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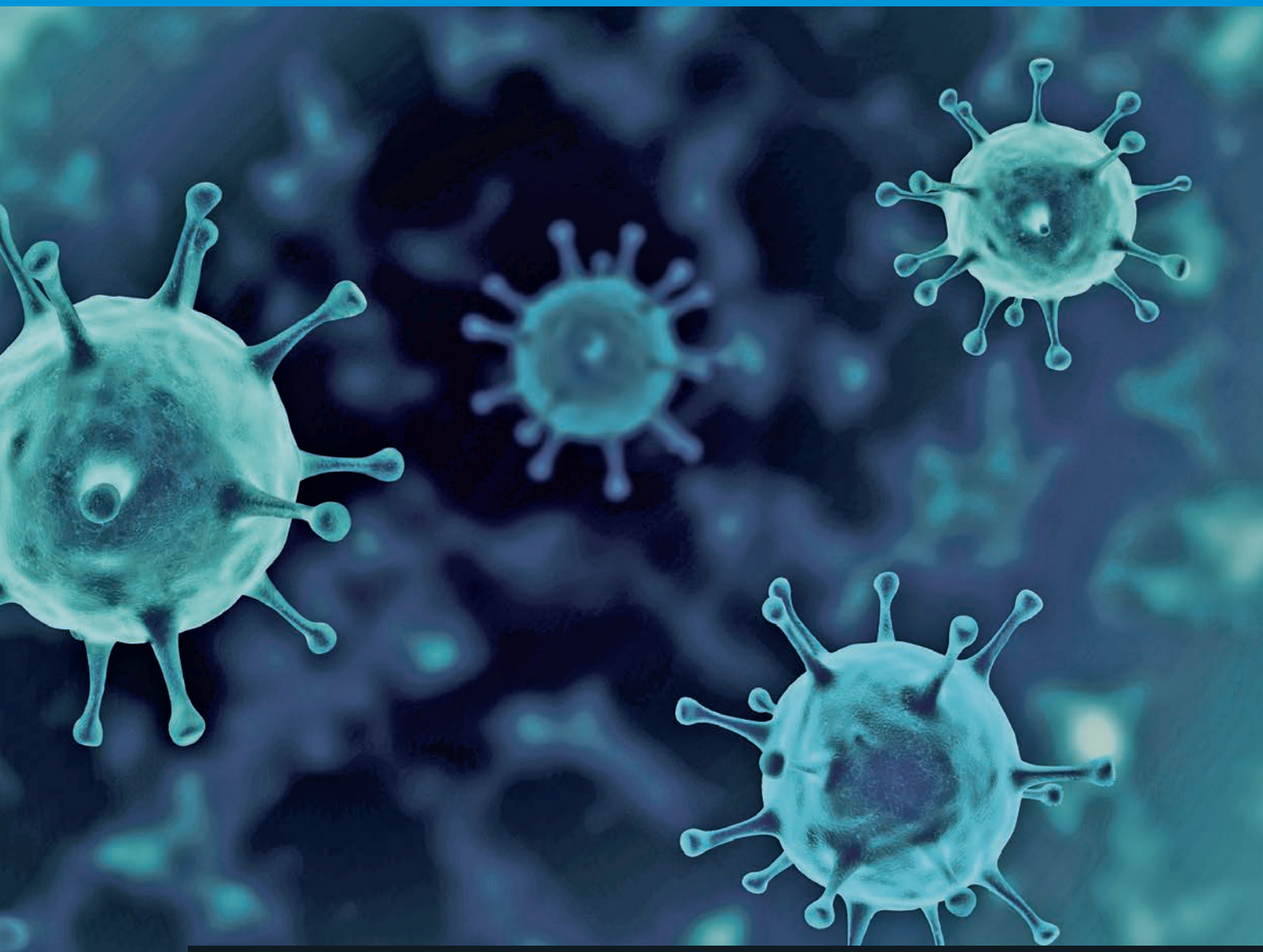


FFP2 **FACE MASKS** & SARS-COV-2 **ANTIGEN RAPID TEST**

corona@rutronik.com

KRÖNER
MEDIZINTECHNIK
Technik und Leidenschaft

LEPU MEDICAL

KRÖNER MEDIZINTECHNIK Technik und Leidenschaft

SARS-CoV-2 Antigen Rapid Test

The Rapid Antigen Test for Novel Coronavirus (SARS-Cov-2) is an in vitro diagnostic test for the qualitative detection of novel coronavirus antigens in nasopharyngeal swabs and oropharyngeal swabs using the rapid immunochromatographic method. Identification is based on the monoclonal antibodies specific for the novel coronavirus antigen. This product is intended for professional use in the laboratory and at the point of care.

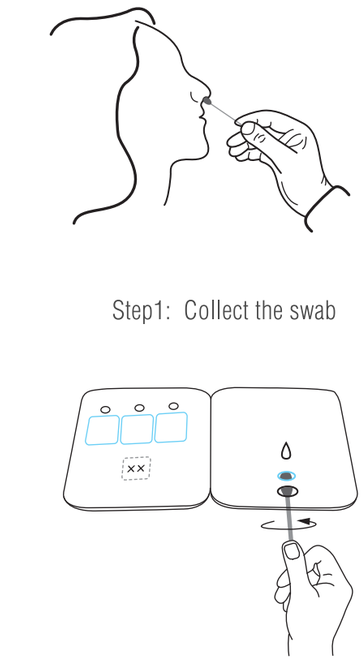
available at Rutronik24.com

Features

- High clinical sensitivity (92.00%) and specificity (99.26%)
- Rapid and reliable test results in 15 minutes
- Can be performed with nasal samples
- All test components are included
- Tested by Paul-Ehrlich-Institute
- Officially listed by the federal institute for pharmaceuticals and medical products

PU 25

Test carrier, package insert, sterilised swab, nozzle with filter and sample collection buffer



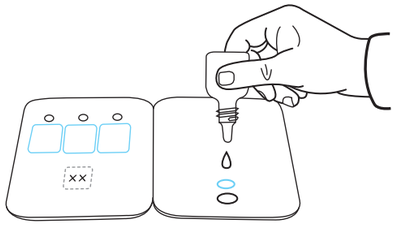
Airport *Hotel* *Hospital* *Station* *Company* *Personal*

The current test card is based on the specific antibody-antigen reaction and immunoanalysis technology. The test card contains colloidal gold labeled SARS-CoV-2 N protein monoclonal antibody which is pre-coated on the combination pad, matched SARS-CoV-2 N protein monoclonal antibody immobilized on the Test area and corresponding antibody in the quality control area. During testing, the N protein in the sample combines with the colloidal gold labeled SARS-CoV-2 N protein monoclonal antibody which is pre-coated on the combination pad. The conjugates migrate upward under capillary effect, and subsequently captured by the N protein monoclonal antibody immobilized in the Test area. The higher the contents of N protein in the sample, the more the conjugates captures and the darker the color in the test area is. If there is no virus in the sample or the virus content is lower than the detection limit, then there is no color demonstrated in the test area. Regardless of the presence or absence of the virus in the sample, a purple stripe will appear in the quality control area. The purple stripe in the quality control area is a criterion for the judgment of whether or not there is enough sample and whether or not the chromatography procedure is normal.

Contact: **Rutronik Elektronische Bauelemente GmbH | Tilo Rollwa** Director Digital Marketing - Tel.: +49 7231 801 1540 | tilo.rollwa@rutronik.com
Stefanie Piller - Tel.: +49 7231 801 1542 | stefanie.piller@rutronik.com | **Nikolai Schnarz** - Tel.: +49 7231 801 1427 | nikolai.schnarz@rutronik.com

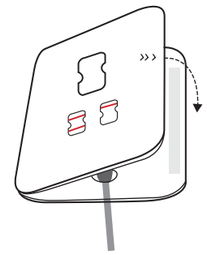
Operation steps

Step1: Collect the swab



Step2: Add 4 drops of buffer to hole A

Step3: Insert the sample through hole B to hole A, rotate the swab clockwise first and counterclockwise, twice each.



Step4: Peel off the adhesive, and fold the left side over, wait for 15 minutes.

Result Interpretation

Top line only

Both bottom line and top line

Bottom line only, or no line

LEPU MEDICAL

Document No.: CE-DOC-CG27
Rev.: 1/0

Declaration of Conformity

Manufacture Address:	Beijing Lepu Medical Technology Co., Ltd. Building 7-1 No.37 Chaoqian Road, Changping District, Beijing, 102200, P.R. China
European Representative:	Lepu Medical (Europe) Cooperatief U.A. Abe Lenstra Boulevard 36, 8448 JB, Heerenveen, The Netherlands
Product information:	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) Model: 1 test/kit; 5 tests/kit; 10 tests/kit; 25 tests/kit; 50 tests/kit
Classification:	Others (not in List A and List B)
Conformity Assessment Route:	Section 2 to 5 in annex III of IVDD 98/79/EC We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premise of the manufacturer.
General Applicable Directive:	DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on *in vitro* diagnostic medical devices
Standards Applied:	All applicable harmonized standards (published in the official journal of the European Communities on 25th March 2020). The applicable standards are listed in Annex 1.
Place, date of issue	Beijing, P.R. China, 3th, Sept., 2020
Signature of Management Representative	Zhao Chengyue

Beijing Lepu Medical Technology Co., Ltd.
Building 7-1 No.37 Chaoqian Road, Changping District, Beijing, 102200, P.R. China

CE

Annex 1

EN ISO 13485:2016 Medical devices – quality management systems - requirements for regulatory purposes
EN ISO 14971:2019 Medical devices – application of risk management to medical devices
EN ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041:2008+A1:2013 Information supplied by the manufacturer of medical devices
EN ISO 18113-1:2011 In vitro diagnostic medical devices – information supplied by the manufacturer (labelling) – Part 1: terms, definitions and general requirements
EN ISO 18113-2:2011 In vitro diagnostic medical devices – information supplied by the manufacturer (labelling) – Part 2: in vitro diagnostic reagents for professional use
EN ISO 23640:2015 In vitro diagnostic medical devices – evaluation of stability of in vitro diagnostic regents
EN 13612:2002/AC: 2002 Performance evaluation of in vitro diagnostic medical devices
IEC 62366-1:2015 Application of usability engineering to medical devices

FFP2 EN149:2001+A1:2009 SANOCARE+

KRÖNER MEDIZINTECHNIK Technik und Leidenschaft

Particle Filtering Face Mask

The **SANO**CARE+ FFP2 mask offers a comfortable fit thanks to the pleasantly soft inner fleece and extra-wide, tight-fitting ear straps. It meets all standards and certifications. The 5 layers offer optimal protection against fine dust and aerosols. The flexible nasal clip enables a good and firm fit.

Brand	**SANO**CARE+
Model #	FH-1
PU	20 pcs (single packaging)
Certification #	CE 0598
Tested according to norm	EN 149:2001+A1:2009
Filter	FFP2
Layers	5
Nasal clip	Yes
Material	54% Fleece | 24,5% Meltblown- Fleece 21,5% Hot-Air Cotton
Reusable	No

available at Rutronik24.com

RUTRONIK 24 next generation e-commerce

CE 0598

5 Layers

Contact: **Rutronik Elektronische Bauelemente GmbH | Tilo Rollwa** Director Digital Marketing - Tel.: +49 7231 801 15 40 | tilo.rollwa@rutronik.com
Stefanie Piller - Tel.: +49 7231 801 15 42 | stefanie.piller@rutronik.com | **Nikolai Schnarz** - Tel.: +49 7231 801 14 27 | nikolai.schnarz@rutronik.com

ANLEGEINSTRUKTION

1 Maske mit Hilfe der Bänder auffalten. Außenseite mit Aufdruck muss nach vorne zeigen, der Nasenbügel befindet sich oben.

2 Maske über Mund und Nase positionieren, beide Gummibänder hinter den Kopf führen und Schlaufen hinter den Ohren fixieren.

3 Den Nasenbügel mithilfe beider Hände durch leichten Druck an die Nasenkontur angleichen für einen bestmöglichen Dichtsitz.

4 Dichtsitz kontrollieren: Beide Hände um die Maske legen, ohne dass diese sich dabei bewegt, und kräftig ausatmen. Wenn Luft um Ihre Nase entweicht, drücken Sie den Bügel fester um Ihren Nasenrücken.

WARNUNGEN & HINWEISE

1 Die Warnungen & Hinweise müssen vor Verwendung der Maske gelesen und verstanden werden. Falsche Anwendung oder Nichtbeachtung kann zu Krankheit, Verletzungen und Gesundheitsschäden führen. Maske vor Gebrauch prüfen.

2 Stellen Sie sicher, dass die Klassifizierung der Maske für den vorgesehenen Einsatzzweck geeignet ist. Der Anwender trägt die Verantwortung dafür, dass die Atemschutzmaske die notwendige Schutzstufe für die Art und Konzentration der Verschmutzung in dem Bereich, in dem sie angewendet werden soll, erreicht.

3 Die Maske muss dicht sitzen. Führen Sie vor Verwendung unbedingt eine Dichtsitzkontrolle durch.

4 Es ist unwahrscheinlich, dass ein ausreichender Dichtsitz erreicht wird, falls sich Gesichtshaare wie Bärte oder Koteletten unter der Dichtlinie am Gesicht befinden.

5 Mindestens 18 Vol.% Sauerstoffgehalt in der Atemluft sind notwendig, um die Maske sicher benutzen zu können.

6 Diese Maske mit der Kennzeichnung NR ist zum einmaligen Gebrauch bestimmt und ist nach einer Schicht bzw. maximal 8h Gebrauchsdauer zu vernichten.

7 Bei Beschädigungen der Maske oder bei ansteigendem Atemwiderstand ist die Maske umgehend abzulegen und zu wechseln.

8 Die Maske sollte in Innenräumen bei einer Temperatur von -25 bis 40°C sowie einer Luftfeuchtigkeit von maximal 80% gelagert werden.
Direkte Sonneneinstrahlung und Feuchtigkeit sind zu vermeiden.

9 Nehmen Sie keine Veränderungen oder Reparaturen an der Maske vor.

10 Die Maske bietet Schutz vor festen und flüssigen Aerosolen im Rahmen der Schutzklasse FFP2, kann jedoch die Möglichkeit einer Ansteckung oder Erkrankung nicht gänzlich eliminieren.

EINSATZBEREICH

Diese Atemschutzmaske bietet Schutz vor festen und flüssigen Aerosolen bis zum 10-fachen des Arbeitsplatzgrenzwertes sowie zusätzlich gegen biologische Arbeitsstoffe der Gruppe 2.

MATERIAL & HALTBARKEIT

54% Vlies, 24,5% Schmelzgeblasener Vliesstoff, 21,5% Heißluftbaumwolle

- Haltbarkeit: 3 Jahre
- Herstellungsdatum: siehe Beipackzettel
- Chargennummer: siehe Beipackzettel

Hersteller: Name, Anschrift
Shenzhen Baishi Health Medicine Co.,Ltd, 601, 10TH Plant, Longxing Street, Dakang Community, Yuan shan road, Long gang District, Shenzhen city, P.R.China

Beauftragte notifizierten Stelle der Konformitätsbewertung: Name, Anschrift, Kennnummer
SGS FIMKO OY, Takomotie 8, FI-00380 Helsinki, Finland, Tel: +358 9 696 361, www.sgs.com / **CE 0598**

Link zur EU Konformitätserklärung zu finden unter:
www.hms24.eu/sanocare-plus/

Name und Fundstelle der Verordnung:
Verordnung (EU) 2016/425, Amtsblatt der Europäischen Union, Nr. L 81/51, 2016

Name und Fundstelle der Norm:
EN 149:2001+A1:2009 www.beuth.de

FFP2 NR
geprüft nach EN 149:2001+A1:2009

SANOCARE+
Partikelfiltrierende **Atemschutzmaske**

Herstellerinformationen sind unbedingt zu beachten

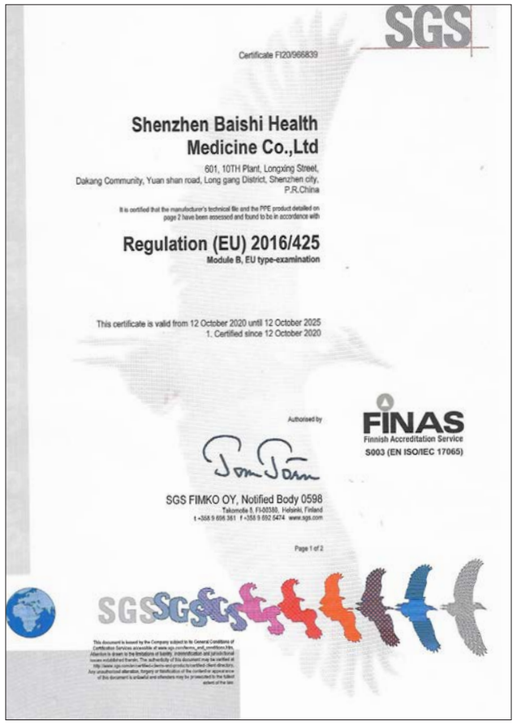
-25°C +40°C Zulässiger Temperaturbereich bei Lagerung

<80% Zulässige relative Luftfeuchte bei Lagerung

Zur einmaligen Verwendung

MADE IN CHINA

4 270001 314970



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Certificate FI20/966839

Shenzhen Baishi Health Medicine Co.,Ltd

601, 10TH Plant, Longxing Street, Dakang Community, Yuan shan road, Long gang District, Shenzhen city, 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 12 October 2020 until 12 October 2025
1. Certified since 12 October 2020

Authorised by

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

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

Page 1 of 2

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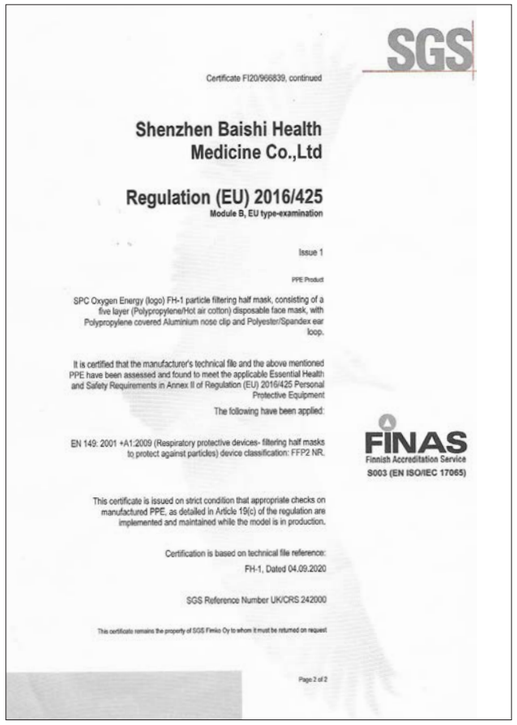

SGS

Certificate FI20/966839, continued

Shenzhen Baishi Health Medicine Co.,Ltd

Regulation (EU) 2016/425
Module B, EU type-examination

Issue 1

PPE Product

SPC Oxygen Energy (logo) FH-1 particle filtering half mask, consisting of a five layer (Polypropylene/Hot air cotton) disposable face mask, with Polypropylene covered Aluminium nose clip and Polyester/Spandex ear loop.

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 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:
FH-1, Dated 04.09.2020

SGS Reference Number UK/CRS 242000

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

Page 2 of 2

Certificate CN20/42709

The management system of

Shenzhen Baishi Health Medicine Co.,Ltd

601, 10TH Plant, Longxing Street, Dakang Community, Yuan shan road, Long gang District, Shenzhen city, P.R.China

has been assessed and certified as meeting the requirements of

Regulation (EU) 2016/425
Module C2

For the following activities

Manufacture of SPC Oxygen Energy (logo) FH-1 particle filtering half mask.

(Note: All products marked CE0598 must have a valid EU type-examination certificate issued under Module B or a valid EC type-examination certificate issued under Article 10 of Directive 89/686/EEC.)

This certificate is valid from 22 December 2020 and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 22 December 2020

Authorised by

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

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

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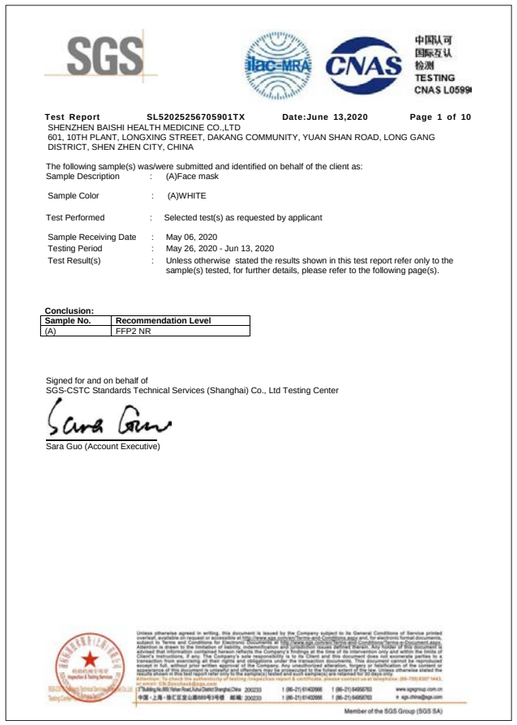

SGS

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L0599

Test Report SL52025256705901TX **Date:June 13,2020** **Page 1 of 10**

SHENZHEN BAISHI HEALTH MEDICINE CO.,LTD
601, 10TH PLANT, LONGXING STREET, DAKANG COMMUNITY, YUAN SHAN ROAD, LONG GANG DISTRICT, SHEN ZHEN CITY, CHINA

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

Sample Description	:	(A)Face mask
Sample Color	:	(A)WHITE
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	May 06, 2020
Testing Period	:	May 26, 2020 - Jun 13, 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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Member of the SGS Group (SGS SA)

Test Result

Personal Protective Equipment - 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

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.	Comply	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.	7.00	6.77	5.84	5.10	6.91	6.32
Luo	2	A.R.	5.82	8.49	6.46	7.53	7.33	7.13
Lu	3	A.R.	5.36	5.60	7.45	7.08	6.40	6.38
Wang	4	A.R.	5.22	4.65	5.79	6.08	4.91	5.33
Bao	5	A.R.	7.72	7.88	7.32	6.49	6.77	7.24
Ding	6	T.C.	5.81	5.34	6.36	4.77	4.90	5.44
Li	7	T.C.	7.53	8.56	7.52	6.48	8.70	7.76
Chen	8	T.C.	6.36	4.57	5.84	5.41	4.88	5.41
Song	9	T.C.	7.29	5.85	5.59	7.04	6.46	6.45
Ye	10	T.C.	6.85	7.18	7.53	8.67	8.94	7.83

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
Lu	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. Classification: FFP1 — Maximum penetration of test aerosol: Sodium chloride test 95 l/min, %, max. 20; Paraffin oil test 95 l/min, %, max. 20 FFP2 — 6 — 6 FFP3 — 1 — 1	Detail refer to Appendix 2	Meet FFP1, Meet FFP2

Appendix 2: Summarization of Test Data

Penetration of filter material

Aerosol	Condition	Sample No.	Penetration (%)
Sodium chloride test	As received	1	0.269
		2	0.274
		3	0.283
	Simulated wearing treatment	4	0.265
		5	0.274
		6	0.283
	Mechanical strength +Temperature conditioned	7	0.347
		8	0.425
		9	0.365
Paraffin oil test	As received	10	1.609
		11	1.656
		12	1.527
	Simulated wearing treatment	13	1.561
		14	1.630
		15	1.704
	Mechanical strength +Temperature conditioned	16	4.681
		17	5.237
		18	5.014
Flow conditioning : Single filter: 95.0 L/min			

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	0.4637
	2	0.4627
	3	0.4630
		Mean value:0.46

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	

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. Classification: FFP1 — Maximum penetration of test aerosol: Sodium chloride test 95 l/min, %, max. 20; Paraffin oil test 95 l/min, %, max. 20 FFP2 — 6 — 6 FFP3 — 1 — 1	Optional for single shift device only	N.A.

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.

Test	Uncertainty
Total inward leakage	3.4%
Penetration of filter material	4.8%
Carbon dioxide content of the inhalation air	3.9%
Breathing resistance (30L/min)	5.9%
Breathing resistance (95L/min)	4.9%
Breathing resistance (160L/min)	4.3%

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. Classification: FFP1 — Maximum permitted resistance (mbar): Inhalation 30 l/min 0.6, 95 l/min 2.1, Exhalation 160 l/min 3.0 FFP2 — 0.7 — 2.4 — 3.0 FFP3 — 1.0 — 3.0 — 3.0	Detail refer to Appendix 5	Meet FFP1, Meet FFP2, Meet FFP3

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	0.2	0.3	0.2	0.3	0.3	0.2	0.3	0.2	0.4	0.2	0.3	0.2	0.3	0.2
	Inhalation 95	0.8	0.7	0.7	0.9	0.8	0.7	0.9	0.7	0.9	0.9	0.8	0.7	0.8	0.9	0.7
	Exhalation 160	1.7	1.7	1.8	1.9	1.8	1.7	1.7	1.8	1.9	1.8	1.9	1.8	1.9	1.7	1.9
	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	0.4	0.3	0.3	0.4	0.3	0.4	0.3	0.4	0.3	0.4	0.3	0.4	0.3
	Inhalation 95	0.9	0.9	0.8	1.0	0.9	0.8	1.0	0.9	0.8	1.0	0.9	0.8	1.0	0.8	0.9
	Exhalation 160	1.8	1.8	1.7	1.9	1.9	1.8	1.9	1.8	1.8	1.9	1.8	1.7	1.9	1.8	1.9
	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	0.3	0.2	0.3	0.2	0.3	0.4	0.2	0.3	0.3	0.2	0.4	0.3	0.4	0.3
	Inhalation 95	0.8	0.8	0.9	0.8	0.9	1.0	0.8	0.9	0.8	0.9	1.0	0.8	0.9	1.0	0.8
	Exhalation 160	2.0	2.0	2.1	2.0	1.9	2.0	1.9	2.0	1.9	2.0	1.9	2.0	2.1	2.0	1.9

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

Sample Photo

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