„TENRY gehört zu den am schnellsten wachsenden und innovative medizinische Firmen in China und wird NIEMALS Kompromisse bei der Produktqualität eingehen!”

TENRY 腾瑞制药

NEANDER T&C
BRIDGING EURASIA

TENRY 腾瑞制药

FFP2 MASK
NON MEDICAL
EN149:2001+A1:2009

TENRY 腾瑞制药

NEANDER T&C
BRIDGING EURASIA

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TENRY 腾瑞制药

TENRY 腾瑞制药

1 PCS

TENRY 腾瑞制药

NEANDER T&C
BRIDGING EURASIA

TENRY 腾瑞制药

1 PCS

NEANDER T&C
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TENRY 腾瑞制药

TENRY 腾瑞制药

6 PCS

NEANDER T&C
BRIDGING EURASIA

TENRY 腾瑞制药

TENRY 腾瑞制药

20 PCS

TENRY 腾瑞制药

TENRY
FALTBARE PARTIKEL ATEMSCHUTZMASKE
Particulate Respirator Protective Mask
Standard: EN 149:2001+A1:2009
Klasse:FFP2 NR
CE 0598
Nicht medizinisch
TENRY
腾瑞制药
FFP2 NR
STANDARD: EN 149:2001+A1:2009
Faltbare Partikel Atemschutzmaske
Particulate Respirator Protective Mask
CE 0598
6 Stück
合格证
CERTIFICATION
Made in China
FALTBARE PARTIKEL ATEMSCHUTZMASKE
PARTICULATE RESPIRATOR PROTECTIVE
Klasse: FFP2 NR
NICHT MEDIZINISCH
STANDARD:EN 149:2001+A1:2009
1 Stück
TENRY TR-ZD01
EN 149:2001+A1:2009
FFP2 NR
CE 0598

Ⓐ Hidden nose clip

Easy to adjust fitting

Ⓑ Strong spot welding

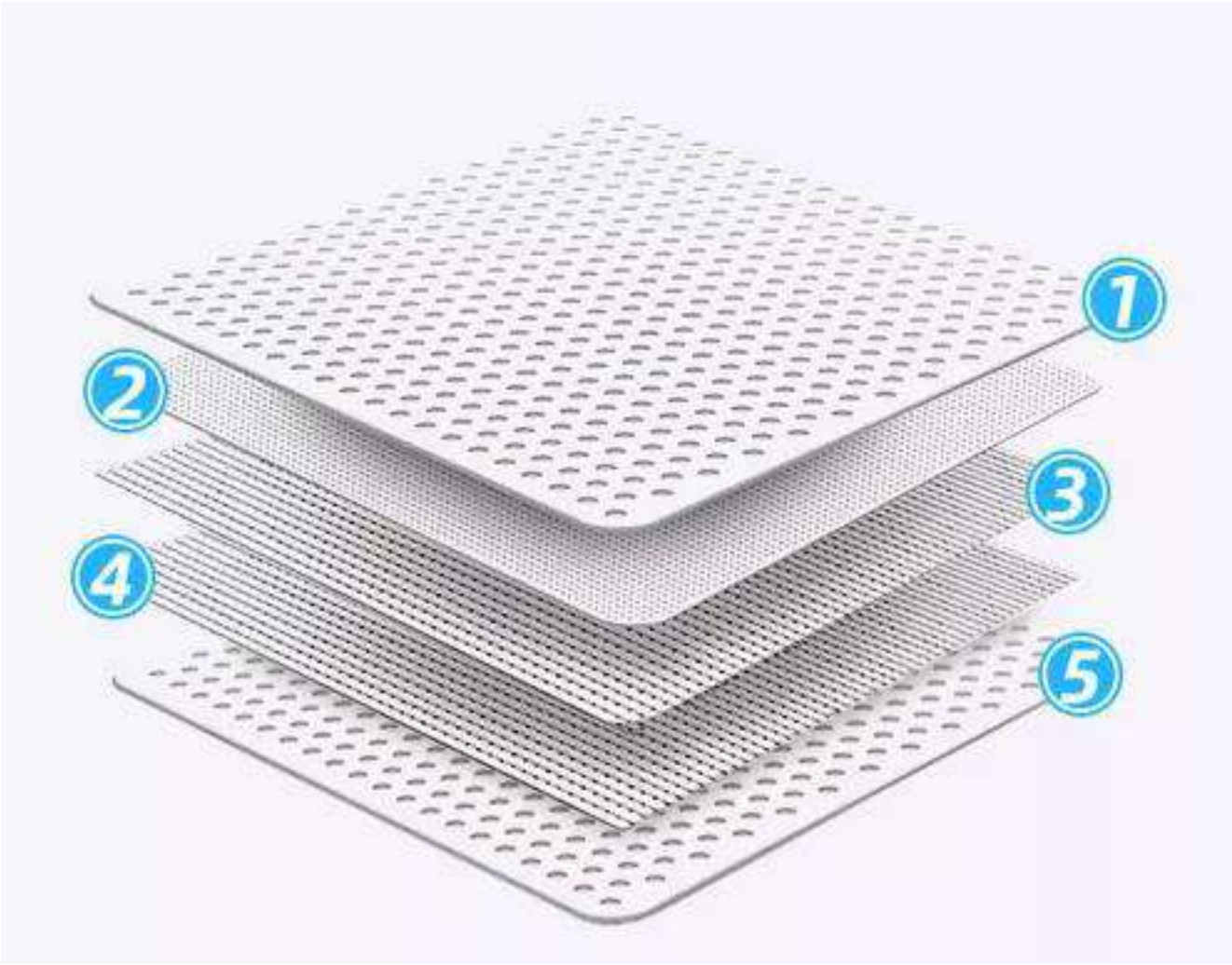
Ultrasonic welding to preventthe earloop falling off

Ⓒ Wider knit earloop

Reduce strangulationand improve comfort

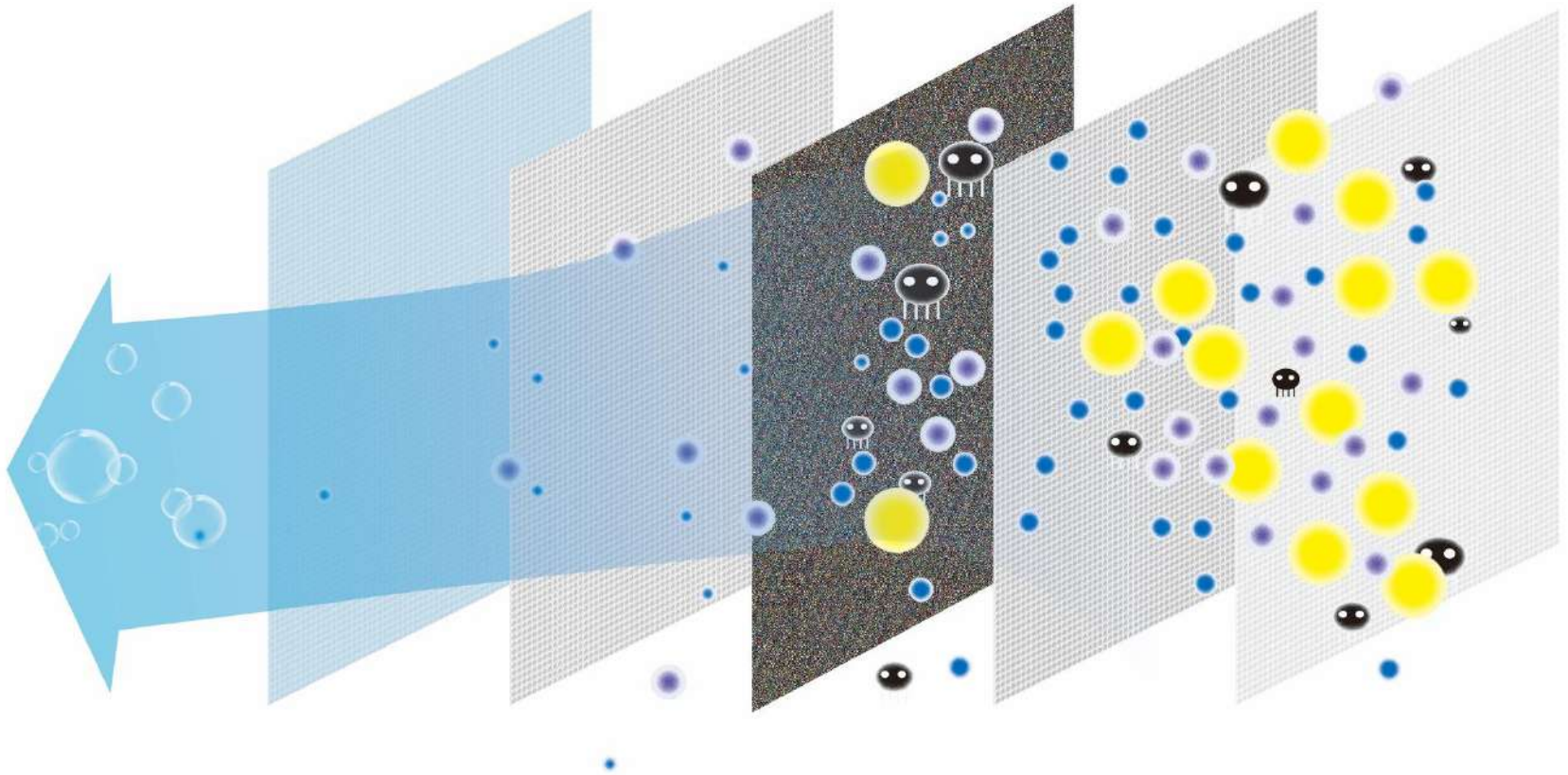
Ⓓ PP Hook

Easy to adjust comfort



5-Ply Protection System

01. PP Non-woven Fabric
02. Hot Air Cotton
03. Meltblown
04. Meltblown
05. PP Non-woven Fabric



High filtration efficiency

Effectively block 0.3 μm particles

Oil filtration efficiency higher than 95%

Low respiratory resistance

Shanghai Tenry Pharmaceutical Co.,Ltd
No.151, Lane 1236, Xinsiping Road, Situan Town,
Fengxian District, Shanghai, China.

EU-KONFORMITÄTSERKLÄRUNG

Diese Konformitätserklärung wurde unter der alleinigen Verantwortung des Herstellers
Shanghai Tenry Pharmaceutical Co.,Ltd.
No.151, Lane 1236, Xinsiping Road, Situan Town, Fengxian District, Shanghai, China.

ausgestellt.
EG-Vertreter: Neander Trade & Consulting GmbH
Berliner Allee 59 ,40212 Düsseldorf ,Germany

Hiermit wird erklärt, dass die folgende persönliche Schutzausrüstung (PSA)
Produktbeschreibung: TENRY FALTBARE PARTIKEL ATEMSCEHUTZMASKE
Produktmodell (e): TR-ZD01 FFP2 NR ohne Ventil

den Bestimmungen der folgenden europäischen Verordnung entspricht:
PSA-Verordnung (Persönliche Schutzausrüstung)

Das Modell entspricht den Bestimmungen der Verordnung (EU) 2016/425, PSA zur Verwendung durch Angehörige der Gesundheitsberufe gemäß der Empfehlung der Kommission 2020/403 und der Nationalen Norm zur Umsetzung der harmonisierten europäischen Normnummer (n):

EN 149: 2001 + A1: 2009

und ist identisch mit der PSA, die Gegenstand einer EU-Typprüfung ist (Modul B der Verordnung (EU) 2016/425), auf die auf der Zertifikatsnummer verwiesen wird:

Zertifikat Nr.: FI20/967030 (Issue Date: 09/17/2020)

herausgegeben von **SGS FIMKO OY**
Takomotie 8, FI-00380,Helsinki, Finland(Notified Body No.0598).

Shanghai , China, 11/01/2020

Shusheng Wang Shusheng Wang
(Nachname name)
Plant Leader
Shanghai Tenry Pharmaceutical Co.,Ltd.

Shanghai Tenry Pharmaceutical Co.,Ltd
No.151, Lane 1236, Xinsiping Road, Situan Town, Fengxian District, Shanghai， China.

EU DECLARATION OF CONFORMITY

This Declaration of Conformity, issued under the sole responsibility of the manufacturer

Shanghai Tenry Pharmaceutical Co.,Ltd.
No.151, Lane 1236, Xinsiping Road, Situan Town, Fengxian District, Shanghai, China.
EC Representative: Neander Trade & Consulting GmbH
Berliner Allee 59 , 40212 Düsseldorf ,Germany

hereby declaring the following Personal Protective Equipment (PPE)
Product Description: TENRY Particulate Respirator Protective Mask
Product Model/s: TR-ZD01 FFP2 NR without valve

is/are in conformity with the provisions of the following European Regulation
PPE (Personal Protective Equipment) Regulation

The model is/are in conformity with the provisions of Regulation (EU) 2016/425, PPE for use by healthcare professionals as per Commission recommendation 2020/403, and with the National Standard transposing the harmonised European Standard Number(s):

EN 149: 2001+A1:2009

and is/are identical to the PPE which is/are the subject of EU type examination (Module B of Regulation (EU) 2016/425) referenced on the certificate number:

Certificate No.: FI20/967030 (Issue Date: 09/17/2020)

issued by
SGS FIMKO OY
Takomotie 8, FI-00380,Helsinki, Finland(Notified Body No. 0598).

Shanghai , China, 11/01/2020

Shusheng Wang Shusheng Wang
(Surname name)
Plant Leader
Shanghai Tenry Pharmaceutical Co.,Ltd.

dermatest®
RESEARCH INSTITUTE FOR RELIABLE RESULTS
TAKING YOUR SUCCESS PERSONALLY

Dermatest® GmbH Engelstr. 37 48143 Münster

Shanghai Tenry Pharmaceutical Co.,Ltd
No.151, Lane 1236, Xinsiping Road
Situan Town, Fengxian District
Shanghai, China

Münster, 05.02.2021

Zertifikat

über das Produkt

TENRY FFP2 NR Maske

Dermatologische Prüfungen am Menschen 2021

Studiennummer: 2101226612

Die von mir unter fachärztlicher Kontrolle durchgeführten dermatologischen Prüfungen Ihres o. g. Produktes bestand das Produkt mit

„sehr gut“

Bei dem genannten Präparat traten im Epikutantest nach internationalen Richtlinien keine toxisch-irritativen Unverträglichkeitsreaktionen auf.
Das Präparat kann deshalb mit dermatologisch getestet deklariert werden.

Dr. med. Gerrit Schlippe
Facharzt für Dermatologie,
Venerologie

Dermatest GmbH
Engelstrasse 37
48143 Münster Germany
dermatest®
Fon: +49-(0)251-4816370
Fax: +49-(0)251-48163766
www.dermatest.de

Dr. med. Werner Voss
Facharzt für Dermatologie,
Venerologie, Allergologie,
Phlebologie und Umweltmedizin

TÜVRheinland ZERTIFIZIERT Management System ISO 9001:2015

Dermatest® GmbH
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Germany

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Geschäftsführer

Amtsgericht Münster HRB 1348

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Deutsche
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D-ZM-11321-01-00

Product Service

Certificate

No. Q6 108661 0001 Rev. 00

Holder of Certificate: **Shanghai Tenry Pharmaceutical Co., Ltd**
No.151, Lane 1236, Xinsiping Road, Situan Town
Fengxian District
201413 Shanghai
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Shanghai Tenry Pharmaceutical Co., Ltd
No.151, Lane 1236, Xinsiping Road, Situan Town, Fengxian District, 201413 Shanghai, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Production and Distribution of Medical Surgical Mask, Medical Respirator**

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.: SH20170501

Valid from: 2020-08-11
Valid until: 2023-08-10

Date, 2020-08-11

Christoph Dicks
Head of Certification/Notified Body

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

TÜV®

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

Certificate FI20/967030

Shanghai Tenry Pharmaceutical Co., Ltd

No.151, Lane.1236, Xinsiping Road, Situan Town, Fengxian District, Shanghai, 201413, P.R.China

It is certified that the manufacturer's technical file and the PPE product detailed on page 2 have been assessed and found to be in accordance with

Regulation (EU) 2016/425

Module B, EU type-examination

This certificate is valid from 27 October 2020 until 27 October 2025
1. Certified since 27 October 2020

Authorised by

FINAS
Finnish Accreditation Service
S003 (EN ISO/IEC 17065)

SGS FIMKO OY, Notified Body 0598
Takomotie 8, FI-00380, Helsinki, Finland
t +358 9 696 361 f +358 9 692 5474 www.sgs.com

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Shanghai Tenry Pharmaceutical Co., Ltd

Regulation (EU) 2016/425

Module B, EU type-examination

Issue 1

PPE Product

TENRY (logo) TR-ZD01 particle filtering half mask, consisting of a white five layer (polypropylene/ polypropylene/ polypropylene / polypropylene / polypropylene) disposable face mask, with nose clip, nylon/spandex ear loop and adjustable hook.

It is certified that the manufacturer's technical file and the above mentioned PPE have been assessed and found to meet the applicable Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 Personal Protective Equipment

The following have been applied:

EN 149:2001+A1:2009 (Respiratory protective devices - filtering half masks to protect against particles) device classification: FFP2 NR.

FINAS
Finnish Accreditation Service
S003 (EN ISO/IEC 17065)

This certificate is issued on the strict condition that appropriate checks on manufactured PPE, as detailed in Article 19 (c) of the Regulation are implemented and maintained while the model is in production

Certification is based on technical file reference:

Particulate Respirator Protective Mask /TR-ZD01,

version 1, dated: 2020-09-17.

SGS Reference Number UK/CRS 242225.

This certificate remains the property of SGS Fimko Oy to whom it must be returned on request

Test Report **SL52025246208001TX** **Date:June 08,2020**

SHANGHAI TENRY PHARMACEUTICAL CO., LTD.
NO.151. LANE 1236 XINSIPING ROAD. SITUAN TOWN, FENGXIAN DISTRICT. SHANGHAI, CHINA

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

Sample Description	:	(A)Particulate Respirator Protective Mask
Claimed Level	:	FFP2
Style No.	:	TR-ZD01
Composition	:	(A)The product is composed of mask body, nose bridge clip and mask belt.
Sample Color	:	(A)White
Manufacturer	:	SHANGHAI TENRY PHARMACEUTICAL CO., LTD.
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Apr 29, 2020
Testing Period	:	May 07, 2020 - Jun 08, 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).

Conclusion:

Sample No.	Recommendation Level
(A)	FFP2 NR

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

Sara Guo (Account Executive)

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Test Result

Respiratory Protective Devices — Filtering Half Masks to Protect against Particles — Requirements, Testing, Marking
(EN 149:2001+A1:2009)

Clause 7.4 Packaging
(EN 149:2001+A1:2009 Clause 8.2)

Test Requirement	Results	Comment
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.	Comply	Pass

Clause 7.5 Material
(EN 149:2001+A1:2009, Clause 8.2 & 8.3.1 & 8.3.2)

Test Requirement	Results	Comment
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.	Comply	Pass
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.	Comply	
When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	Comply	
Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Comply	

Clause 7.6 Cleaning and Disinfecting
(EN 149:2001+A1:2009, Clause 8.4 & 8.5 & 8.11)

Test Requirement	Results	Comment
If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer. With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.	Not applicable (Not designed to be re-usable)	N.A.

Clause 7.7 Practical Performance
(EN 149:2001+A1:2009, Clause 8.4)

Test Requirement	Results	Comment
The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard.	No imperfections	Pass

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Clause 7.8 Finish of Parts
(EN 149:2001+A1:2009, Clause 8.2)

Test Requirement	Results	Comment
Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	No sharp edges or burrs	Pass

Clause 7.9.1 Total Inward Leakage
(EN 149:2001+A1:2009, Clause 8.5)

Test Requirement	Results	Comment
The total inward leakage consists of three components: face seal leakage, exhalation value leakage(if exhalation value fitted) and filter penetration. 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	Detail refer to Appendix 1	Meet FFP1 Meet FFP2

Appendix 1: Summarization of Test Data

Inward Leakage Test Data

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head up/down(%)	Talk(%)	Walk(%)	Mean(%)
Zhou	1	A.R.	6.02	5.91	5.94	6.07	6.14	6.02
Luo	2	A.R.	8.24	6.18	6.65	8.23	6.44	7.15
Lu	3	A.R.	4.78	7.41	6.73	5.27	6.28	6.09
Wang	4	A.R.	5.55	6.63	4.63	4.35	5.51	5.33
Bao	5	A.R.	6.91	6.33	7.29	7.50	7.82	7.17
Ding	6	T.C.	6.29	6.41	4.21	5.22	5.58	5.54
Li	7	T.C.	8.33	7.74	7.23	8.62	6.45	7.67
Chen	8	T.C.	6.13	5.46	5.89	5.87	4.82	5.63
Song	9	T.C.	7.39	6.69	6.62	5.41	5.68	6.36
Ye	10	T.C.	6.38	8.31	7.97	7.34	7.65	7.53

Facial Dimension(mm)

Subject	Face length	Face Width	Face Depth	Mouth Width
Chen	125	150	120	58
Lu	115	132	107	48
Zhou	115	135	106	52
Li	125	130	107	46
Luo	125	136	100	43
Zheng	128	140	112	55
Wang	120	147	103	48
Song	120	140	100	50
Bao	130	134	104	50
Ding	134	150	110	52

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Liu	120	135	117	50
Ye	126	137	105	52

Clause 7.9.2 Penetration of Filter Material
(EN 149:2001+A1:2009, Clause 8.11 & EN 13274-7:2019)

Test Requirement	Results	Comment
The penetration of the filter of the particle filtering half mask shall meet the requirements of the following table.	Detail refer to Appendix 2	Pass

Classification	Maximum penetration of test aerosol	
	Sodium chloride test 95 l/min % max.	Paraffin oil test 95 l/min % max.
FFP1	20	20
FFP2	6	6
FFP3	1	1

Appendix 2: Summarization of Test Data

Penetration of filter material

Aerosol	Condition	Sample No.	Penetration (%)
Sodium chloride test	As received	1	0.379
		2	0.415
		3	0.402
	Simulated wearing treatment	4	0.467
		5	0.392
		6	0.452
	Mechanical strength +Temperature conditioned	7	0.705
		8	0.651
		9	0.732
Paraffin oil test	As received	10	3.273
		11	3.867
		12	3.256
	Simulated wearing treatment	13	3.558
		14	3.742
		15	2.979
	Mechanical strength +Temperature conditioned	16	5.272
		17	5.407
		18	4.995
Flow conditioning : Single filter: 95.0 L/min			

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Clause 7.10 Compatibility with Skin
(EN 149:2001+A1:2009, Clause 8.4 & 8.5)

Test Requirement	Results	Comment
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.	No irritation or any other adverse effect to health	Pass

Clause 7.11 Flammability

(EN 149:2001+A1:2009, Clause 8.6)

Test Requirement	Results	Comment
The material used shall not present a danger for the wearer and shall not be of highly flammable nature 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.	Detail refer to Appendix 3	Pass

Appendix 3: Summarization of Test Data

Flammability

Condition	Sample No.	Result
As received	1	NIL
	2	NIL
Temperature conditioned	3	NIL
	4	NIL

Clause 7.12 Carbon Dioxide Content of The Inhalation Air
(EN 149:2001+A1:2009, Clause 8.7)

Test Requirement	Results	Comment
The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume)	Detail refer to Appendix 4	Pass

Appendix 4: Summarization of Test Data

Carbon Dioxide Content of The Inhalation Air

Condition	Sample No.	Result(%)	
As received	1	0.5953	Mean value:0.59
	2	0.5837	
	3	0.5946	

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Clause 7.13 Head Harness
(EN 149:2001+A1:2009, Clause 8.4 & 8.5)

Test Requirement	Results	Comment
The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.	Comply	Pass
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.	Comply	

Clause 7.14 Field of Vision
(EN 149:2001+A1:2009, Clause 8.4)

Test Requirement	Results	Comment
The field of vision is acceptable if determined so in practical performance tests.	Comply	Pass

Clause 7.15 Exhalation Valve(s)
(EN 149:2001+A1:2009, Clause 8.2 & 8.9.1 & 8.3.4 & 8.8)

Test Requirement	Results	Comment
(a) A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.	Not applicable due to No exhalation valve	N.A.
(b) 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.	Not applicable due to No exhalation valve	
(c) 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.	Not applicable due to No exhalation valve	
(d) When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10N applied for 10 s.	Not applicable due to No exhalation valve	

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Clause 7.16 Breathing Resistance

(EN 149:2001+A1:2009, Clause 8.9)

Test Requirement	Results	Comment
The penetration of the filter of the particle filtering half mask shall meet the requirements of the following table.	Detail refer to Appendix 5	Pass

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

Appendix 5: Summarization of Test Data

Breathing resistance (mbar)

	Flow rate(l/min)		1					2					3				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
As received	Inhalation	30	0.2	0.3	0.2	0.3	0.3	0.3	0.2	0.3	0.2	0.3	0.2	0.3	0.2	0.2	0.3
		95	0.8	0.9	0.8	0.9	0.9	1.0	1.0	1.0	0.8	0.8	0.9	0.9	0.9	0.9	0.8
	Exhalation	160	2.0	2.2	2.2	2.2	2.1	2.2.	2.2	2.2	2.1	2.2	2.2	2.1	2.2	2.0	2.0
	Flow rate(l/min)		4					5					6				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
Simulated wearing treatment	Inhalation	30	0.3	0.3	0.3	0.2	0.3	0.3	0.4	0.4	0.4	0.3	0.3	0.4	0.4	0.3	0.3
		95	0.8	1.0	0.9	0.9	1.0	0.8	0.8	0.8	0.8	0.9	1.0	1.0	0.9	0.8	0.9
	Exhalation	160	2.0	2.2	2.2	2.1	2.2	2.3	2.3	2.3	2.2	2.3	2.3	2.2	2.2	2.0	2.1
	Flow rate(l/min)		7					8					9				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
Temperature conditioned	Inhalation	30	0.3	0.2	0.2	0.3	0.2	0.3	0.2	0.2	0.3	0.2	0.2	0.2	0.3	0.3	0.2
		95	0.8	0.8	1.0	0.9	0.9	1.0	0.8	0.8	0.9	1.0	1.0	0.9	0.8	0.9	0.9
	Exhalation	160	2.0	2.1	2.1	2.1	2.0	2.0	2.0	2.1	2.1	2.2	2.2	2.3	2.2	2.2	2.0

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

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Clause 7.17 Clogging
(EN 149:2001+A1:2009, Clause 8.9 & 8.10)

Test Requirement	Results	Comment
Clause 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	Optional for single shift device only	N.A.
Clause 7.17.3 Penetration of filter material All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement shall also meet the requirements.	Optional for single shift device only	N.A.

Classification	Maximum penetration of test aerosol	
	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
	%	%
	max.	max.
FFP1	20	20
FFP2	6	6
FFP3	1	1

Clause 7.18 Demountable Parts
(EN 149:2001+A1:2009, Clause 8.2)

Test Requirement	Results	Comment
All demountable parts (if fitted) shall be readily connected and secured, where possible by hand	No demountable parts	N.A.

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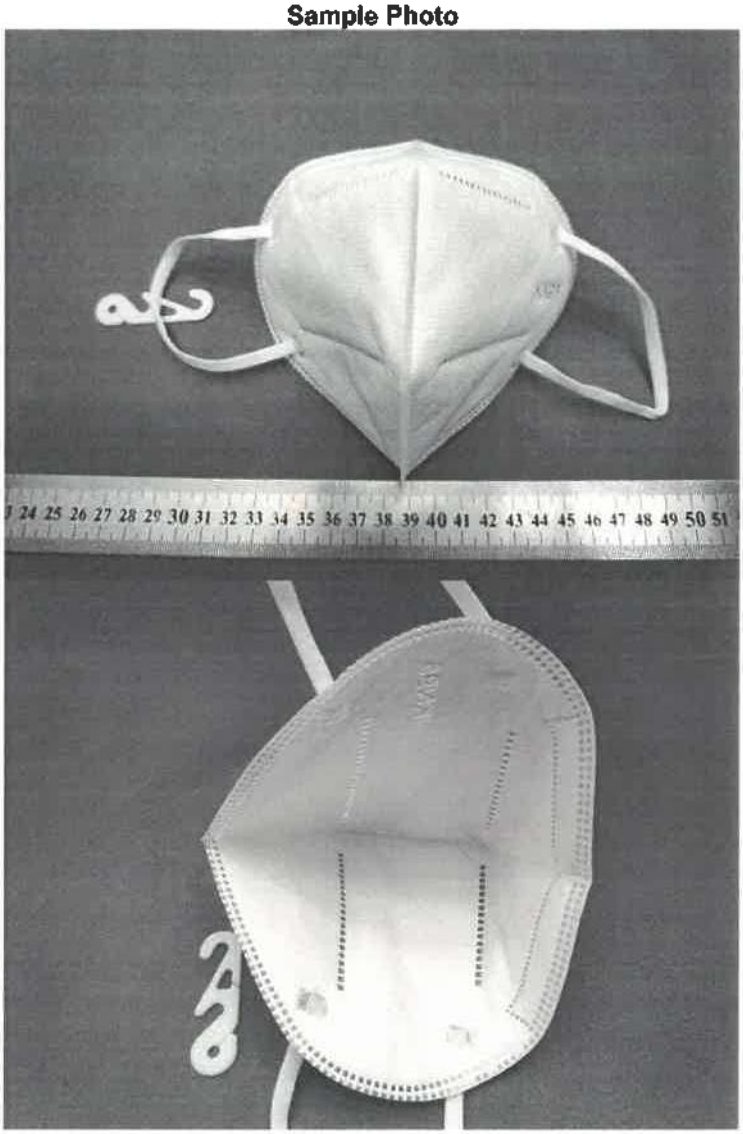
Sample Photo



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.

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