62
委托单位	江苏常美医疗器械有限公司		
受检单位	江苏常美医疗器械有限公司		
受检地址	常州市武进区洛阳镇新科西路 27 号		
受检区域	口罩车间		
受检区域净化级别（洁净度）	净化区域	100 级	/
	净化区域	10000 级	/
	净化区域	100000 级	7 间
	净化区域	300000 级	/
检测依据	《医药工业洁净室(区)悬浮粒子的测试方法》(GB/T 16292-2010) 《医药工业洁净室(区)沉降菌的测试方法》(GB/T 16294-2010) 《洁净室施工及验收规范》(GB 50591-2010)		
判定依据	《医药工业洁净厂房设计标准》(GB 50457-2019) 《无菌医疗器具生产管理规范》(YY 0033-2000) 《医疗器械生产质量管理规范》		
检测结论	根据检测结果，本次检测的洁净区域的检测项目符合《医疗器械生产质量管理规范》、《无菌医疗器具生产管理规范》(YY 0033-2000)及《医药工业洁净厂房设计标准》(GB 50457-2019)的相应规定，详见本报告后页。		

编制人：高阳娟 审核人：吕洪杰 批 准 人：[illegible]
签发日期：2020.04.07

检 测 报 告

检测项目、方法、判定依据及仪器

序号	检测项目	检测方法	判定依据	检测仪器 设备名称	型号	编号	检定有效期限 证书编号
1	温度	GB 50591-2010	医疗器械生产质量管理规范	手持式温湿度测试仪	971	SB-05-12	2020.07.15
2	相对湿度						SZJZ2019071618
3	静压差	GB 50591-2010	医疗器械生产质量管理规范	数字微压仪	922	SB-22-08	2020.06.20
							801225247-002
4	悬浮粒子	GB/T 16292-2010	YY 0033-2000	激光尘埃粒子计数器	BCJ-28.3	SB-02-26	2020.06.28
							SZJZ20190629113
5	沉降菌	GB/T 16294-2010	YY 0033-2000	Φ90mm 培养皿	/	/	/
6	换气次数	GB 50591-2010	YY 0033-2000	套冒式风量罩	6710	SB-01-09	2020.08.30
							SZJZ2019083102
7	照度	GB 50591-2010	GB 50457-2019	照度计	TES-1330A	SB-45-12	2020.05.26
							801210853-001

杭州神州洁净空气检测有限公司
Hangzhou Shenzhou Clean-air Inspection Co.,Ltd

报告编号:SZ200439

检 测 报 告

洁净区域名称	缓冲（手消毒）			检测日期	2020 年 04 月 03 日		洁净度级别	100000 级
项目	单位	级别	标准		检测结果			项目结论
悬浮粒子	粒/m³	100000 级	≥0.5μm	≤3500000	≥0.5μm	Amax	1696	符合规定
						UCL	3041	符合规定
			≥5μm	≤20000	≥5μm	Amax	59	符合规定
						UCL	122	符合规定
沉降菌	个/皿·30min		≤10		<1			符合规定
换气次数	次/h		≥15		61			符合规定
静压差	Pa		>10（相对室外）		50			符合规定
温度	℃		18～28		20			符合规定
相对湿度	%		45～65		50			符合规定
照度	lx		主要工作室宜为 300 辅助工作室、走廊、气闸室人净和物净室不宜低于 200		304			符合规定

地址：杭州市西湖区万塘路 30 号 3 幢 5 楼 3503 室　电话：0571-85029896　传真：0571-85127176

杭州神州洁净空气检测有限公司
Hangzhou Shenzhou Clean-air Inspection Co.,Ltd

报告编号:SZ200439

检 测 报 告

洁净区域名称	洗手			检测日期	2020 年 04 月 03 日		洁净度级别	100000 级
项目	单位	级别	标准		检测结果			项目结论
悬浮粒子	粒/m³	100000 级	≥0.5μm	≤3500000	≥0.5μm	Amax	2296	符合规定
						UCL	5861	符合规定
			≥5μm	≤20000	≥5μm	Amax	35	符合规定
						UCL	129	符合规定
沉降菌	个/皿·30min		≤10		1			符合规定
换气次数	次/h		≥15		67			符合规定
静压差	Pa		>10（相对室外）		40			符合规定
温度	℃		18～28		20			符合规定
相对湿度	%		45～65		50			符合规定
照度	lx		主要工作室宜为 300 辅助工作室、走廊、气闸室人净和物净室不宜低于 200		296			符合规定

地址：杭州市西湖区万塘路 30 号 3 幢 5 楼 3503 室　电话：0571-85029896　传真：0571-85127176

杭州神州洁净空气检测有限公司
Hangzhou Shenzhou Clean-air Inspection Co.,Ltd

报告编号:SZ200439

检 测 报 告

洁净区域名称	二更			检测日期	2020 年 04 月 03 日		洁净度级别	100000 级
项目	单位	级别	标准		检测结果			项目结论
悬浮粒子	粒/m³	100000 级	≥0.5μm	≤3500000	≥0.5μm	Amax	4381	符合规定
						UCL	13669	符合规定
			≥5μm	≤20000	≥5μm	Amax	188	符合规定
						UCL	688	符合规定
沉降菌	个/皿·30min		≤10		<1			符合规定
换气次数	次/h		≥15		62			符合规定
静压差	Pa		>10（相对室外）		44			符合规定
温度	℃		18～28		20			符合规定
相对湿度	%		45～65		50			符合规定
照度	lx		主要工作室宜为 300 辅助工作室、走廊、气闸室人净和物净室不宜低于 200		289			符合规定

地址：杭州市西湖区万塘路 30 号 3 幢 5 楼 3503 室　电话：0571-85029896　传真：0571-85127176

杭州神州洁净空气检测有限公司
Hangzhou Shenzhou Clean-air Inspection Co.,Ltd

报告编号:SZ200439

检 测 报 告

洁净区域名称	缓冲（手消毒）			检测日期	2020 年 04 月 03 日		洁净度级别	100000 级
项目	单位	级别	标准		检测结果			项目结论
悬浮粒子	粒/m³	100000 级	≥0.5μm	≤3500000	≥0.5μm	Amax	1696	符合规定
						UCL	3041	符合规定
			≥5μm	≤20000	≥5μm	Amax	59	符合规定
						UCL	122	符合规定
沉降菌	个/皿·30min		≤10		<1			符合规定
换气次数	次/h		≥15		61			符合规定
静压差	Pa		>10（相对室外）		50			符合规定
温度	℃		18～28		20			符合规定
相对湿度	%		45～65		50			符合规定
照度	lx		主要工作室宜为 300 辅助工作室、走廊、气闸室人净和物净室不宜低于 200		304			符合规定

地址：杭州市西湖区万塘路 30 号 3 幢 5 楼 3503 室　电话：0571-85029896　传真：0571-85127176

杭州神州洁净空气检测有限公司
Hangzhou Shenzhou Clean-air Inspection Co.,Ltd

报告编号:SZ200439

检 测 报 告

洁净区域名称	房间 2		检测日期	2020 年 04 月 03 日		洁净度级别	100000 级
项目	单位	级别	标准	检测结果			项目结论
悬浮粒子	粒/m³	100000 级	≥0.5μm ≤3500000	≥0.5μm	Amax	1307	符合规定
					UCL	1579	符合规定
			≥5μm ≤20000	≥5μm	Amax	82	符合规定
					UCL	103	符合规定
沉降菌	个/皿·30min		≤10	2			符合规定
换气次数	次/h		≥15	32			符合规定
静压差	Pa		>10 (相对室外)	57			符合规定
温度	℃		18～28	21			符合规定
相对湿度	%		45～65	51			符合规定
照度	lx		主要工作室宜为 300 辅助工作室、走廊、气闸室人净和物净室不宜低于 200	381			符合规定

地址：杭州市西湖区万塘路 30 号 3 幢 5 楼 3503 室 电话：0571-85029896 传真：0571-85127176

杭州神州洁净空气检测有限公司
Hangzhou Shenzhou Clean-air Inspection Co.,Ltd

报告编号:SZ200439

检 测 报 告

洁净区域名称	洁具间		检测日期	2020 年 04 月 03 日		洁净度级别	100000 级
项目	单位	级别	标准	检测结果			项目结论
悬浮粒子	粒/m³	100000 级	≥0.5μm ≤3500000	≥0.5μm	Amax	789	符合规定
					UCL	1444	符合规定
			≥5μm ≤20000	≥5μm	Amax	23	符合规定
					UCL	23	符合规定
沉降菌	个/皿·30min		≤10	3			符合规定
换气次数	次/h		≥15	33			符合规定
静压差	Pa		>10 (相对室外)	39			符合规定
温度	℃		18～28	20			符合规定
相对湿度	%		45～65	52			符合规定
照度	lx		主要工作室宜为 300 辅助工作室、走廊、气闸室人净和物净室不宜低于 200	282			符合规定

地址：杭州市西湖区万塘路 30 号 3 幢 5 楼 3503 室 电话：0571-85029896 传真：0571-85127176

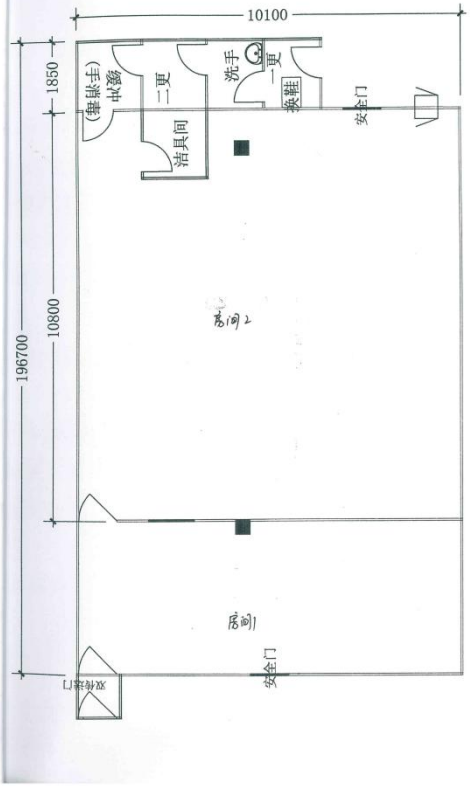
杭州神州洁净空气检测有限公司
Hangzhou Shenzhou Clean-air Inspection Co.,Ltd

报告编号:SZ200439

检 测 报 告

洁净区域名称	房间 1		检测日期	2020 年 04 月 03 日		洁净度级别	100000 级
项目	单位	级别	标准	检测结果			项目结论
悬浮粒子	粒/m³	100000 级	≥0.5μm ≤3500000	≥0.5μm	Amax	4369	符合规定
					UCL	7058	符合规定
			≥5μm ≤20000	≥5μm	Amax	12	符合规定
					UCL	43	符合规定
沉降菌	个/皿·30min		≤10	3			符合规定
换气次数	次/h		≥15	32			符合规定
静压差	Pa		>10 (相对室外)	57			符合规定
温度	℃		18～28	20			符合规定
相对湿度	%		45～65	51			符合规定
照度	lx		主要工作室宜为 300 辅助工作室、走廊、气闸室人净和物净室不宜低于 200	398			符合规定

地址：杭州市西湖区万塘路 30 号 3 幢 5 楼 3503 室 电话：0571-85029896 传真：0571-85127176

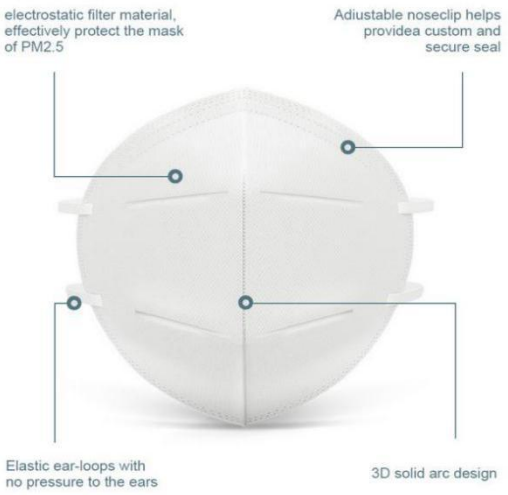


2. Product Introduction

2.1 Product structure

Particle filtering half mask consists of 5-layer non-woven fabrics, melt-blown fabrics,nose bridge and ear loop. The four layers are folded and composed by non-woven fabric and melt-blown.

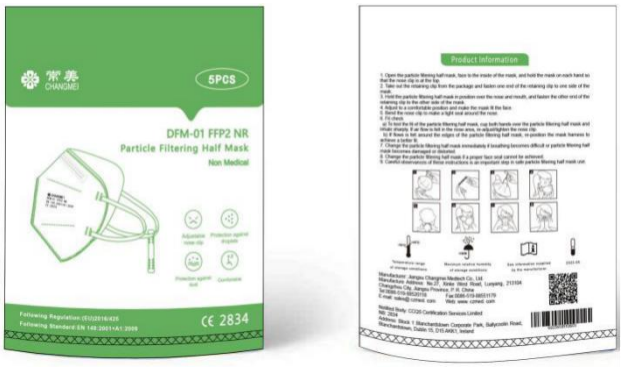
Composition	Color	Raw material
Outer layer	White	Non-woven fabric
Filter layer	White	Melt-blown non-woven fabric
Filter layer	White	Hot air cotton
Filter layer	White	Melt-blown non-woven fabric
Inner layer	White	Non-woven fabric



2.2 Product size

2.2.1 Mask size 16.0cm*11.0cm

2.2.2 Inner bag size 180*140mm（5Pcs/bag）



2.2.3 Inner box size 150*140*120mm（25pcs/box=5bag/box）

2.2.4 Outer carton size 625*305*328mm（500Pcs/carton=20box/carton）

Volume of carton is 0.063CBM

2.3 Product package

Item	Outer package	Inner box	N.W.	G.W.
Particle filtering half mask	500pcs/carton	25pcs/box	3.15kg	5.65kg

3. Product Certificates

3.1 EN149:2001+A1:2009 FFP2 NR certificates from CCQS

Module B EU Type-Examination Certificate

For the requirements of PPE Regulation 2016/425

Certificate No.: CE-PC-200330-138-01-9B

Certificate holder:	**Jiangsu Changmei Medtech Co., Ltd.** No.27, Xinke West Road, Luoyang, 213104 Changzhou City, Jiangsu Province, P. R. China
Product:	**Particle Filtering Half Mask** Detailed product description listed in the Annex
Model(s):	DFM-01
Standard(s):	EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking
Issue date:	2020-05-01
Revision date:	2020-06-18
Expiry date:	2025-04-30

The product(s) on this certificate and the Technical File have been assessed and found to be in conformance with the applicable Essential Health and Safety Requirements in Annex II of the PPE regulation 2016/425.
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

ISO 17065 INAB ACCREDITED PRODUCT CERTIFICATION DETAILED IN SCOPE REG NO.6028

Approved by:

Owen Bian, Director

CCQS Ireland Certification

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 2
(Fm220-017, Rev.1)

江苏常美医疗器械有限公司

Module B EU Type-Examination Certificate

Annex

For the requirements of PPE Regulation 2016/425

Certificate No.: CE-PC-200330-138-01-9B

Applicable standards and specification:

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

Model reference	Product description
DFM-01	Folding filtering half mask without valve fitted with ear loops with head harness clip, internal metal nose clip Classification: FFP2 NR Test Report No.: 2020 (D) - 0145T

Certificate Revision	Revision date	Revision details
A	2020-05-01	Initial issue
B	2020-06-18	Extension of expiry date to 5 years

江苏常美医疗器械有限公司

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.

3.2 EU Declaration of Conformity

常美医疗 Changmei Medtech

江苏常美医疗器械有限公司
Jiangsu Changmei Medtech Co., Ltd.

EU Declaration of Conformity

Annex IX PPE Regulation (EU) 2016/425

This EU Declaration of conformity refers to the following products

Product Name	Model	Classification/Type	Batch No./Serial No./Identifier
Particle filtering half mask	DFM-01	FFP2 NR	

The Manufacturer 's name and address is as follows:

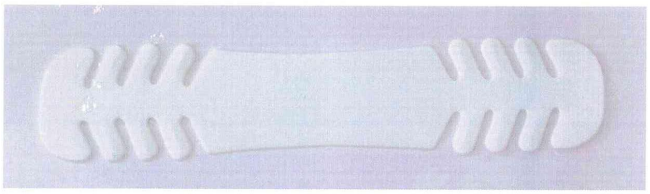
Name:	Jiangsu Changmei Medtech Co., Ltd.
Address:	No.27, Xinke West Road, Luoyang, 213104 Changzhou City, Jiangsu Province, P. R. China

This Declaration of Conformity is issued under the sole responsibility of the Manufacturer.

Detailed description of the PPE to allow traceability/identification of the PPE.

DFM-01	White folder half mask without valve 1. The mask photo

Jiangsu Changmei Medtech Co., Ltd.
No.27, Xinke West Road, Luoyang, 213104 Changzhou City, Jiangsu Province, P. R. China
Tel: +86 0519-88520118
Email sales@czmed.com

	2. The retaining clip photo 

The article identified in (4) above is in conformance with the relevant Union Harmonization Legislation Regulation (EU) 2016/425.

References to the relevant harmonized standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:

No.	Harmonized standard name
1	EN 149:2001+A1:2009

CCQS Certification Services Limited. (NB 2834) performed the EU Type Examination (Module B) and issued the Type Examination Certificate Number:

No.	EU Type Examination (Module B) Certificate Number
1	CE-PC-200330-138-01-9B

Product Category:

☐ This product is Category II.

☒ This product is Category III and is subject to Module C2 internal production control plus supervised product checks at random intervals and is under the surveillance of CCQS Certification Services Limited. (NB 2834)

☐ This product is Category III and is subject to Module D Conformity to type based on quality assurance of the production process and is under the surveillance of CCQS Certification Services Limited. (NB 2834)

Signature : _____ Date : 2020.6.18 Company stamp and/or legal signature : _____

Jiangsu Changmei Medtech Co., Ltd.
No.27, Xinke West Road, Luoyang, 213104 Changzhou City, Jiangsu Province, P. R. China
Tel: +86 0519-88520118
Email sales@czmed.com

3.3 Testing report for particle filtering half mask

National Quality Supervision and Testing Center for Personal Protective Equipment (Beijing)
(Testing Laboratory for Labour Protection Products of Beijing Municipal Institute for Labour Protection)
No.55 Taoranting Street, Xicheng District, Beijing, China.
Phone: +86 10 63519250 +86 10 63520770 +86 10 83530311
Fax: +86 10 63519250 +86 10 63520770

TESTING
CNAS L1499

The Testing Center is accredited for compliance with ISO/IEC 17025.
The results of tests, calibrations and/or measurements included in this document are traceable to Chinese/national standards.
CNAS is a signatory to the ILAC mutual recognition arrangement for the mutual recognition of the equivalence of testing, calibration and inspection reports.

TEST REPORT
Particulate respirator-half facepiece
EN 149: 2001 +A1: 2009 Respiratory protective devices — Filtering half masks to protect against particles — Requirements, testing, marking

Product:	**Particle filtering half mask**
Report No:	**2020 (D) – 0145T**
Client:	**CCQS Certification Services Limited**
Model (s):	**DFM-01**
Date(s) of tests:	**2020.03.31-2020.04.15**

DESCRIPTION OF SAMPLES

General Information	**Classification**	**Main Components**
	FFP2 NR	White folding mask
Manufacturer	Jiangsu Changmei Medtech Co., Ltd.	
Manufacturer Address	No.27, Xinke West Road, Luoyang, 213104 Changzhou City, Jiangsu Province, P. R. China	

Signed:

陈倬为 Chen Zhuowei
Authorized Signatory, Lab Director

Issued: 2020.4.15

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国家劳动保护用品质量监督检验中心(北京)

江苏常美医疗器械有限公司

Conditions:

The test results presented in this report relate to the samples tested only.

This report may be reproduced and distributed to your clients, provided that it is reproduced and distributed in full.

The authenticity of this test report and its contents can be verified by contacting the laboratory.

Note. This test report is the replacement and cancellation for test report No. 2020 (D) – 0145.

江苏常美医疗器械有限公司

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Test Results

7.3 Visual inspection **Not tested[1]**

The visual inspection shall include the marking and information supplied by the manufacturer.

Note1: As requested by the client, marking and information supplied by the manufacturer was not inspected.

7.4 Package **Pass[2]**

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.

Note2: In accordance with the requirement.

7.5 Material **Pass[3]**

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.

Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.

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.

Note3: No mechanical failure after undergoing the conditioning described in 8.3.1. No collapse when conditioned in accordance with 8.3.1 and 8.3.2.

7.6 Cleaning and disinfecting **N/A[4]**

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.

Note4: Single shift use only.

7.7 Practical performance **Pass[5]**

The particle filtering half mask shall undergo practical performance tests under realistic conditions.

Note5: No imperfections.

7.8 Finish of parts **Pass[6]**

Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.

Note6: No sharp edges or burrs.

7.9.1 Total inward leakage **Pass[7]**

For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than:
25% for FFP1, 11% for FFP2, 5% for FFP3

and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than
22% for FFP1, 8% for FFP2, 2% for FFP3

Note7: FFP2 respirator. Test results are shown in Annex A Table 7.9.1-A&B.

7.9.2 Penetration of filter material **Pass[8]**

The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.

	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP1	≤20%	≤20%

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FFP2	≤6%	≤6%
FFP3	≤1%	≤1%

Note8: FFP2 respirator. Test results are shown in Annex A Table 7.9.2.

7.10 Compatibility with skin **Pass[9]**

Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.

Note9: No irritation or any other adverse effect to health.

7.11 Flammability **Pass[10]**

When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame.

Note10: Test results are shown in Annex A Table 7.11.

7.12 Carbon dioxide content of the inhalation air **Pass[11]**

The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume)

Note11: Test results are shown in Annex A Table 7.12.

7.13 Head harness **Pass[12]**

The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.

The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position and be capable of maintaining total inward leakage requirements for the device.

Note12: Head harness can be donned and removed easily, adjustable or self-adjusting and have sufficiently robust to hold the particle filtering half mask firmly.

7.14 Field of vision **Pass[13]**

The field of vision is acceptable if determined so in practical performance tests.

Note13: Pass the practical performance tests.

7.15 Exhalation valve **N/A[14]**

A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.

If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9.

Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.

When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.

Note14: No exhalation valve.

7.16 Breathing resistance **Pass[15]**

Classification	Maximum permitted resistance (mbar)		
	Inhalation		Exhalation
	30 l/min	95 l/min	160 l/min
FFP1	0.6	2.1	3.0
FFP2	0.7	2.4	3.0
FFP3	1.0	3.0	3.0

Note15: FFP2 respirator. Test results are shown in Annex A Table 7.16.

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7.17 Clogging **N/A[16]**

7.17.2 Breathing resistance

Valved particle filtering half masks:
After clogging the inhalation resistances shall not exceed:
FFP1: 4 mbar, FFP2: 5 mbar, FFP3: 7 mbar at 95L/min continuous flow
The exhalation resistance shall not exceed 3 mbar at 160 L/min continuous flow

Valveless particle filtering half masks
After clogging the inhalation and exhalation resistances shall not exceed:
FFP1: 3 mbar, FFP2: 4 mbar, FFP3: 5 mbar at 95L/min continuous flow

7.17.3 Penetration of filter material

	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP1	≤20%	≤20%
FFP2	≤6%	≤6%
FFP3	≤1%	≤1%

Note16: Single shift use only.

7.18 Demountable parts **Pass[17]**

All demountable parts (if fitted) shall be readily connected and secured, where possible by hand
Note17: In accordance with the requirement.

9 Marking **Not tested**

9.1 Packaging

The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.

9.1.1 The name, trademark or other means of identification of the manufacturer or supplier.
9.1.2 Type-identifying marking.
9.1.3 Classification
The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.
9.1.4 The number and year of publication of this European Standard.
9.1.5 At least the year of end of shelf life. The end of shelf life may be informed by a pictogram as shown in Figure 12a, where yyyy/mm indicates the year and month.
9.1.6 The sentence 'see information supplied by the manufacturer', at least in the official language(s) of the country of destination, or by using the pictogram as shown in Figure 12b.
9.1.7 The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d.
9.1.8 The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D". This letter shall follow the classification marking preceded by a single space.

9.2 Particle filtering half mask

Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:

9.2.1 The name, trademark or other means of identification of the manufacturer or supplier.

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9.2.2 Type-identifying marking.

9.2.3 The number and year of publication of this European Standard.

9.2.4 Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.

9.2.5 If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the classification marking preceded by a single space

9.2.6 Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.

End of Test Results

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Annex A: Summarization of Test Data

Table 7.9.1-A Inward leakage test data

Test specification: EN 149-2001 Clause 8.5

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head up/down(%)	Talk(%)	Walk(%)	Mean(%)
Yi	1	A.R.	7.19	7.25	7.34	7.27	7.13	7.2
Gong	2	A.R.	7.47	7.51	7.64	7.52	7.42	7.5
Yu	3	A.R.	7.34	7.48	7.53	7.44	7.31	7.4
Zhi	4	A.R.	7.21	7.32	7.46	7.21	7.17	7.3
Fang	5	A.R.	7.65	7.78	7.83	7.71	7.66	7.7
Hu	6	T.C.	7.56	7.62	7.71	7.68	7.52	7.6
Xu	7	T.C.	7.82	7.97	8.07	7.93	7.82	7.9
Deng	8	T.C.	8.74	8.85	8.93	8.81	8.87	8.8
Zhang	9	T.C.	7.31	7.47	7.53	7.43	7.38	7.4
Zhou	10	T.C.	8.43	8.53	8.67	8.52	8.47	8.5
50 out of the 50 individual exercise results ≤ 11 % 8 of the 10 individual arithmetic means ≤ 8 %					Pass			

Table 7.9.1-B Facial dimension

Subject	Face length	Face Width	Face Depth	Mouth Width
Yi	120	130	109	59
Gong	122	140	115	65
Yu	119	160	139	55
Hu	112	122	119	63
Xu	110	130	118	60
Deng	115	119	110	59
Zhang	112	123	113	55
Liu	103	130	100	50
Zhi	118	139	130	63
Fang	115	129	120	50
Chen	116	150	132	56
Zhou	110	121	110	53

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Table -7.9.2 Penetration of filter material

Test specification: EN 149-2001 Clause 8.11

Aerosol	Condition	Sample No.	Penetration (%)	Assessment
Sodium chloride test	As received	11	0.298	Pass
		12	0.332	
		13	0.316	
	Simulated wearing treatment	14	0.326	
		15	0.431	
		16	0.345	
	Mechanical strength+ Temperature conditioned	17	0.432	
		18	0.416	
		19	0.391	
Paraffin oil test	As received	20	5.21	
		21	5.17	
		22	5.38	
	Simulated wearing treatment	23	5.73	
		24	5.45	
		25	5.66	
	Mechanical strength+ Temperature conditioned	26	5.72	
		27	5.86	
		28	5.75	
Flow conditioning： Single filter: 95.0 L/min				

Table 7.11 Flammability

Test specification: EN 149-2001 Clause 8.6

Condition	Sample No.	Result	Assessment
As received	29	Burn for 2 s	Pass
	30	Burn for 2 s	
Temperature conditioned	31	Burn for 1 s	
	32	Burn for 2 s	

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Table 7.12 Carbon dioxide content of the inhalation air

Test specification: EN 149-2001 Clause 8.7

Condition	Sample No.	Result		Assessment
As received	33	0.41%	Mean value 0.4%	Pass
	34	0.40%		
	35	0.41%		

Table 7.16 Breathing resistance (mbar)

Test specification: EN 149-2001 Clause 8.9

	Flow rate		36					37					38				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
As received	Inhalation	30 l/min	0.4	0.5	0.5	0.4	0.4	0.4	0.5	0.4	0.4	0.4	0.4	0.5	0.4	0.4	0.5
		95 l/min	1.5	1.6	1.5	1.5	1.5	1.5	1.5	1.4	1.5	1.5	1.5	1.6	1.4	1.5	1.5
	Exhalation	160 l/min	1.8	1.9	1.8	1.8	1.8	1.9	1.9	1.8	1.8	1.8	1.8	1.9	1.8	1.8	1.8
	Flow rate		39					40					41				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
Simulated wearing treatment	Inhalation	30 l/min	0.4	0.5	0.5	0.4	0.4	0.4	0.5	0.5	0.4	0.4	0.4	0.4	0.5	0.4	0.4
		95 l/min	1.5	1.5	1.4	1.5	1.5	1.5	1.5	1.4	1.5	1.5	1.5	1.5	1.4	1.5	1.5
	Exhalation	160 l/min	1.8	1.9	1.8	1.8	1.9	1.8	1.9	1.8	1.8	1.9	1.8	1.9	1.9	1.8	1.8
	Flow rate		42					43					44				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
Temperature conditioned	Inhalation	30 l/min	0.4	0.4	0.5	0.4	0.4	0.4	0.4	0.5	0.4	0.4	0.4	0.4	0.5	0.4	0.4
		95 l/min	1.5	1.5	1.4	1.5	1.5	1.5	1.5	1.4	1.5	1.5	1.5	1.5	1.4	1.5	1.5
	Exhalation	160 l/min	1.9	1.9	1.8	1.8	1.9	1.8	1.9	1.8	1.8	1.8	1.8	1.9	1.8	1.8	1.7
Assessment	Pass																

A: facing directly ahead; B: facing vertically upwards; C: facing vertically downwards; D: lying on the left side; E: lying on the right side

End of Annex A

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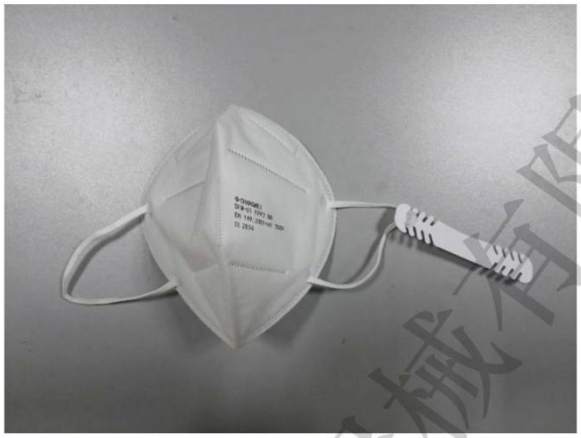
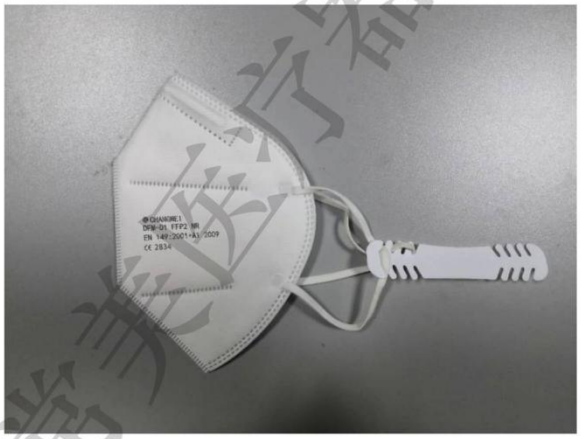
ANNEX B PHOTOS OF SAMPLES





End of Annex B

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3.4 REACH testing report for particle filtering half mask

SGS

Test Report (SVHC) No. SHAHG2007923501 Date: 19 May 2020 Page 1 of 20

JIANGSU CHANGMEI MEDTECH CO., LTD.
NO. 27, XINKE WEST ROAD, LUOYANG, 213104 CHANGZHOU CITY, JIANGSU PROVINCE, P.R. CHINA

The following sample(s) was/were submitted and identified on behalf of the clients as : PARTICLE FILTERING HALF MASK FFP2 NR

SGS Job No. :	SHHL2005516186MD - SH
Manufacturer :	JIANGSU CHANGMEI MEDTECH CO., LTD.
Style No. :	DFM-01
Date of Sample Received :	13 May 2020
Testing Period :	13 May 2020 - 19 May 2020
Test Requested :	As requested by client, SVHC screening is performed according to: (i) Two hundred and five (205) substances in the Candidate List of Substances of Very High Concern (SVHC) for authorization published by European Chemicals Agency (ECHA) on and before Jan 16, 2020 regarding Regulation (EC) No 1907/2006 concerning the REACH. (ii) Five (5) substances in the Public Consultation List of potential Substances of Very High Concern (SVHC) published by European Chemicals Agency (ECHA) on Mar 3, 2020 regarding Regulation (EC) No 1907/2006 concerning the REACH.
Test Results :	Please refer to next page(s).

Summary :

According to the ruling of the Court of Justice of the European Union on the definition of an article under REACH, and the specified scope and evaluation screening, the test results of SVHC are ≤ 0.1% (w/w) in the articles of the submitted sample.	PASS

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

Halery Han

Halery Han
Approved Signatory

scan to see the report
SHAHG2007923501

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Remark :

1. The chemical analysis of specified SVHC is performed by means of currently available analytical techniques against the following SVHC related documents published by ECHA: http://echa.europa.eu/web/guest/candidate-list-table
   These lists are under evaluation by ECHA and may subject to change in the future.
2. REACH obligation:
   2.1 Concerning article(s):
   Communication:
   Article 33 of Regulation (EC) No 1907/2006 requires supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0.1% weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance in the Candidate List.

   Notification:
   In accordance with Regulation (EC) No 1907/2006, any EU producer or importer of articles shall notify ECHA, in accordance with paragraph 4 of Article 7, if a substance meets the criteria in Article 57 and is identified in accordance with Article 59(1) of the Regulation, if (a) the substance in the Candidate List is present in those articles in quantities totaling over one tonne per producer or importer per year; and (b) the substance in the Candidate List is present in those articles above a concentration of 0.1% weight by weight (w/w).

   SGS adopts the ruling of the Court of Justice of the European Union on the definition of an article under REACH unless indicated otherwise. Detail explanation is available at the following link:
   http://www.sgs.com/-/media/global/documents/technical-documents/technical-bulletins/sgs-crs-position-statement-on-svhc-in-articles-a4-en-16-06.pdf?la=en

   2.2 Concerning material(s):
   Test results in this report are based on the tested sample. This report refers to testing result of tested sample submitted as homogenous material(s). In case such material is being used to compose an article, the results indicated in this report may not represent SVHC concentration in such article. If this report refers to testing result of composite material group by equal weight proportion, the material in each composite test group may come from more than one article.

   If the sample is a substance or mixture, and it directly exports to EU, client has the obligation to comply with the supply chain communication obligation under Article 31 of Regulation (EC) No. 1907/2006 and the conditions of Authorization of substance of very high concern included in the Annex XIV of the Regulation (EC) No. 1907/2006.

   2.3 Concerning substance and preparation:
   If a SVHC is found over 0.1% (w/w) and/or the specific concentration limit which is set in Regulation (EC) No 1272/2008 and its amendments, client is suggested to prepare a Safety

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Data Sheet (SDS) against the SVHC to comply with the supply chain communication obligation under Regulation (EC) No 1907/2006, in which:
- a substance that is classified as hazardous under the CLP Regulation (EC) No 1272/2008.
- a mixture that is classified as hazardous under the CLP Regulation (EC) No 1272/2008, when it contains a substance with concentration equal to, or greater than the classification limit as set in Regulation (EC) No. 1272/2008; or
- a mixture is not classified as hazardous under the CLP Regulation (EC) No 1272/2008, but contains either:
(a) a substance posing human health or environmental hazards in an individual concentration of ≥ 1 % by weight for mixtures that are solid or liquids (i.e., non-gaseous mixtures) or ≥ 0.2 % by volume for gaseous mixtures; or
(b) a substance that is PBT, or vPvB in an individual concentration of ≥ 0.1 % by weight for mixtures that are solid or liquids (i.e., non-gaseous mixtures); or
(c) a substance on the SVHC candidate list (for reasons other than those listed above), in an individual concentration of ≥ 0.1 % by weight for non-gaseous mixtures; or
(d) a substance for which there are Europe-wide workplace exposure limits.

3. If a SVHC is found over the reporting limit, client is suggested to identify the component which contains the SVHC and the exact concentration of the SVHC by requesting further quantitative analysis from the laboratory.

Test Sample :

Sample Description :

Specimen No.	SGS Sample ID	Description
SN1	SHA20-079235.001	Textile group
SN2	SHA20-079235.003	Metal group

Test Method :

SGS In-House method-SHTC-CHEM-SOP-97-T, SHTC-CHEM-SOP-302-T, Analyzed by ICP-OES, UV-VIS, GC-MS, HPLC-DAD/MS and Colorimetric Method.

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Test Result: (Substances in the Candidate List of SVHC)

Batch	Substance Name	CAS No.	001 Concentration (%)	RL (%)
-	All tested SVHC in candidate list	-	ND	-

Test Result: (Substances in the Consultation List of potential SVHC)

Batch	Substance Name	CAS No.	001 Concentration (%)	RL (%)
-	All tested SVHC in consultation list	-	ND	-

Test Result: (Substances in the Candidate List of SVHC)

Batch	Substance Name	CAS No.	003 Concentration (%)	RL (%)
-	All tested SVHC in candidate list	-	ND	-

Test Result: (Substances in the Consultation List of potential SVHC)

Batch	Substance Name	CAS No.	003 Concentration (%)	RL (%)
-	All tested SVHC in consultation list	-	ND	-

江苏常美医疗器械有限公司

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Notes :

(1)The table above only shows detected SVHC, and SVHC that below RL are not reported. Please refer to Appendix for the full list of tested SVHC.

(2) RL = Reporting Limit (Test data will be shown if it ≥ RL. RL is not regulatory limit.)
ND = Not detected (lower than RL), ND is denoted on the SVHC substance.

(3) ▵CAS No. of diastereoisomers identified (α-HBCDD, β-HBCDD, γ-HBCDD): 134237-50-6, 134237-51-7, 134237-52-8
☆CAS No. of Hexahydromethylphathalic anhydride, Hexahydro-4-methylphathalic anhydride, Hexahydro-1-methylphathalic anhydride, Hexahydro-3-methylphathalic anhydride: 25550-51-0, 19438-60-9, 48122-14-1, 57110-29-9; EC No. of those: 247-094-1, 243-072-0, 256-356-4, 260-566-1.

(4) * The test result is based on the calculation of selected element(s) and to the worst-case scenario.
** The test result is based on the calculation of selected marker(s) and to the worst-case scenario.
For detail information, please refer to the SGS REACH website:

http://www.sgs.com/en/Consumer-Goods-Retail/Toys-and-Juvenile-Products/Toys/REACH/Management-of-SVHC.aspx

Calculated concentration of boric compounds are based on the total boron for liquid, powder and paste samples and water extractive boron for other samples by ICP-OES.
RL = 0.01% is evaluated for element (i.e. cobalt, arsenic, lead, chromium (VI), aluminum, zirconium, boron, strontium, zinc, antimony, titanium, barium and cadmium respectively), except molybdenum RL=0.001%, boron RL=0.005% (only for Lead bis(tetrafluoroborate)), chromium (VI) RL=0.005% (only for Pentazinc chromate octahydroxide).

(5) § The substance is proposed for the identification as SVHC only where it contains Michler's ketone (CAS Number: 90-94-8) or Michler's base (CAS Number: 101-61-1) ≥0.1% (w/w).

(6) Composite test has been performed in equal proportion for the components/material per client requested. And the result is calculated using the minimum sample weight.

(7) In consideration of the analysis requirement and the limit of sample volume, the screening test for the article is based on components / material enough to test.

(8) / = Substances in the Consultation List of SVHC

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Appendix
Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
I	1	4,4' -Diaminodiphenylmethane(MDA)	101-77-9	0.100
I	2	5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	81-15-2	0.100
I	3	Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	85535-84-8	0.100
I	4	Anthracene	120-12-7	0.100
I	5	Benzyl butyl phthalate (BBP)	85-68-7	0.100
I	6	Bis (2-ethylhexyl)phthalate (DEHP)	117-81-7	0.100
I	7	Bis(tributyltin)oxide (TBTO)	56-35-9	0.100
I	8	Cobalt dichloride*	7646-79-9	0.010
I	9	Diarsenic pentaoxide*	1303-28-2	0.010
I	10	Diarsenic trioxide*	1327-53-3	0.010
I	11	Dibutyl phthalate (DBP)	84-74-2	0.100
I	12	Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified (α-HBCDD, β-HBCDD, γ-HBCDD)△	25637-99-4, 3194- 55-6	0.100
I	13	Lead hydrogen arsenate*	7784-40-9	0.010
I	14	Sodium dichromate*	7789-12-0, 10588-01-9	0.010
I	15	Triethyl arsenate*	15606-95-8	0.010
II	16	2,4-Dinitrotoluene	121-14-2	0.100
II	17	Acrylamide	79-06-1	0.100
II	18	Anthracene oil**	90640-80-5	0.100
II	19	Anthracene oil, anthracene paste**	90640-81-6	0.100
II	20	Anthracene oil, anthracene paste, anthracene fraction**	91995-15-2	0.100

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Appendix
Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
II	21	Anthracene oil, anthracene paste, distn. lights**	91995-17-4	0.100
II	22	Anthracene oil, anthracene-low**	90640-82-7	0.100
II	23	Diisobutyl phthalate	84-69-5	0.100
II	24	Lead chromate molybdate sulphate red (C.I. Pigment Red 104)*	12656-85-8	0.010
II	25	Lead chromate*	7758-97-6	0.010
II	26	Lead sulfochromate yellow (C.I. Pigment Yellow 34)*	1344-37-2	0.010
II	27	Pitch, coal tar, high temp.**	65996-93-2	0.100
II	28	Tris(2-chloroethyl)phosphate	115-96-8	0.100
III	29	Ammonium dichromate*	7789-09-5	0.010
III	30	Boric acid*	10043-35-3, 11113-50-1	0.010
III	31	Disodium tetraborate, anhydrous*	1303-96-4, 1330-43-4, 12179-04-3	0.010
III	32	Potassium chromate*	7789-00-6	0.010
III	33	Potassium dichromate*	7778-50-9	0.010
III	34	Sodium chromate*	7775-11-3	0.010
III	35	Tetraboron disodium heptaoxide, hydrate*	12267-73-1	0.010
III	36	Trichloroethylene	79-01-6	0.100
IV	37	2-Ethoxyethanol	110-80-5	0.100
IV	38	2-Methoxyethanol	109-86-4	0.100
IV	39	Chromic acid,Oligomers of chromic acid and dichromic acid,Dichromic acid*	7738-94-5 - 13530-68-2	0.010

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Appendix
Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
IV	40	Chromium trioxide*	1333-82-0	0.010
IV	41	Cobalt(II) carbonate*	513-79-1	0.010
IV	42	Cobalt(II) diacetate*	71-48-7	0.010
IV	43	Cobalt(II) dinitrate*	10141-05-6	0.010
IV	44	Cobalt(II) sulphate*	10124-43-3	0.010
V	45	1,2,3-trichloropropane	96-18-4	0.100
V	46	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	71888-89-6	0.100
V	47	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	68515-42-4	0.100
V	48	1-methyl-2-pyrrolidone	872-50-4	0.100
V	49	2-ethoxyethyl acetate	111-15-9	0.100
V	50	Hydrazine	7803-57-8, 302-01-2	0.100
V	51	Strontium chromate*	7789-06-2	0.010
VI	52	1,2-Dichloroethane	107-06-2	0.100
VI	53	2,2'-dichloro-4,4'-methylenedianiline	101-14-4	0.100
VI	54	2-Methoxyaniline; o-Anisidine	90-04-0	0.100
VI	55	4-(1,1,3,3-tetramethylbutyl)phenol	140-66-9	0.100
VI	56	Aluminosilicate Refractory Ceramic Fibres *	650-017-00-8 (Index no.)	0.010
VI	57	Arsenic acid*	7778-39-4	0.010
VI	58	Bis(2-methoxyethyl) ether	111-96-6	0.100
VI	59	Bis(2-methoxyethyl) phthalate	117-82-8	0.100

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Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
VI	60	Calcium arsenate*	7778-44-1	0.010
VI	61	Dichromium tris(chromate) *	24613-89-6	0.010
VI	62	Formaldehyde, oligomeric reaction products with aniline	25214-70-4	0.100
VI	63	Lead diazide, Lead azide*	13424-46-9	0.010
VI	64	Lead dipicrate*	6477-64-1	0.010
VI	65	Lead styphnate*	15245-44-0	0.010
VI	66	N,N-dimethylacetamide	127-19-5	0.100
VI	67	Pentazinc chromate octahydroxide*	49663-84-5	0.010
VI	68	Phenolphthalein	77-09-8	0.100
VI	69	Potassium hydroxyoctaoxodizincatedichromate*	11103-86-9	0.010
VI	70	Trilead diarsenate*	3687-31-8	0.010
VI	71	Zirconia Aluminosilicate Refractory Ceramic Fibres*	650-017-00-8 (Index no.)	0.010
VII	72	[4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Blue 26)§	2580-56-5	0.100
VII	73	[4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3)§	548-62-9	0.100
VII	74	1,2-bis(2-methoxyethoxy)ethane (TEGDME; triglyme)	112-49-2	0.100
VII	75	1,2-dimethoxyethane; ethylene glycol dimethyl ether (EGDME)	110-71-4	0.100
VII	76	4,4'-bis(dimethylamino) benzophenone (Michler's Ketone)	90-94-8	0.100
VII	77	4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol§	561-41-1	0.100
VII	78	Diboron trioxide*	1303-86-2	0.010

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Batch	No.	Substance Name	CAS No.	RL (%)
VII	79	Formamide	75-12-7	0.100
VII	80	Lead(II) bis(methanesulfonate)*	17570-76-2	0.010
VII	81	N,N,N',N'-tetramethyl-4,4'-methylenedianiline (Michler's base)	101-61-1	0.100
VII	82	TGIC (1,3,5-tris (oxiranylmethyl) -1,3,5-triazine-2,4,6(1H,3H,5H)-trione)	2451-62-9	0.100
VII	83	α,α-Bis[4-(dimethylamino)phenyl]-4 (phenylamino)naphthalene-1-methanol (C.I. Solvent Blue 4) §	6786-83-0	0.100
VII	84	β-TGIC (1,3,5-tris[(2S and 2R)-2,3-epoxypropyl]-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione)	59653-74-6	0.100
VIII	85	[Phthalato(2-)]dioxotrilead*	69011-06-9	0.010
VIII	86	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	84777-06-0	0.100
VIII	87	1,2-Diethoxyethane	629-14-1	0.100
VIII	88	1-Bromopropane	106-94-5	0.100
VIII	89	3-Ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	143860-04-2	0.100
VIII	90	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated	-	0.100
VIII	91	4,4'-Methylenedi-o-toluidine	838-88-0	0.100
VIII	92	4,4'-Oxydianiline and its salts	101-80-4	0.100
VIII	93	4-Aminoazobenzene	60-09-3	0.100
VIII	94	4-Methyl-m-phenylenediamine	95-80-7	0.100
VIII	95	4-Nonylphenol, branched and linear	-	0.100
VIII	96	6-Methoxy-m-toluidine	120-71-8	0.100
VIII	97	Acetic acid, lead salt, basic*	51404-69-4	0.010

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Batch	No.	Substance Name	CAS No.	RL (%)
VIII	98	Biphenyl-4-ylamine	92-67-1	0.100
VIII	99	Bis(pentabromophenyl) ether (DecaBDE)	1163-19-5	0.100
VIII	100	Cyclohexane-1,2-dicarboxylic anhydride, cis-cyclohexane-1,2-dicarboxylic anhydride, trans-cyclohexane-1,2-dicarboxylic anhydride	85-42-7, 13149-00-3, 14166-21-3	0.100
VIII	101	Diazene-1,2-dicarboxamide (C,C'-azodi(formamide))	123-77-3	0.100
VIII	102	Dibutyltin dichloride (DBTC)	683-18-1	0.100
VIII	103	Diethyl sulphate	64-67-5	0.100
VIII	104	Diisopentylphthalate	605-50-5	0.100
VIII	105	Dimethyl sulphate	77-78-1	0.100
VIII	106	Dinoseb	88-85-7	0.100
VIII	107	Dioxobis(stearato)trilead*	12578-12-0	0.010
VIII	108	Fatty acids, C16-18, lead salts*	91031-62-8	0.010
VIII	109	Furan	110-00-9	0.100
VIII	110	Henicosafluoroundecanoic acid	2058-94-8	0.100
VIII	111	Heptacosafluorotetradecanoic acid	376-06-7	0.100
VIII	112	Hexahydromethylphathalic anhydride, Hexahydro-4-methylphathalic anhydride, Hexahydro-1-methylphathalic anhydride, Hexahydro-3-methylphathalic anhydride	☆	0.100
VIII	113	Lead bis(tetrafluoroborate)*	13814-96-5	0.010
VIII	114	Lead cyanamidate*	20837-86-9	0.010
VIII	115	Lead dinitrate*	10099-74-8	0.010
VIII	116	Lead monoxide*	1317-36-8	0.010

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Batch	No.	Substance Name	CAS No.	RL (%)
VIII	117	Lead oxide sulfate*	12036-76-9	0.010
VIII	118	Lead tetroxide (orange lead)*	1314-41-6	0.010
VIII	119	Lead titanium trioxide*	12060-00-3	0.010
VIII	120	Lead titanium zirconium oxide*	12626-81-2	0.010
VIII	121	Methoxyacetic acid	625-45-6	0.100
VIII	122	Methyloxirane (Propylene oxide)	75-56-9	0.100
VIII	123	N,N-dimethylformamide	68-12-2	0.100
VIII	124	N-Methylacetamide	79-16-3	0.100
VIII	125	N-Pentyl-isopentylphthalate	776297-69-9	0.100
VIII	126	o-Aminoazotoluene	97-56-3	0.100
VIII	127	o-Toluidine	95-53-4	0.100
VIII	128	Pentacosafluorotridecanoic acid	72629-94-8	0.100
VIII	129	Pentalead tetraoxide sulphate*	12065-90-6	0.010
VIII	130	Pyrochlore, antimony lead yellow*	8012-00-8	0.010
VIII	131	Silicic acid, barium salt, lead-doped*	68784-75-8	0.010
VIII	132	Silicic acid, lead salt*	11120-22-2	0.010
VIII	133	Sulfurous acid, lead salt, dibasic*	62229-08-7	0.010
VIII	134	Tetraethyllead*	78-00-2	0.010
VIII	135	Tetralead trioxide sulphate*	12202-17-4	0.010
VIII	136	Tricosafluorododecanoic acid	307-55-1	0.100
VIII	137	Trilead bis(carbonate)dihydroxide (basic lead carbonate)*	1319-46-6	0.010

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Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
VIII	138	Trilead dioxide phosphonate*	12141-20-7	0.010
IX	139	4-Nonylphenol, branched and linear, ethoxylated	-	0.100
IX	140	Ammonium pentadecafluorooctanoate (APFO)**	3825-26-1	0.100
IX	141	Cadmium oxide*	1306-19-0	0.010
IX	142	Cadmium*	7440-43-9	0.010
IX	143	Dipentyl phthalate (DPP)	131-18-0	0.100
IX	144	Pentadecafluorooctanoic acid (PFOA)	335-67-1	0.100
X	145	Cadmium sulphide*	1306-23-6	0.010
X	146	Dihexyl phthalate	84-75-3	0.100
X	147	Disodium 3,3'-[[1,1'-biphenyl] -4,4'-diylbis(azo)] bis(4-aminonaphthalene-1-sulphonate) (C.I. Direct Red 28)	573-58-0	0.100
X	148	Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo] [1,1'-biphenyl]-4-yl]azo] -5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate (C.I. Direct Black 38)	1937-37-7	0.100
X	149	Imidazolidine-2-thione; (2-imidazoline-2-thiol)	96-45-7	0.100
X	150	Lead di(acetate)*	301-04-2	0.010
X	151	Trixylyl phosphate	25155-23-1	0.100
XI	152	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	68515-50-4	0.100
XI	153	Cadmium chloride*	10108-64-2	0.010
XI	154	Sodium perborate; perboric acid, sodium salt*	-	0.010
XI	155	Sodium peroxometaborate*	7632-04-4	0.010
XII	156	2- (2H-benzotriazol-2-yl) -4,6-ditertpentylphenol (UV-328)	25973-55-1	0.100

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Batch	No.	Substance Name	CAS No.	RL (%)
XII	157	2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)	3846-71-7	0.100
XII	158	2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)	15571-58-1	0.100
XII	159	Cadmium fluoride*	7790-79-6	0.010
XII	160	Cadmium sulphate *	10124-36-4,31119-53-6	0.010
XII	161	Reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate & 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE & MOTE)	-	0.100
XIII	162	1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate	68515-51-5,68648-93-1	0.100
XIII	163	5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual isomers of [1] and [2] or any combination thereof]	-	0.100
XIV	164	1,3-propanesultone	1120-71-4	0.100
XIV	165	2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl) phenol (UV-327)	3864-99-1	0.100
XIV	166	2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350)	36437-37-3	0.100
XIV	167	Nitrobenzene	98-95-3	0.100
XIV	168	Perfluorononan-1-oic-acid and its sodium and ammonium salts	375-95-1,21049-39-8, 4149-60-4	0.100
XV	169	Benzo[def]chrysene (Benzo[a]pyrene)	50-32-8	0.100
XVI	170	4,4'-isopropylidenediphenol (bisphenol A)	80-05-7	0.100

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XVI	171	4-Heptylphenol, branched and linear	-	0.100
XVI	172	Nonadecafluorodecanoic acid (PFDA) and its sodium and ammonium salts	3108-42-7 335-76-2 3830-45-3	0.100
XVI	173	p-(1,1-dimethylpropyl)phenol	80-46-6	0.100
XVII	174	Perfluorohexane-1-sulphonic acid and its salts	-	0.100
XVIII	175	1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo[12.2.1.16,9.02,13.05,10]octadeca-7,15-diene ("Dechlorane Plus"™) [covering any of its individual anti- and syn-isomers or any combination thereof]	-	0.100
XVIII	176	Benz[a]anthracene	56-55-3, 1718-53-2	0.100
XVIII	177	Cadmium nitrate*	10022-68-1, 10325-94-7	0.010
XVIII	178	Cadmium carbonate*	513-78-0	0.010
XVIII	179	Cadmium hydroxide*	21041-95-2	0.010
XVIII	180	Chrysene	218-01-9, 1719-03-5	0.100
XVIII	181	Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) [with ≥0.1% w/w 4-heptylphenol, branched and linear]	-	0.100
XIX	182	Benzene-1,2,4-tricarboxylic acid 1,2-anhydride (trimellitic anhydride)	552-30-7	0.100
XIX	183	Benzo[ghi]perylene	191-24-2	0.100
XIX	184	Decamethylcyclopentasiloxane (D5)	541-02-6	0.100
XIX	185	Dicyclohexyl phthalate (DCHP)	84-61-7	0.100
XIX	186	Disodium octaborate*	12008-41-2	0.010
XIX	187	Dodecamethylcyclohexasiloxane (D6)	540-97-6	0.100

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Appendix
Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
XIX	188	Ethylenediamine (EDA)	107-15-3	0.100
XIX	189	Lead*	7439-92-1	0.010
XIX	190	Octamethylcyclotetrasiloxane (D4)	556-67-2	0.100
XIX	191	Terphenyl, hydrogenated	61788-32-7	0.100
XX	192	1,7,7-trimethyl-3-(phenylmethylene)bicyclo[2.2.1]heptan-2-one (3-benzylidene camphor)	15087-24-8	0.100
XX	193	2,2-bis(4'-hydroxyphenyl)-4-methylpentane	6807-17-6	0.100
XX	194	Benzo[k]fluoranthene	207-08-9	0.100
XX	195	Fluoranthene	206-44-0, 93951-69-0	0.100
XX	196	Phenanthrene	85-01-8	0.100
XX	197	Pyrene	129-00-0, 1718-52-1	0.100
XXI	198	2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof)	-	0.100
XXI	199	2-methoxyethyl acetate	110-49-6	0.100
XXI	200	4-tert-butylphenol (PTBP)	98-54-4	0.100
XXI	201	Tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with ≥ 0.1% w/w of 4-nonylphenol, branched and linear (4-NP)	-	0.100
XXII	202	2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone	119313-12-1	0.100
XXII	203	2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one	71868-10-5	0.100
XXII	204	Diisohexyl phthalate	71850-09-4	0.100
XXII	205	Perfluorobutane sulfonic acid (PFBS) and its salts	-	0.100

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Appendix

Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
/	206	1-vinylimidazole	1072-63-5	0.100
/	207	2-methylimidazole	693-98-1	0.100
/	208	Butyl 4-hydroxybenzoate	94-26-8	0.100
/	209	Dibutylbis(pentane-2,4-dionato-O,O')tin	22673-19-4	0.100
/	210	Resorcinol	108-46-3	0.100

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SGS Sample ID	Photo No.	Material Description
001	P1	Colorful non-woven fabrics
001	P2	White silk wadding
001	P3	White non-woven fabrics
001	P4	White non-woven fabrics
001	P5	White elastic
001	P6	White plastic
001	P7	White plastic
003	P8	Silvery metal

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Sample photo:

SHAHG2007923501

SHA20-079235.001

SHAHG2007923501

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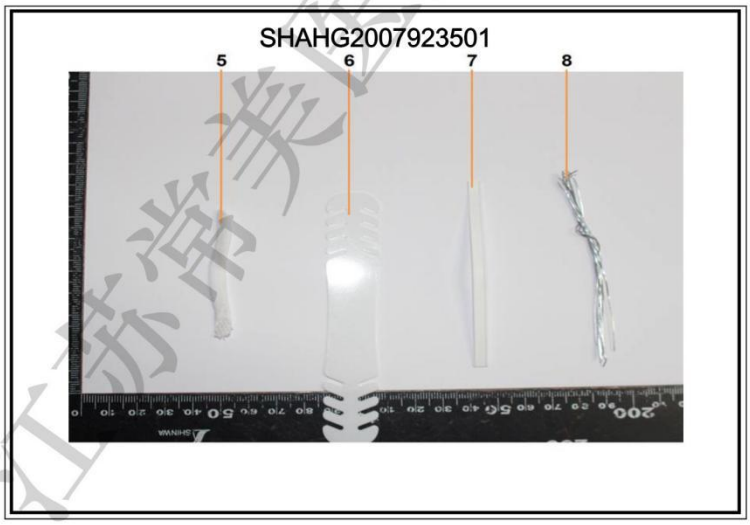

SGS authenticate the photo on original report only

*** End of Report ***

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3.5 IFU for particle filtering half mask

Particle Filtering Half Mask

Model: DFM-01 FFP2 NR

Following standard: EN 149:2001+A1:2009

Following Regulation (EU)2016/425

CE 2834

Use Instruction

1. Failure to follow all instructions and limitations could seriously reduce the effectiveness of this particle filtering half mask and could lead to illness, injury or death.
2. A properly selected particle filtering half mask is essential, before occupational use, the wearer must be trained by the employer in the correct use of the particle filtering half mask in accordance with applicable safety and health standards.
3. This particle filtering half mask does not supply the oxygen. Use only in adequately ventilated is as containing sufficient oxygen to support life.
4. Discard the particle filtering half mask and replace with a new one if excessive clogging of the particle filtering half mask cause breathing difficulty or the particle filtering half mask becomes damaged.
5. Leave the contaminated area if dizziness, irritation or other distress occurs.

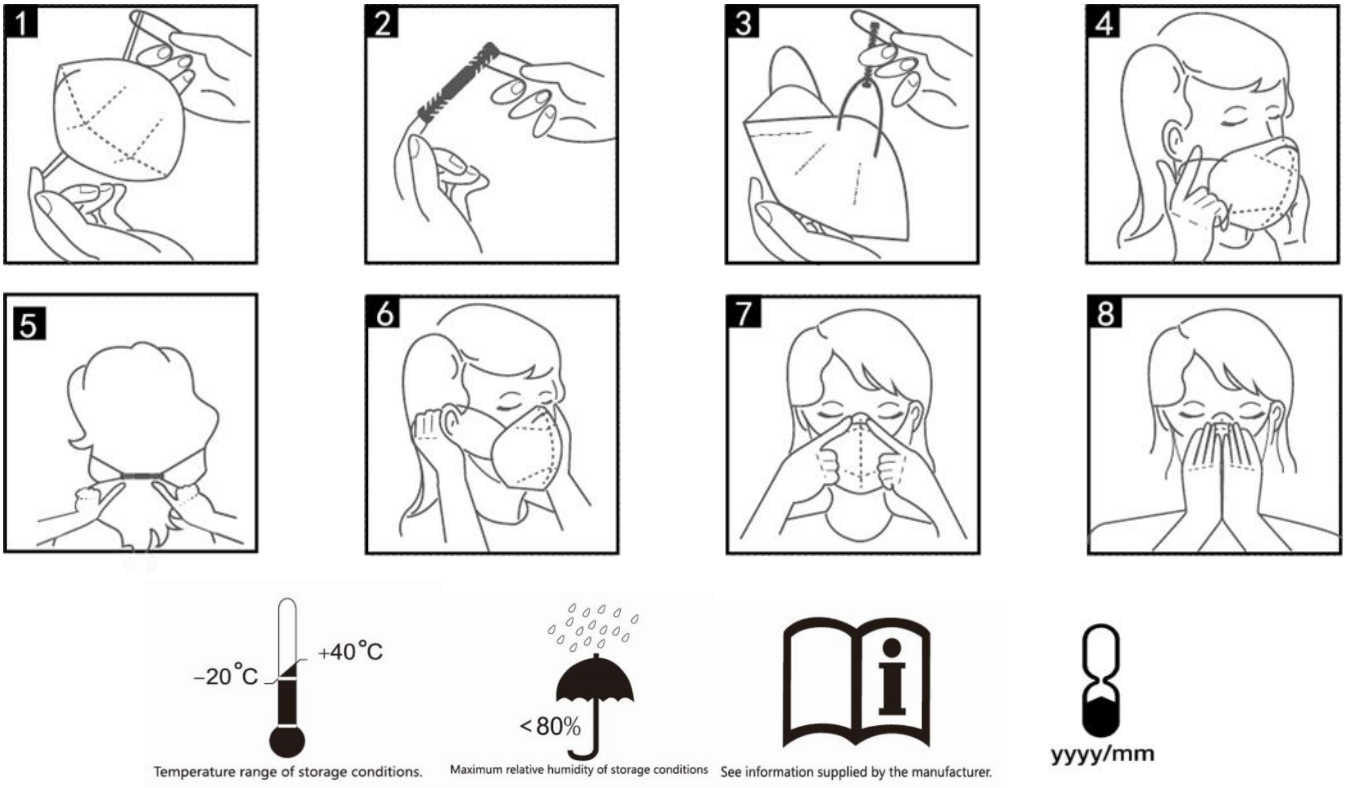
Use Limitation

1. Do not use the particle filtering half mask or enter or stay in a contaminated area under the following circumstance:
   a) Atmosphere contains less than 19.5% oxygen.
   b) If you smell or taste contaminant.
   c) For protection against gases or vapors.
   d) Contaminants or their concentrations are unknown or immediately dangerous to life or health.
   e) For sandblasting, paint-spray operations and asbestos.
   f) In underwater, fire and explosive atmospheres.
2. Do not modify or misuse the mask.
3. Do not use the particle filtering half mask with facial hair or any other conditions that may prevent a good face-seal, the requirements for leakage will be achieved.
4. Particle filtering half mask need to be inspected prior to each use to assure there are no holes in the breathing zone other than punctures around and staples and no damaged has occurred. Enlarged holes resulting from ripped or torn filter material around staple punctures are considered damage.
5. This particle filtering half mask helps protect against certain particulate contaminants but does not eliminate exposure to the risk of contracting disease or infection. Misuse may result in sickness or death.
6. This particle filtering half mask marked “NR”, shall not be used for more than one shift.

Fitting Instruction

1. Open the particle filtering half mask, face to the inside of the mask, and hold the mask on each hand so that the nose clip is at the top.
2. Take out the retaining clip from the package and fasten one end of the retaining clip to one side of the mask.
3. Hold the particle filtering half mask in position over the nose and mouth, and fasten the other end of the retaining clip to the other side of the mask.
4. Adjust to a comfortable position and make the mask fit the face.
5. Bend the nose clip to make a tight seal around the nose.
6. Fit check
   a) To test the fit of the particle filtering half mask, cup both hands over the particle filtering half mask and inhale sharply. If air flow is felt in the nose area, re-adjust/tighten the nose clip.
   b) If flows is felt around the edges of the particle filtering half mask, re-position the mask harness to achieve a better fit.
7. Change the particle filtering half mask immediately if breathing becomes difficult or

particle filtering half mask becomes damaged or distorted.
8. Change the particle filtering half mask if a proper face seal cannot be achieved.
9. Careful observances of these instructions is an important step in safe particle filtering half mask use.



Notified Body: CCQS Certification Services Limited
NB: 2834
Address: Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin 15, D15 AKK1, Ireland
Manufacturer: Jiangsu Changmei Medtech Co., Ltd.
Address: No.27, Xinke West Road, Luoyang, 213104 Changzhou City, Jiangsu Province, P. R. China

3.6 Testing report according to GB2626-2006 standard

中国认可
国际互认
检测
TESTING
CNAS L2313

Test Report

Report No.:LFCWT199-2020

Product Name: Non-powered Air-purifying Particle Respirator

Inspected Company: Jiangsu Changmei Medtech Co., Ltd

Inspection Category: Entrusted Inspection

Technology Inspection Centre of Shengli Oilfield Branch, SINOPEC

Statement

1. The report is invalid without a business seal.

2. The copy of the report is invalid. The copy of the report approved by the test unit shall be confirmed with a new business seal.

3. The report shall be invalid without approval by an authorized signatory.

4. Report alteration is invalid.

5. The entrusted inspection is only responsible for the test results of the performance indicators measured by the entrusted samples under the test conditions. All the inspection analysis data and report contents cannot be used as the basis for judicial proceedings or other commercial publicity purposes.

6. The Test Report without the seal of qualification identification is only used for internal reference and scientific research, and does not have the function of social proof.

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Zip code: 257000

Telephone: 0546-8511087

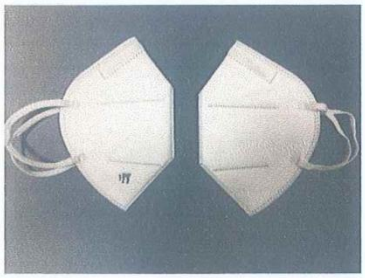
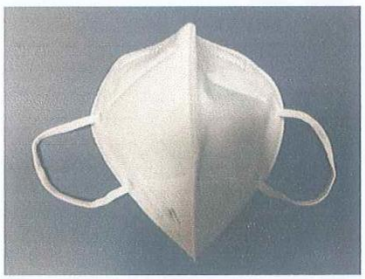
Fax: 0546-8511087

E-Mail: shenghua.slyt@sinopec.com

Technology Inspection Centre of Shengli Oilfield Branch, SINOPEC

Test Report

No.: LFCWT199-2020

Product Name	Non-powered Air-purifying Particle Respirator	Product category	Disposable.No –exhalation Valve. KN95
Inspected Company	Jiangsu Changmei Medtech Co., Ltd	Brand Name	CHANGMEI
Correspondence Address	No.27, Xinke West Road, Luoyang, Changzhou City, Jiangsu Province, China	Model	/
Touch People	Shen Yufang	Contact Phone	15806123625
Sample Quantity	40	Sample Arrival Date	May 13, 2020
Sample status	In good condition	The Date of Production	/
Inspection Category	Entrusted inspection	Send Samples	Express
Inspection Basis	GB2626--2006 Respiratory Protective Equipment—Non-powered Air-purifying Particle Respirator		
Inspection Items	General requirements, visual inspection, filter efficiency, inhalation resistance, exhalation resistance, dead space, field of vision, head harness, flammability, total leakage rate TIL		
Sample Photos	 		
Inspection Conclusion	The sample was tested according to GB2626-2006 《Respiratory protective equipment—non-powered air-purifying particle respirator》 and the test results showed that the data of the checked items meet the requirements of the standard (KN95). (special seal for inspection) Date of issue: May 21, 2020		
Remarks	/		
Ratify:	Review:	The main inspection:	

Test Report

Summary of inspection results						
No.	Inspection items	Standard Requirement	Inspection results		Conclusion on this item	Remarks
1	General requirements	The design, composition and installation of the components do not pose any danger to the user.	The requirement was met.		Conformity	/
		Adjustable head harness, easy to wear and remove, can be firmly fixed on the face mask, wearing without obvious pressure or tenderness phenomenon.	The requirement was met.			
		For the disposable mask, the structure can ensure the face close.	The requirement was met.			
		For the replaceable half mask, the head harness can be replaced, and the replaceable components can easily check the air tightness of the wearer.	/			
2	Visual inspection	The sample surface should not be damaged, deformed or have obvious other defects;	The requirement was met.		Conformity	/
		Component materials and structures should be able to withstand normal operating conditions and possible temperature and humidity;	The requirement was met.			
		The head harness should be adjustable and the replaceable head harness should be replaceable;	The head harness could be adjustable.			
		After temperature and humidity pretreatment, the parts should not fall off, damage and deformation;	The requirement was met.			
3	Head harness	Each head harness, buckle and other adjusting parts of the disposable mask shall not slip or break under the tension of 10N and 10s.	Without pretreatment	No slippage or fracture was observed.	Conformity	/
			With temperature and humidity pretreatment	No slippage or fracture was observed.		
		Each head harness buckle and other adjusting parts of the replaceable half	Without pretreatment	/		

Test Report

No.: LFCWT199-2020

Summary of inspection results								
No.	Inspection items	Standard Requirement	Inspection results			Conclusion on this item	Remarks
		facepiece shall not slip or break under the tension of 50N and duration of 10s.	With temperature and humidity pretreatment	/			
		Each head strap, buckle and other adjusting parts of the full cover are subjected to a tension of 150N and a duration of 10s.There should be no slippage or fracture.	Without pretreatment	/			
			With temperature and humidity pretreatment	/			
4	Flammability	Components exposed to the flame shall not burn after being removed from the flame;If it burns, the afterburn time should not exceed 5s.	Without pretreatment	38#	0s	Conformity	/
				39#	0s		
			With temperature and humidity pretreatment	16#	0s		
				17#	0s		
5	Inhalation resistance	The total inspiratory resistance of each sample is ≤350Pa.	Without pretreatment	33#	125Pa	Conformity	/
				34#	134Pa		
			With temperature and humidity pretreatment	11#	138Pa		
				12#	127Pa		
6	Exhalation resistance	The total expiratory resistance of each sample was ≤250Pa.	Without pretreatment	35#	116Pa	Conformity	/
				36#	149Pa		
			With temperature and humidity pretreatment	13#	152Pa		
				14#	133Pa		
7	Dead space	When expressed as the volume fraction of carbon dioxide in the inhaled gas, the average value should be less than 1%.	0.6%			Conformity	/
		Ambient temperature :(16 ~ 32)℃.	20℃				
8	Field of vision	Half facepiece	Lower visual field ≥60°;	68°		Conformity	/
		Full facepiece Large eye	Total visual field ≥70°;	/			

Technology Inspection Centre of Shengli Oilfield Branch, SINOPEC

Test Report

No.: LFCWT199-2020

<table>
<tr><td colspan="8">Summary of inspection results</td></tr>
<tr><td>No.</td><td>Inspection items</td><td colspan="3">Standard Requirement</td><td colspan="3">Inspection results</td><td>Conclusion on this item</td><td>Remarks</td></tr>
<tr><td></td><td></td><td></td><td>window</td><td>Binocular visual field ≥80°;</td><td colspan="3">/</td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td rowspan="2">Small eye window</td><td>Total visual field ≥70°;</td><td colspan="3">/</td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td>Visual field ≥20°.</td><td colspan="3">/</td><td></td><td></td></tr>
<tr><td rowspan="15">9</td><td rowspan="15">Filter efficiency</td><td colspan="3" rowspan="14">≥95.0% (KN95)</td><td rowspan="9">Without pretreatment</td><td>18#</td><td>99.8%</td><td rowspan="15">Conformity</td><td rowspan="15">/</td></tr>
<tr><td>19#</td><td>99.6%</td></tr>
<tr><td>20#</td><td>99.8%</td></tr>
<tr><td>21#</td><td>99.7%</td></tr>
<tr><td>22#</td><td>99.7%</td></tr>
<tr><td>23#</td><td>99.6%</td></tr>
<tr><td>24#</td><td>99.8%</td></tr>
<tr><td>25#</td><td>99.8%</td></tr>
<tr><td>26#</td><td>99.6%</td></tr>
<tr><td>27#</td><td>99.5%</td></tr>
<tr><td rowspan="5">With temperature and humidity pretreatment</td><td>1#</td><td>99.6%</td></tr>
<tr><td>2#</td><td>99.4%</td></tr>
<tr><td>3#</td><td>99.5%</td></tr>
<tr><td>4#</td><td>99.4%</td></tr>
<tr><td>5#</td><td>99.6%</td></tr>
<tr><td colspan="3">Ambient temperature :(25±5)℃;
Relative humidity :(30±10) %.</td><td colspan="3">Ambient temperature: 26℃
Relative humidity: 35%</td></tr>
<tr><td rowspan="5">10</td><td rowspan="5">Total leakage rate (TIL) (disposable mask)</td><td rowspan="5">When the evaluation is based on TIL of each action (i.e., 10 people ×5 actions), TIL has at least 46 actions out of 50.</td><td rowspan="2">< 13% (KN90/KP90);</td><td>/</td><td>/</td><td rowspan="5">Conformity</td><td rowspan="5">/</td></tr>
<tr><td>/</td><td>/</td></tr>
<tr><td rowspan="2">< 11% (KN95/KP95);</td><td>Without pretreatment</td><td>TIL of 25 Actions < 11%</td></tr>
<tr><td>With temperature and humidity pretreatment</td><td>TIL of 25 Actions < 11%</td></tr>
<tr><td>< 5%</td><td>/</td><td>/</td></tr>
</table>

Technology Inspection Centre of Shengli Oilfield Branch, SINOPEC

Test Report

No.: LFCWT199-2020

<table>
<tr><td colspan="8">Summary of inspection results</td></tr>
<tr><td>No.</td><td>Inspection items</td><td colspan="2">Standard Requirement</td><td colspan="2">Inspection results</td><td>Conclusion on this item</td><td>Remarks</td></tr>
<tr><td rowspan="6"></td><td rowspan="6"></td><td></td><td>(KN100/KP100).</td><td>/</td><td>/</td><td rowspan="6"></td><td rowspan="6"></td></tr>
<tr><td rowspan="5">On the basis of human population TIL, at least 8 out of 10 subjects had population TIL.</td><td>< 10% (KN90/KP90);</td><td>/</td><td>/</td></tr>
<tr><td rowspan="2">< 8% (KN95/KP95);</td><td>/</td><td>/</td></tr>
<tr><td>Without pretreatment</td><td>Total TIL of 5 subjects< 8%</td></tr>
<tr><td>With temperature and humidity pretreatment</td><td>Total TIL of 5 subjects< 8%</td></tr>
<tr><td rowspan="2">< 2% (KN100/KP100).</td><td>/</td><td>/</td></tr>
<tr><td>/</td><td>/</td></tr>
<tr><td colspan="2">Main inspection equipment</td><td colspan="6">Microcomputer controlled electronic universal testing machine (lfsy-053), mask flame retardancy test device (lfsy-161), high and low temperature humid and thermal alternator (lfsy-188), leakage performance test device (lfsy-166), respiratory resistance test device (lfsy-159), automatic filter material tester (lfsy-156), CO_2 concentration test system (lfsy-158), fire mask visual field tester (lfsy-148), etc.</td></tr>
<tr><td colspan="2">For note</td><td colspan="6">/</td></tr>
</table>

Inspection date: May 18, 2020 ~ May 22, 2020

END