HENAN GORE MEDICAL INSTRUMENTS CO., LTD
THE NORTH INDUSTRIAL AREA OF DING LUAN,CHANGYUAN COUNTRY,453412 HENAN,CHINA

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

Sample Description	:	(A)Medical protective mask(Claimed Type II)
Style No.	:	arch
Sample Color	:	White
Sample Receiving Date	:	May 15, 2020
Testing Period	:	May 22, 2020 - Jun 12, 2020
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).
Test Performed	:	Selected test(s) as requested by applicant

Comment:

Medical Face Masks-Requirements and Test Methods(EN 14683:2019+AC:2019)	(A)
Clause 5.2.2 Bacterial filtration efficiency (BFE)	M
Clause 5.2.3 Breathability	M
Clause 5.2.5 Microbial Cleanliness	M

Remark: M=Meet EN 14683:2019+AC:2019 Type II requirement

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

Sara Guo (Account Executive)

Dongjing Liu (Authorized Signatory)

Test Result

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

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

Sample: A

	1#	2#	3#	4#	5#
(BFE), %	99.9	99.7	99.8	99.7	99.9

Remark: Performance Requirement: Type I≥95%, Type II≥98%, Type IIR ≥98%
* This test standard is not within the accredited scope in SGS Shanghai testing centre, it is carried out by external laboratory accredited by CMA (China Metrology Accreditation).

Clause 5.2.3 Breathability (Differential Pressure)
(EN 14683 :2019 Annex C, Flow rate 8 l/min)

Sample: A

	1#	2#	3#	4#	5#
Differential pressure △P (Pa/cm^2)	26	26	28	28	26

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

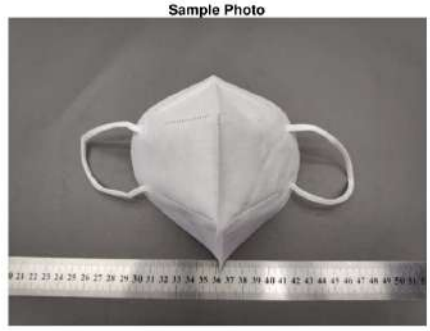
Clause 5.2.5 Microbial Cleanliness
(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

Sample: A

	1#	2#	3#	4#	5#
CFU/g	1	<1	<1	<1	<1

Remark: Performance Requirement: Type I≤30 CFU/g, Type II≤30 CFU/g, Type IIR≤30 CFU/g

Sample Photo



The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report

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Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com
3rd Building,No.889,Yishan Road,Xuhui District Shanghai,China 200233 t (86-21) 61402666 f (86-21) 64958783 www.sgsgroup.com.cn
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64958783 e sgs.china@sgs.com
Member of the SGS Group (SGS SA)

产品说明书

CE Mark: conforms to essential requirements of the Medical Device Regulation 2017/745 (EU)

Date of manufacture, Indicates the date when the medical device was manufactured

Use-by date, Indicates the date after which the medical device is not to be used

Do not re-use, indicates a medical device that is intended for one use, or for use on a single patient during a single procedure

Do not use if package is damaged, indicates a medical device that should not be used if the package has been damaged or opened

Non-sterile

UDI-DI code of product identification

Batch code, Indicates the manufacturer's batch code so that the batch or lot can be identified.

Fragile, handle with care, indicates a medical device that can be broken or damaged if not handled carefully.

Keep away from sunlight, indicates a medical device that needs protection from light sources.

Keep dry, indicates a medical device that needs to be protected from moisture.

Name: Henan Gore Medical Instruments Co., Ltd.
Add:The North Industrial Area of Ding Luan, Changyuan County, 453412 Henan, China.
Tel: +86-0373-8969880
Fax: +86-0373-8967288

Name: Llins Service & Consulting GmbH
Address: Obere Seegasse 34/2, 69124, Heidelberg, Germany
DIMDI Code: DE/0000048234
Tel: +49 175 4870 819
Email: info@llins-service.com

产品说明书

Medical protective mask

Instruction for Use

[Product Name]
Medical protective mask
[Model/Size]
Rectangle、Arch、Butterfly
[Intended use]
It is used for the protection of medical units in non-invasive operation.
[Contraindications]
People who are allergic to product materials.
[Directions for use]
1. Open the package, take out the mask and expand it longitudinally to form a space between the nose and mouth to make the breathing smooth.
2. Face the mask with light color, dark color and nose clip upward (a plastic strip).
3. after wearing the face, adjust the nose clip to make it have good tightness and prevent harmful substances in the air from leaking into the sealing place.
4. After use, it shall be discarded in the specified dirt box and treated in a unified way to avoid product reuse hazards and environmental pollution.
[Precautions]
1. Read the manual carefully before use;
2. This product is disposable, can not be washed and reused;
3. Do not use in sterile ward or invasive operating room;
4. Pay attention to the "non sterile" and "sterile" instruction marks of the product packaging, please use them after handling according to the clinical requirements;
5. It is forbidden to use the package if the seal is disconnected, damaged or beyond the validity period of the product.
[Package]
Plastic packaging bag, Single packing.
[Expiry]
2 years.
[Production Date]
Refer to the package label
[Storage conditions]
1. Products shall be protected from heavy pressure, direct sunlight and rain and snow during transportation;
2. It shall be stored in a ventilated, dry and non corrosive gas environment. Keep away from fire sources and inflammables.
[Sterilization Method]
None
[Symbol Description]

Caution, Indicates the need for the user to consult the instructions for use for important cautionary information, such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

EC REP CERTIFICATE

CMC MEDICAL DEVICES & DRUGS SL
NO. CMC/CE/2020/04062020.15

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

Henan Gore Medical Instruments Co., Ltd.
The North Industrial Area of Ding Luan, Changyuan County, 453412 Henan, 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/1228/2020**

CE

Issued on: 04/06/2020 Valid until: 03/06/2021

Authorized Signatory
CMC Medical Devices & Drugs SL

EC REP CERTIFICATE

ANNEX I Medical Device Products

Protective clothing

Surgical mask

Disposable medical gloves

Medical protective mask

Disposable isolation clothing

CE

www.cmcmedicaldevices.com

Certificate Of Registration

HENAN GORE MEDICAL INSTRUMENTS CO., LTD
The North Industrial Area of Ding Luan, Changyuan County, 453412
Henan, China
Has Completed With The U.S. Food And Drug Administration Pursuant To 21 CFR Part 807: Establishment Registration And Device Listing

Owner/Operator No.: 10065726
Device Listing: See Next pager

Huawin 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. Huawin makes no other representations or warranties, nor does this certificate make 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. Huawin assumes no liability to any person or entity in connection with the foregoing.

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. Huawin is not affiliated with the U.S. Food and Drug Administration.

APPROVED

Manager: Guy Su
Issue date: May 28, 2020
Expire Date: Dec. 31, 2020

Shenzhen Huawin Testing Certification Co., Ltd.
Add: 7F, U Center, No.743, Zhoushi Road, Bao'an, Shenzhen, China
Http://www.huawinlab.com E-mail: info@huawinlab.com

Certificate Of Registration

Device Listing:

Listing No.	Code No.	Proprietary Name	Model No.
D382100	KHA	Surgical mask(Ear loop/Tie band)	-
		Disposable Medical Mask(Ear loop/Tie band)	-
		Medical protective mask	-
D382098	OEA	Disposable isolation clothing(one-piece type)	-
		Disposable medical protective clothing(split type/one-piece type)	-
		Disposable isolation clothing(split type)	-

APPROVED

Manager: Guy Su
Issue date: May 28, 2020
Expire Date: Dec. 31, 2020

Shenzhen Huawin Testing Certification Co., Ltd.
Add: 7F, U Center, No.743, Zhoushi Road, Bao'an, Shenzhen, China
Http://www.huawinlab.com E-mail: info@huawinlab.com

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

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

TÜV SÜD
Product Service

Certificate

No. Q6 104197 0001 Rev. 00

Holder of Certificate: **Henan Gore Medical Instruments Co., Ltd.**
The North Industrial Area of Ding Luan
453412 Changyuan County, Henan
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Henan Gore Medical Instruments Co., Ltd.
The North Industrial Area of Ding Luan, 453412 Changyuan County, Henan, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Production and Distribution of Disposable Medical Mask, Disposable Medical Cap, Medical Absorbent Gauze Patches, Medical Cotton Swab, Disposable Medical Bedsheet, Disposable Surgical Gown, Disposable Anesthesia Gas Filter, Medical Oxygen Mask, Disposable Airflow Atomizer, Trachea Cannula, Medical Bandage, Disposable Intravenous Indwelling Needle**

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

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.:	SH19149901
Valid from:	2020-03-11
Valid until:	2023-03-10

Date, 2020-03-11

Christoph Dicks
Head of Certification/Notified Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 104197 0003 Rev. 00

Manufacturer

Henan Gore Medical Instruments Co., Ltd.
The North Industrial Area of Ding Luan
453412 Changyuan County, Henan
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Disposable Medical Mask,
Disposable Medical Cap,
Medical Absorbent Gauze Patches,
Medical Cotton Swab,
Disposable Medical Bedsheet,
Disposable Surgical Gown

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: SH19149901

Valid from: 2020-03-11
Valid until: 2024-05-26

Date, 2020-03-11

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV®

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

南德 TUV 认证产品清单

S/N	Category	Name of Product	Types/Sizes/ Models	Classification/ Rule of classification	UMDNS Code
1	MD 0101 MDS7006_1	Trachea Cannula(气管插管)	Ordinary Type: 2.0-11.0 Reinforced Type: 2.0-11.0	Class IIa/ Rule 5	14085
2	MD 0101 MDS7006_1	Disposable Anaesthesia Gas Filter（一次性使用麻醉气体过过滤器）	Normal（常规）	Class IIa/ Rule 2	15649
3	MD 0101 MDS7006_1	Medical Oxygen Mask（医用吸氧面罩）	XL, L, M, S	Class IIa/ Rule 2	12448
4	MD 0101 MDS7006_1	Disposable Airflow Atomizer（一次性使用气流雾化器）	Type I（（大杯））: mouthpiece, mask(XL/L/M/S), Type II（小杯）: mouthpiece, mask(XL/L/M/S)	Class IIa/ Rule 2	10226
5	MD 0301 MDS7006_1	Disposable Medical Cap（一次性使用医用帽）	Straight（直筒型）,cylinder（圆顶形）,strip（条形）	Class Is/ rule 1	16081
6	MD 0301 MDS7006_1	Disposable Medical Mask（一次性使用医用口罩）	Lacing（系带型）,hanger（挂耳型）	Class Is/ rule 1	12447
7	MD 0301 MDS7006_1	Medical Absorbent Gauze Patches（医用脱脂纱布块）	Length（2cm～1000cm）× Width(2cm～80cm)×Layers(1～32)	Class Is/ rule 4	11859
8	MD 0301 MDS7006_1	Medical Cotton Swab（医用棉拭）	6cm, 8cm, 10cm, 12cm, 15cm, 16cm, 20cm, 22cm, 25cm	Class Is/ rule 4	15066
9	MD 0301 MDS7006_1	Disposable Medical Bedsheet（一次性使用医用床单）	Type I, Type II, Type III	Class Is/ rule 1	15075
10	MD 0301 MDS7006_1	Disposable Surgical Gown（一次性使用手术衣）	extra large, large, middle, small, extra small（特大、大号、中号、小号）	Class Is/ rule 1	11901

CE 一类备案清单

一次性医用防护服 protective clothing	型号：连身式、分身式；规格：160、165、170、175、180、185、190 Model: one-piece, two-piece; Specification: 160, 165, 170, 175, 180, 185、190
医用外科口罩 Surgical mask	系带型、挂耳型 lacing ,hanger
一次性使用医用橡胶检查手套 Disposable medical rubber inspection gloves	5、5.5、6、6.5、7、7.5、8、8.5、9、9.5
医用防护口罩 Medical protective mask	蝶型、拱形、长方形 Butterfly, arch, rectangle
一次性使用隔离衣 Disposable isolation clothing	型号：连身式、分身式、褂式；规格：160、165、170、180、185、190；褂式：110、115、120、130、140、150、160、170、180、190 Model: one-piece, two-piece, jacket; Specification: 160, 165, 170, 180, 185; Jacket style: 110, 115, 120, 130, 140, 150, 160, 170, 180、190

No.202001513(译)

河南省医疗器械检验所

Henan Province Medical Instrument Testing Institute

检验检测报告

Inspection Report

Product Name: Medical Protective Mask

Inspection Type: Emergency Inspection

Client: Henan Drug Administration

Henan Province Medical Instrument Testing Institute

Inspection Report

Report No: 202001513

Sample No: E20200354

sample name	Medical protective mask	Sample Q'ty	50pcs
	Sample sending ( ) sampling (✓)	Specification model	Arched L
Client	Henan Drug Administration	Production batch	20022101
Address	North Industrial Zone, Dingluan Town, Changyuan County	Production Date	21 Feb., 2020
Production company	Henan Gore Medical Instruments Co., Ltd.	Product No	/
Tested Company	Henan Gore Medical Instruments Co., Ltd.	Expiry date	20 Feb., 2022
Sampling Company	/	Inspection type	Emergency inspection
uantity in stock	/	Sample status	normal
Sampling date	/	Sample collection date	2020.03.17
Sampling location	/	Inspection location	Laboratory of this inspection institute
Sample number	/	Inspection date	2020.03.17-2020.03.25
Test items	Some items		
Test Standard	GB 19083-2010《*Technical requirements for medical protective masks*》		
Test results	The inspected items meet requirements of GB 19083-2010《Technical Requirements for Medical Protective Masks》 Date of issue: March 26, 2020		
Remarks	In the report, "————"Indicates that this item is not applicabl; In the report, " / "Indicates that this item is blank or non-test.		

Approved by: 李 Checked by: 闫钧

Inspector: 邵燕娜 何敬翰

Henan Province Medical Instrument Testing Institute

Inspection Report

Sample No: E20200354

Medical protective mask				
Test items	Standard Terms	standard requirement	test result	conclusion
Nose clip	4.2.1	Nose clip should be on the mask	Meet requirements	qualified
	4.2.2	Nose clips should be adjustable	Meet requirements	qualified
Mask belt	4.3.1	Mask belt should be easy to adjust	Meet requirements	qualified
	4.3.2	There should be sufficient strength to fix the position of the mask. The breaking strength of the connection point between mask belt and mask body should not be less than 10N.	Meet requirements	qualified
Filtration efficiency	4.4	At flow rate of 85 L / min, non-oily particles filtration efficiency should meet requirements of Table 1. (95%)	Before temperature pretreatment Mini: 97%, after temperature pretreatment mini: 98%	qualified
Synthetic blood penetration	4.6	Spray 2mL of Synthetic blood at pressure 10.7kPa (80mmHg) to the mask, should be no penetration to inner side of mask.	Meet the requirements	qualified
Microbiological index	4.8.1	Masks should meet the requirements of microbiological indicators in GB15979-2002, see Table 2	Bacteria< "20cfu/g, fungus <20 / g, coliform bacteria, Staphylococcus aureus, P. aeruginosa Bacteria and hemolytic streptococci were not detected.	qualified
Leakproofness	4.12	The mask design should provide good leakproofness, and the total fit factors of the mask should be no less than 100	Meet requirements	qualified
Note: Blank				

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检测
TESTING
CNAS L10118

国检检测
CHINA COMPONENTS TEST

Test Report

（2020） WSZ FHL NO.W381

Product Name Filtering half mask

Client Henan Gore Medical Instruments Co., Ltd.

Manufacturer Henan Gore Medical Instruments Co., Ltd.

Test Type Entrusted inspection

江苏国健检测技术有限公司
检验专用章

Jiangsu Guojian Testing Technology Co., Ltd.

Test Report

[2020] WSZ FHL NO.5420

Product name	Filtering half mask	Specification	—
		Brand	—
Client/Add/Tel	Henan Gore Medical Instruments Co., Ltd/The North Industrial Area of Ding Luan, Changyuan County, 453412 Henan, China		
Manufacturer/ Add/Tel	Henan Gore Medical Instruments Co., Ltd/The North Industrial Area of Ding Luan, Changyuan County, 453412 Henan, China		
Sample grade	FFP2	Sample number	GW0381-2020
Sample quantity	110 pcs	Receiving date of sample	11/05/2020
Test type	Entrusted inspection	Article number/Batch number/Style number	—
Test date	16/05/2020~03/06/2020	Testing sites	Testing room
Sample state	Meeting the requirements of testing	Sample description	—
Test standard(s)	EN 149:2001+A1:2009 Respiratory protective devices-Filtering half masks to protect against particles- Requirements,testing, marking		
Test items	Visual inspection, practical performance, finish of parts, compatibility with skin, flammability, carbon dioxide content of the inhalation air, material, head harness, field of vision, penetration of filter material, breathing resistance, total inward leakage		
Test conclusion	The sample upon testing, the test items meet the requirements of the EN 149:2001+A1:2009 standard. The detail of test results see on Pages 2-5. Issue date: 16/06/2020		
Note	For the entrusted sample test, the technical responsibilities are undertaken for the test results of the supplied samples only. 		

Approver: 苏 Reviewer: Chief Tester:

Test Report

[2020] WSZ FHL NO.5420 Page 2 of 5

S.No.	Test item		Unit	Technical requirements	Test result		Single item decision
1	Visual inspection	Packaging	—	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.	Packaging withstands mechanical damage and contamination.		Qualified
		Material	—	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.	Materials withstand handling and wear.		
2	Practical performance	Head harness comfort	—	Head harness should be comfort.	Sample 1 has the feeling of comfortable wearing		Qualified
					Sample 2 has the feeling of comfortable wearing		
		Security of fastenings	—	Fastenings are safe and reliable	Sample 1: All fastenings are firm.		
					Sample 2: All fastenings are firm		
		Field of vision	—	Field of vision is acceptable	Sample 1: Having a wider visual field		
					Sample 2: Having a wider visual field		
3	Finish of parts		—	Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	Parts of the device have no sharp edges and burrs		Qualified
4	Compatibility with skin		—	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.	A.R.	5 pcs all don't cause irritation	Qualified
					T.C.	5 pcs all don't cause irritation	
5	Flammability		—	When tested,the particle filtering half mask shall not burn or not to continue to burn for more than 5s after removal from the flame.	A.R.	The Sample is burning. Burning time:0.1s	Qualified
						The Sample is burning. Burning time:0.1s	
					T.C.	The Sample is burning. Burning time:0.1s	
						The Sample is burning. Burning time:0.1s	

Test Report

[2020] WSZ FHL NO.5420 Page 3 of 5

S.No.	Test item		Unit	Technical requirements	Test result				Single item decision
6	Carbon dioxide content of the inhalation air		—	≤1.0% (by volume)	Sample 1	0.7110%			Qualified
					Sample 2	0.7120%			
					Sample 3	0.7130%			
					Report value	0.71%			
7	Material		—	After undergoing S.W., none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.	Sample 1: neither facepiece nor straps have mechanical failure				Qualified
					Sample 2: neither facepiece nor straps have mechanical failure				
					Sample 3: neither facepiece nor straps have mechanical failure				
				After undergoing S.W. and T.C. , none of the particle filtering half masks shall not collapse.	Sample 1: no collapse				
					Sample 2 : no collapse				
					Sample 3: no collapse				
8	Head harness		—	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	A.R.	All of 5 pieces particle filtering half mask meet the requirements			Qualified
					T.C.	All of 5 pieces particle filtering half mask meet the requirements			
9	Field of vision		—	The field of vision is acceptable if determined so in practical performance tests.	The two samples both have a wider visual field				Qualified
10	Penetration of filter material	Sodium chloride	—	≤6%	A.R.	0.1%	0.1%	0.1%	Qualified
					S.W.	0.2%	0.1%	0.2%	
					M.S+T.C.	0.3%	0.4%	0.4%	
		Paraffin oil	—	≤6%	A.R.	0.6%	0.7%	0.6%	Qualified
					S.W.	0.7%	0.6%	0.7%	
					M.S+T.C.	1.8%	1.9%	1.8%	

Test Report

[2020] WSZ FHL NO.5420 Page 4 of 5

S.No	Test item		Unit	Technical requirements	Test result						Single item decision
					Exercises	Facing directly ahead	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side	
11	Breathing resistance	Inhalation 30 L/min	mbar	≤0.7	A.R.	0.3	0.4	0.3	0.4	0.3	Qualified
						0.5	0.5	0.5	0.4	0.4	
						0.4	0.5	0.4	0.5	0.4	
					S.W.	0.4	0.4	0.4	0.5	0.5	
						0.5	0.4	0.5	0.4	0.5	
						0.5	0.5	0.5	0.5	0.5	
					T.C.	0.4	0.5	0.5	0.4	0.4	
						0.4	0.4	0.5	0.5	0.4	
						0.5	0.5	0.4	0.4	0.4	
		Inhalation 95 L/min		≤2.4	A.R.	2.1	2.2	2.1	2.2	2.2	Qualified
						2.2	2.1	2.2	2.1	2.1	
						2.2	2.1	2.1	2.2	2.2	
					S.W.	2.1	2.2	2.2	2.1	2.1	
						2.2	2.2	2.1	2.1	2.2	
						2.2	2.2	2.2	2.1	2.1	
					T.C.	2.2	2.1	2.2	2.1	2.2	
						2.2	2.2	2.2	2.1	2.1	
						2.2	2.2	2.2	2.2	2.1	
		Exhalation 160 L/min		≤3.0	A.R.	2.7	2.8	2.7	2.8	2.7	Qualified
						2.8	2.8	2.7	2.7	2.7	
						2.8	2.8	2.7	2.7	2.8	
					S.W.	2.8	2.8	2.7	2.7	2.8	
						2.8	2.7	2.7	2.8	2.8	
						2.7	2.8	2.8	2.7	2.7	
					T.C.	2.8	2.8	2.7	2.7	2.7	
						2.7	2.8	2.7	2.8	2.7	
						2.8	2.8	2.7	2.7	2.8	

Test Report

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S.No.	Test item	Unit	Technical requirements	Test result							Single ite decisio
				Exercises		E1 (%)	E2 (%)	E3 (%)	E4 (%)	E5 (%)	TIL (%)	
12	Total inward leakage	—	At least 46 out of the 50 individual exercise results shall be not greater than 11%; And in addition,at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than 8%.	A.R.	1#	6.0	6.5	6.7	6.8	6.2	6.4	Qualifie
					2#	6.2	6.9	7.3	7.1	6.6	6.8	
					3#	5.7	6.6	6.5	6.3	5.9	6.2	
					4#	6.3	7.1	7.2	7.0	6.5	6.8	
					5#	6.6	7.2	7.2	7.0	6.6	6.9	
				T.C.	6#	6.5	6.8	7.2	7.2	6.5	6.8	
					7#	5.9	6.3	6.4	6.7	6.0	6.3	
					8#	6.3	6.8	6.9	7.2	6.5	6.7	
					9#	6.6	7.7	7.6	7.6	7.0	7.3	
					10#	6.8	7.8	7.6	7.5	7.1	7.4	
Note												

The end


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