Medical Protective Mask KN95 SG-201

Brand: Sheng Guang

EU Standard: EN149 2001 + A1:2009, tested by BSI (0086) and IFA Germany

Inspection: The Netherlands Ministry of Labor and the Tax Investigation Bureau provide the passed proof

Features: Against COVID-19, purchased by German Federal Ministry of Health

Classifications: Medical KN95

Material: PP Nonwoven fabric + BFE99 Meltblown fabric (5 Layers)

Size: Universal

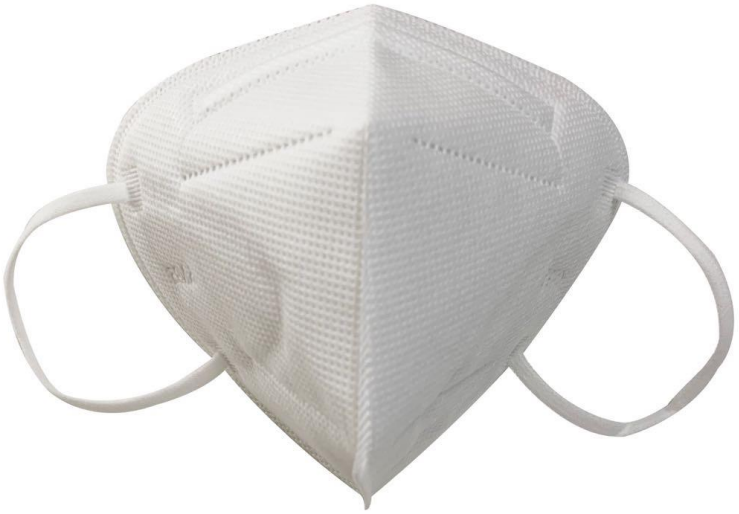
Earloop design: Breathable and comfortable for prolonged wearing

Date of manufacture: From 23rd May 2020

Expiration date: 3 years

Specifications: 1 pc./bag, 50 pcs./box, 12 boxes/carton, 16 cartons/euro pallet

Stocks quantities: From 35,000 pcs., available in Rotterdam The Netherlands and Frankfurt a/m Germany




ShengGuang
圣光 ®
PROTECTIVE FACE MASK
Colorfone
Melbournestraat 68 . 3047BJ . Rotterdam .
The Netherlands
Tel. : +31 (0)10 4298180
PARTICLE FILTRATION EFFICIENCY≥95%
STANDARD: EN149:2001+A1:2009
MODEL: SG-201 FFP2 NR WITHOUT VALVE
MANUFACTURED BY SHENGGUANG MEDICAL INSTRUMENT CO., LTD
ADD: EAST OF LONGSHAN ROAD, JIAXIAN, PINGDINGSHAN CITY,467000 HENAN, CHINA
WEB: WWW.SHENGGUANGMEDICAL.COM EMAIL: SALES@SHENGGUANGMEDICAL.COM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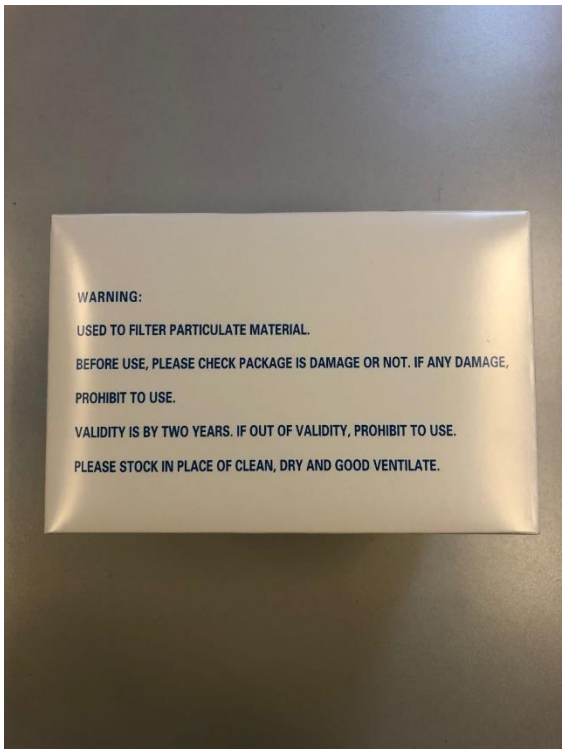
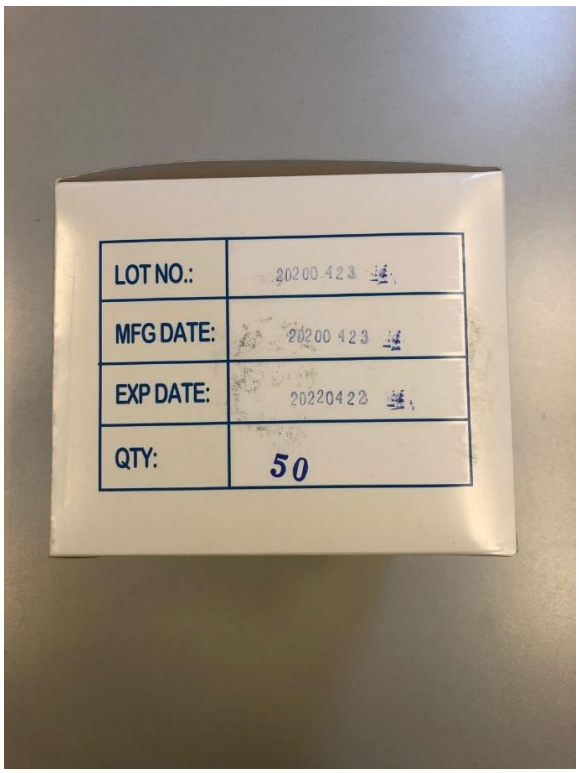

WARNING:
USED TO FILTER PARTICULATE MATERIAL.
BEFORE USE, PLEASE CHECK PACKAGE IS DAMAGE OR NOT. IF ANY DAMAGE,
PROHIBIT TO USE.
VALIDITY IS BY TWO YEARS. IF OUT OF VALIDITY, PROHIBIT TO USE.
PLEASE STOCK IN PLACE OF CLEAN, DRY AND GOOD VENTILATE.


LOT NO.:
20200423
MFG DATE:
20200423
EXP DATE:
20220422
QTY:
50


PROTECTIVE FACE MASK
6 951828 705360
Colorfone
Melbournestraat 68 , 3047BJ , Rotterdam ,
The Netherlands
Tel. : +31 (0)10 4298180

EU Type Examination Certificate

This is to certify that:

ShengGuang Medical Instrument Co., Ltd
East of Longshan Road
Jiaxian
Pingdingshan City
Henan
467000
China

Holds Certificate Number: CE 727836

In respect of:

Model SG-201 Particulate Respirator.
To technical specification Annex II (EHSR) of the PPE Regulation (EU) 2016/425
PPE for use by healthcare professionals as per Commission recommendation 2020/403

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

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Drs. Dave Hagenaars, Managing Director

Previous Notified Body: BSI 0086

First Issued: 2020-06-01

Effective Date: 2020-06-01

Latest Issue: 2020-06-01

Expiry Date: 2021-06-01

PRODUCTS RvA C 646

...making excellence a habit.™

EU Type Examination Certificate

No. CE 727836

Product Specification

Product Name:	Particulate Respirator.
Product Type:	Particulate filtering half masks for use by Healthcare professionals.
Model:	**SG-201**
Classification:	FFP2 NR un-valved.
Technical Specification:	Technical specification to satisfy Annex II of the PPE Regulation (EU) 2016/425.
Product Description:	The respirator is non-reusable, secured to the face of the user by a pair of elasticated ear straps, and has no exhalation valve. The respirator is FFP2 class, vertical fold flat type. The respirator listed on this certificate is for use by healthcare workers, first responders and other personnel involved in the efforts to contain the COVID-19 virus and avoid its further spread. The product covered by this certificate is not approved for industrial applications and the certificate is only valid as long as EU Commission recommendation sheet 2020/403 remains applicable.
Product Assessments:	BSI's PPE for Healthcare Professionals 2020/403 – RPE Technical Specification.

First Issued: 2020-06-01
Latest Issue: 2020-06-01

Effective Date: 2020-06-01
Expiry Date: 2021-06-01

EU Type Examination Certificate

No. CE 727836

Certificate Administration Details

Technical File Reference: Technical File SG/CE-TF056

Certificate Amendment Record:

Issue date	Comments	BSI Review No.
June 2020	First issue.	2797:20:3174666

Certificate validity

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspect of the overall process utilised in the manufacture of the product, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes.

The validity of the Certificate for the products is also dependent on the maintenance of the EU Conformity to Type based on Internal Production Control plus supervised product checks at random intervals, Annex VII (Module C2) as referenced on BSI issued Certificate CE 727837.

First Issued: 2020-06-01
Latest Issue: 2020-06-01

Effective Date: 2020-06-01
Expiry Date: 2021-06-01

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

This is to certify that:

ShengGuang Medical Instrument Co., Ltd
East of Longshan Road
Jiaxian
Pingdingshan City
Henan
467000
China

Holds Certificate Number: CE 727837

In respect of:

For the manufacture of particulate respirators to technical specification to satisfy Annex II of the PPE Regulation (EU) 2016/425.

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

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Drs. Dave Hagenaars, Managing Director

Previous Notified Body: BSI 0086

First Issued: 2020-06-01

Effective Date: 2020-06-01

Latest Issue: 2020-06-01

Expiry Date: 2021-06-01

PRODUCTS RvA C 646

...making excellence a habit.™

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

No. CE 727837

Product manufactured by:

ShengGuang Medical Instrument Co., Ltd
East of Longshan Road
Jiaxian
Pingdingshan City
Henan
467000
China

Product details

The respiratory protective device covered by the scope of this Module C2 Certificate and the Technical Specification to which the product is manufactured are as follows:

Product type:	Particulate filtering half masks for use by Healthcare professionals.
Model and classifications:	SG-201 FFP2 NR
Technical Specification:	Technical specification to satisfy Annex II of the PPE Regulation (EU) 2016/425. BSI's PPE for Healthcare Professionals 2020/403 – RPE Technical Specification.

First Issued: 2020-06-01
Latest Issue: 2020-06-01

Effective Date: 2020-06-01
Expiry Date: 2021-06-01

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

No. CE 727837

Certificate Administration Details:

Certificate Amendment Record and BSI internal Review relating to this Certificate

Issue date	Comments	BSI Review No.
June 2020	First issue.	2797:20:3174667

Certificate validity

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspects of the overall quality system utilized in the manufacture of the products, failure to do so could invalidate the Certificate in respect of product manufactured after the introduction of such changes.

First Issued: 2020-06-01
Latest Issue: 2020-06-01

Effective Date: 2020-06-01
Expiry Date: 2021-06-01

Test Report 3174664.

ShengGuang Medical Instrument Co., Ltd.

Introduction.

This report has been prepared by Paul Waller and relates to the activity detailed below:

Job/Registration Details		Client Details
Job number:	**3174664**	ShengGuang Medical Instrument Co., Ltd
Job type:	Testing Samples Submitted	East of Longshan Road
Start Date:	25/04/2020	Jiaxian
Test type:	Type	Pingdingshan City
Sample ID:	10189436	Henan
Registration:	**CE 727836**	467000
Scheme:	Negative pressure RPE	China
Protocol:	PP123	
Scheme Manager:	Nathan Shipley	

The report has been approved for issue by T Wicksey – Senior Test Engineer

Approved For Issue	
	Issue Date: 12 May 2020

Objectives.

This is an independent test evaluation to only certain clauses or sub-clauses of the agreed specification in accordance with the following test programme:

BSI COVID-19 filtering face piece technical specification, for COVID-19 masks for use by healthcare workers

Product Scope.

COVID-19 masks for use by healthcare workers

Report Summary.

The samples were received on 21 April 2020 and the testing was started on 25 April 2020.

The samples submitted complied with the requirements of the test work conducted.

Test Samples.

Sample ID	ER Number	Description
1 to 19	10189436	Model: SG-201 FFP2 NR

Description of Test Samples.

Sample Description
COVID-19 masks for use by healthcare workers: Model: SG-201 FFP2 NR

Test Requirements.

Testing in accordance with BSI COVID-19 filtering face piece technical specification
Technical testing specification for COVID-19 masks for use by healthcare workers

EN 149:2001+A1:2009 Performance requirement	EN 149:2001+A1:2009 Test method clause	Requirement	Assessment
7.7 Practical performance 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. Where practical performance tests show the apparatus has imperfections related to wearer's acceptance, the test house shall provide full details of those parts of the practical performance tests which revealed these imperfections. *2 test subjects, masks tested 'As received'*	Testing shall be done in accordance with 8.4.	During the tests the particle filtering half mask shall be subjectively assessed by the wearer and after the test, comments on the following shall be recorded: a) head harness comfort; b) security of fastenings; c) field of vision; d) any other comments reported by the wearer on request.	Pass
7.9 Leakage **7.9.1 Total inward leakage** *5 test subjects, masks tested 'As received'*	Testing shall be done in accordance with 8.5.	All samples must achieve All individual exercise results tests shall be not greater than 11 % (for FFP2) and, in addition, all arithmetic means for the total inward leakage shall be not greater than 8 % (for FFP2)	Pass
7.9 Leakage **7.9.2 Penetration of filter material** *3 test samples masks tested 'As received', for NaCl (Sodium Chloride) and PO (Paraffin oil), 3min test*	Testing shall be done in accordance with 8.11	6% for both PO and NaCl	Pass
7.12 Carbon dioxide content of the inhalation air *3 test samples, masks tested 'As received'*	Testing shall be done in accordance with 8.7.	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume).	Pass
7.16 Breathing resistance *3 test samples, masks tested 'As received'*	Testing shall be done in accordance with 8.9	The breathing resistances shall meet the requirements of; 30l/min – 0.7mbar (inhale) 95l/min – 2.4mbar (inhale) 160l/min – 3.0mbar (exhale)	Pass
Appendix A - Test Panel Data			
Product Photographs			

Glossary of Terms.

Pass: Complies. Tested by BSI engineers at BSI laboratories
Pass 1: Complies. Witnessed by BSI engineers in manufacturers laboratory.
Pass 2: Complies. Tests carried out by third party lab; results accepted by BSI.
Pass*: Report resulted in uncertainty and states that Compliance is more probable than non-compliance.
Fail: Non-compliance. Product does not meet the requirements of this clause.
Fail*: Report resulted in uncertainty and states that Non-compliance is more probable than compliance.
N/T: Not Tested
N/A: Not Applicable
AR: As Received
TC: Temperature Conditioned
SW: Simulated Wear
FT: Flow Tested
MS: Mechanical strength
MMDF: Manufactures Minimum Design Flow
MMDC: Manufactures Minimum Design Condition

Conditions of Issue.

This Test Report is issued subject to the conditions stated in current issue of 'BSI Terms of Service'. The results contained herein apply only to the particular sample(s) tested and to the specific tests carried out, as detailed in this Test Report. The issuing of this Test Report does not indicate any measure of Approval, Certification, Supervision, Control or Surveillance by BSI of any product. No extract, abridgement or abstraction from a Test Report may be published or used to advertise a product without the written consent of BSI, who reserve the absolute right to agree or reject all or any of the details of any items or publicity for which consent may be sought.

Should you wish to speak with BSI in relation to this report, please contact Customer Services on +44 (0)8450 80 9000.

BSI
Kitemark House
Maylands Avenue
Hemel Hempstead
Hertfordshire
HP2 4SQ

UKAS TESTING
0135

Opinions and Interpretations expressed herein are outside the scope of our UKAS accreditation.
Unless otherwise stated, any results not obtained from testing in a BSI laboratory are outside the scope of our UKAS accreditation.

Test Results.

Testing in accordance with BSI COVID-19 filtering face piece technical specification

BS EN 149:2001 +A1:2009 Technical testing specification for COVID-19 masks for use by healthcare workers

CLAUSE	REQUIREMENTS	ASSESSMENT
7.7	**Practical performance** 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. Where practical performance tests show the apparatus has imperfections related to wearer's acceptance, the test house shall provide full details of those parts of the practical performance tests which revealed these imperfections. Test in accordance with clause 8.4 of the standard. ***Testing in accordance with BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers*** *During the tests the particle filtering half mask shall be subjectively assessed by the wearer and after the test, comments on the following shall be recorded:* *a) head harness comfort; b) security of fastenings; c) field of vision; d) any other comments reported by the wearer on request.*	Pass

Table A: Practical performance

Test candidate	Sample	Comments				Assessment
		Head harness comfort	Security of fastenings	Field of vision	Any other comments	
AA1	1 AR	OK	OK	OK	Leak around nose	Pass
JS3	2 AR	Quite tight	OK	OK	None	Pass

7.9	**Leakage**	
7.9.1	Total inward leakage The laboratory tests shall indicate that the particle filtering half mask can be used by the wearer to protect with high probability against the potential hazard to be expected. The total inward leakage consists of three components: face seal leakage, exhalation valve leakage (if exhalation valve fitted) and filter penetration. Test in accordance with clause 8.5 of the standard. ***Testing in accordance with BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers*** *5 test subjects, masks tested 'As received'. All individual exercise results tests shall be not greater than 11 % (for FFP2) and, in addition, all arithmetic means for the total inward leakage shall be not greater than 8 % (for FFP2)*	Pass

Table B: Clause 7.9.1 - Total inward leakage

Test candidate	Sample	Pre test condition	Inward Leakage (%)						Assessment
			A	B	C	D	E		
			Walking	Walking with head side to side	Walking with head up & down	Walking and talking	Walking	Average	
SI1*	3	AR	2.33	4.33	3.44	1.34	3.96	3.96	Pass
JS2*	4	AR	1.31	0.76	0.98	0.70	1.02	0.95	Pass
SR1*	5	AR	4.48	5.03	5.35	5.14	5.79	4.96	Pass
GR1*	6	AR	5.27	4.60	4.95	2.60	4.48	4.38	Pass
LM2*	7	AR	3.18	4.52	5.16	4.58	5.01	4.49	Pass

* Samples 3 & 4 used neck straps; samples 4, 5 & 6 used earloops.

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
7.9.2	Penetration of filter material ***Testing in accordance with BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers*** *3 test samples masks tested 'As received', for NaCl (Sodium Chloride) and PO (Paraffin oil), 3 min test. Testing shall be done in accordance with 8.11. 6% limit for both PO and NaCl*	Pass

Table C: Clause 8.11 - Sodium Chloride penetration test

Sample number	Pre-test condition	Flow through filter (l/min)	Penetration (%)	
			Limit	Actual
8	AR	95	< 6	0.29
9	AR			0.26
10	AR			0.32

Table D: Clause 8.11 - Paraffin oil penetration test

Sample number	Pre-test condition	Flow through filter (l/min)	Penetration (%)	
			Limit	Actual
11	AR	95	< 6	0.80
12	AR			0.76
13	AR			0.65

7.12 **Carbon dioxide content of inhalation air**

The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0% (by volume). Pass

Test in accordance with clause 8.7 of the standard.

Table E: Clause 8.7 - Carbon Dioxide content of the inhalation air

Sample	Pre-test condition	Dead space CO_2 (%)	
		Limit	Measured
14	AR	< 1.0	0.49
15	AR		0.54
16	AR		0.49

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
7.16	**Breathing resistance** ***Testing in accordance with BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers*** *3 test samples masks tested 'As received'. Test in accordance with clause 8.9 of the standard.* *The breathing resistances shall meet the requirements of FFP2;* *30l/min – 0.7mbar (inhale), 95l/min – 2.4mbar (inhale), 160l/min – 3.0mbar (exhale)*	Pass

Table F: Clause 8.9 – Breathing resistance. Inhalation resistance at a continuous flow

Sample	Pre-test condition	Continuous flow (l/min)	Inhalation resistance (mbar)	
			Limit	Measured
17	AR	30	< 0.7	0.40
18	AR			0.41
19	AR			0.48
17	AR	95	< 2.4	1.32
18	AR			1.46
19	AR			1.67

Table G: Clause 8.9 – Breathing resistance. Exhalation resistance at a continuous flow, measured in five orientations with the worst case reported

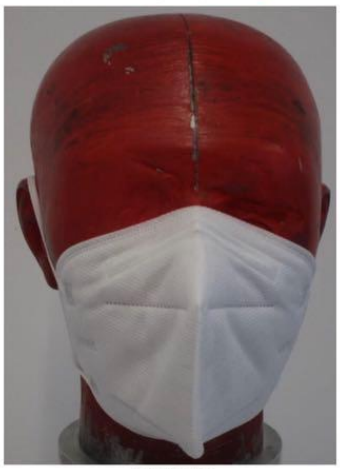
Sample	Pre-test condition	Continuous flow (l/min)	Exhalation resistance (mbar)	
			Limit	Measured
17	AR	160	< 3.0	2.35
18	AR			2.47
19	AR			2.71

Appendix A. – Test Panel Data

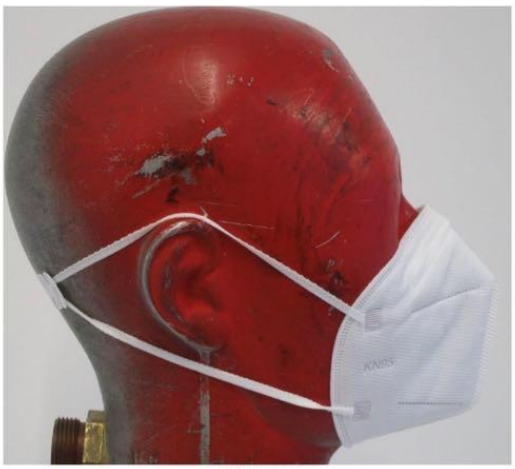
Test Candidate	Facial Dimensions (mm)					Sex
	Length of face	Width of face	Face depth	Width of mouth	Head Circumference	
AA1	125	144	130	47	581	Male
SI1	121	135	142	48	575	Male
GR1	124	145	126	49	590	Male
SR1	118	133	130	52	585	Male
JS3	126	134	124	49	600	Male
LM2	110	148	125	44	589	Male
JS2	126	142	125	57	575	Male

Note: All candidates were clean shaven

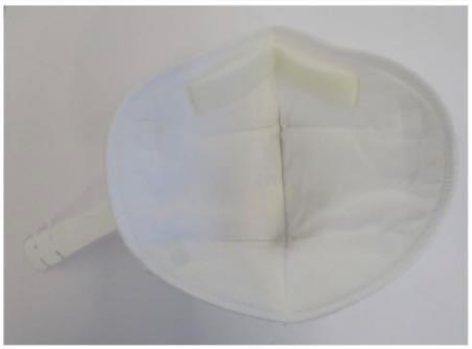
Product photographs.



Front view



Side View



Inside View

End of Report

IFA
Institut für Arbeitsschutz der
Deutschen Gesetzlichen Unfallversicherung
Prüf- und Zertifizierungsstelle im DGUV Test

Bewertung der Konformität von Corona SARS-Cov-2 Pandemie Atemschutz (CPA) nach dem Prüfgrundsatz für Corona SARS-Cov-2 Pandemie Atemschutzmasken

Evaluation of the conformity of corona sars-cov-2 pandemic respiratory protection (CPA) according to the testing principle for corona sars-cov-2 pandemic respiratory protection masks

Nr. 202021688 vom 14.05.2020

Auftraggeber: ***Customer:***	Hubrich medical GmbH & Co. KG Magnolienweg 8 63741 Aschaffenburg Deutschland
Produktbezeichnung: ***Test subject:***	**Corona SARS-Cov-2 Pandemie Atemschutz (CPA)**
Modell: ***Typ:***	ShengGuang GB 19083-2010 SG Medical CPA 202
Prüfbericht: ***Test report:***	202021688/2120 vom 12.05.2020

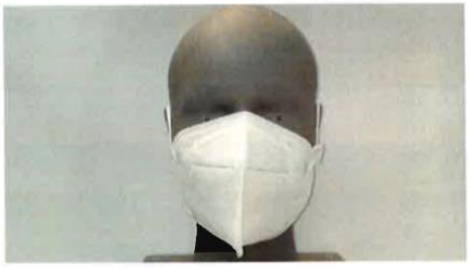
Die Anforderungen des Prüfgrundsatzes sind **erfüllt**
The requirements of the test principle are ***fulfilled***

Die technische Wirksamkeit des oben genannten Produkts ist im Rahmen der Empfehlung (EU) 2020/403 der Europäischen Kommission vom 13. März 2020 über Konformitätsbewertungs- und Marktüberwachungsverfahren im Kontext der COVID-19 Bedrohung zu vermuten. CPA mit Ausatemventil(en) eignen sich grundsätzlich nicht für den Fremdschutz.
The technical efficiency of the above-mentioned product is to be presumed within the framework of the European Commission Recommendation (EU) 2020/403 of 13th March 2020 on conformity assessments and market surveillance procedures in the context of the COVID-19 risk. CPA with exhalation valve(s) are generally not appropriate for external protection.
Der Prüfgrundsatz kann unter dem folgenden Link eingesehen werden:
The test principle can be accessed under the following link:
http://www.zls-muenchen.de/aktuell/index.html

Diese Bewertung ist gültig vom 14.05.2020 bis 13.05.2021.
This evaluation of conformity is valid from 2020-05-14 until 2021-05-13.

Dr. Peter Paszkiewicz
Leiter der Prüf- und Zertifizierungsstelle

Nr. 202021288



Dr. Peter Paszkiewicz
Leiter der Prüf- und Zertifizierungsstelle

IFA
Institut für Arbeitsschutz der
Deutschen Gesetzlichen Unfallversicherung
Prüf- und Zertifizierungsstelle im DGUV Test

Datum/*Date:* 12.05.2020 Krs/MS

PRÜFBERICHT
TEST REPORT

Nr./*No.:* 202021688/2120

1	**Auftraggeber/** ***Customer***	Hubrich medical GmbH & Co. KG Magnolienweg 8 63741 Aschaffenburg Deutschland
2	**Prüfmuster/** ***Test specimen***	Atemschutzgerät
2.1	Produzent/ *Producer*	Shengguang Medical Instrument Co., Ltd East of Longshan Road, Jiaxian, Pingdingshan City, Henan Volksrepublik China
2.2	Bauart, Bezeichnung/ *Type, designation*	Corona SARS-Cov-2 Pandemie Atemschutzmaske (CPA) ShengGuang GB 19083-2010 SG Medical CPA 202
	Kennzeichnung/ *Marking*	ShengGuang GB 19083-2010 SG Medical CPA 202
2.3	Weitere Angaben/ *Further details*	-.-

IFA
Institut für Arbeitsschutz der
Deutschen Gesetzlichen Unfallversicherung
Prüf- und Zertifizierungsstelle im DGUV Test

3	**Prüfung/** ***Testing***	
3.1	Art der Prüfung/ *Type of test*	Teilprüfung
3.2	Datum der Prüfung/ *Date of testing*	April - Mai 2020
3.3	Prüfverfahren, -grundlagen/ *Test method, requirements*	Prüfgrundsatz für SARS-Cov-2 Pandemie Atemschutzmasken Rev. 1 vom 26.03.2020
4	**Beurteilung, Eignung/** ***Assessment, suitability***	-.-

Besondere Hinweise:

5 Gültigkeit des Prüfberichtes/
Validity of Test Report

Die ermittelten Ergebnisse gelten nur für die geprüften Objekte.
The test results apply to the tested objects only.

Einschränkungen der Gültigkeit oder Verwendung dieses Prüfberichtes: keine
Limitation of validity or use of this Test Report: non

6 Allgemeine Hinweise/
General remarks

Dieser Prüfbericht besteht aus **6** Seiten.
The present Test Report consists of *Pages.*

Die Seiten 1 bis 3 enthalten das Gesamtergebnis der Prüfung. Zum vollständigen Prüfbericht gehört das Prüfprotokoll, aus dem die Einzelangaben ersichtlich sind.
Pages 1 to 3 indicate the overall test result. The complete Test Report also includes the test protocol containing all pertinent details.

Dieser Prüfbericht berechtigt n i c h t zur Verwendung des GS-Zeichens, BG-Zeichens oder CE-Zeichens.
The present Test Report does n o t warrant the use of the GS-label, BG-label or CE-mark.

IFA
Institut für Arbeitsschutz der
Deutschen Gesetzlichen Unfallversicherung
Prüf- und Zertifizierungsstelle im DGUV Test

Im Übrigen gilt die Prüf- und Zertifizierungsordnung der Prüf- und Zertifizierungsstellen im DGUV Test in Verbindung mit den Allgemeinen Geschäftsbedingungen der Deutschen Gesetzlichen Unfallversicherung e.V.
In all other respects the Rules of Procedure for Testing and Certification carried out by the Test and Certification Bodies in DGUV Test shall apply in conjunction with the General Business Conditions of the Deutsche Gesetzliche Unfallversicherung e.V.

Für die Prüfung:
For the testing:

J. Krisinger

Dipl.-Ing. Judith Krisinger

Leiter(in) des Prüflabors
Head of Testlaboratory

IFA
Institut für Arbeitsschutz der
Deutschen Gesetzlichen Unfallversicherung
Prüf- und Zertifizierungsstelle im DGUV Test

Prüfprotokoll
Test protocol

1. Prüfgrundlage: Prüfgrundsatz für SARS-Cov-2 Pandemie Atemschutzmasken Rev. 1 vom 26.03.2020

2. Art der Prüfung: Teilprüfung

3. Auftraggeber: Hubrich medical GmbH & Co. KG

4. Prüfmuster

4.1 Bauart: Corona SARS-Cov-2 Pandemie Atemschutzmaske (CPA)

4.2 Bezeichnung: ShengGuang GB 19083-2010 SG Medical CPA 202

4.3 Kennzeichnung: ShengGuang GB 19083-2010 SG Medical CPA 202

4.4 Geräteklasse: -.-

5. Sichtprüfung

Die zur Prüfung eingereichte Masken ShengGuang GB 19083-2010 SG Medical CPA 202 sind so verpackt, dass diese mechanische Beschädigung und Verunreinigung vor dem Gebrauch geschützt sind.

6. Anlegeprüfung

Eine Testperson führt einen Trageversuch durch und beurteilt den Dichtsitz nach folgenden Punkten:

CPA ist leicht an- und abzulegen:	ja
Bänderung ist ausreichend stark, um CPA in Postion zu halten :	ja
Undichtigkeiten im Bereich der Dichtlinie erkennbar:	nein
Luftströmungen bei Beatmung spürbar:	nein

Die Anforderungen werden erfüllt.

7. Konditionierung

7.1 Gebrauchssimulation

Eine entsprechend Tabelle 1 des Prüfgrundsatz für SARS-Cov-2 Pandemie Atemschutzmasken Rev.1 vom 26.03.2020 genannte Anzahl von CPA wurde vor den weiteren in Tabelle 1 genannten Prüfungen einer Gebrauchssimulation gemäß DIN EN 149:2009 Abschnitt 8.3.1 unterzogen.

Nach der Gebrauchssimulation darf keine filtrierende Halbmaske ein mechanisches Versagen des Atemanschlusses aufweisen und die filtrierenden Halbmasken dürfen nicht zusammenfallen.

Die Anforderungen werden erfüllt.

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7.2 Temperaturkonditionierung

Eine entsprechend Tabelle 1 des Prüfgrundsatz für SARS-Cov-2 Pandemie Atemschutzmasken Rev.1 vom 26.03.2020 genannte Anzahl von CPA wurde vor den weiteren in Tabelle 1 genannten Prüfungen einer Temperaturkonditionierung gemäß DIN EN 149:2009 Abschnitt 8.3.2 unterzogen.

Nach der Temperaturkonditionierung darf keine filtrierende Halbmaske zusammenfallen.

Die Anforderung wird erfüllt.

8. Atemwiderstand

8.1 Anforderungen

Max. Einatemwiderstand bei Prüfvolumenstrom 30 l/min: 100 Pa

Max. Einatemwiderstand bei Prüfvolumenstrom 95 l/min: 300 Pa

Max. Ausatemwiderstand bei Prüfvolumenstrom 160 l/min: 300 Pa

8.2 Prüfergebnisse

Prüfung	Konditionierung	Atemwiderstand [Pa]		
		Einatmen mit 30 l/min	Einatmen mit 95 l/min	Ausatmen mit 160 l/min
1	EN 149:2001, 8.3.1 & 8.3.2	34	118	180
2	EN 149:2001, 8.3.1 & 8.3.2	31	106	176

Die Anforderungen werden erfüllt.

9. Filterdurchlass bei Prüfung mit Paraffinöl-Aerosol

9.1 Prüfvolumenstrom: 95 l/min

9.2 Anforderungen

Max. Durchlassgrad: 6,0 %

9.3 Prüfergebnisse

Prüfung	Konditionierung	Durchlassgrad [%]	
		Messwert 1	Messwert 2
1	EN 149:2001, 8.3.1 & 8.3.2	2,5	-,-
2	EN 149:2001, 8.3.1 & 8.3.2	2,2	-,-
3	EN 149:2001, 8.3.1 & 8.3.2	1,5	-,-

Messwert 1: Durchlassgrad nach 3 Minuten

Messwert 2: Maximaler Durchlassgrad während 120 mg Paraffinöl-Exposition

Die Anforderungen werden erfüllt.

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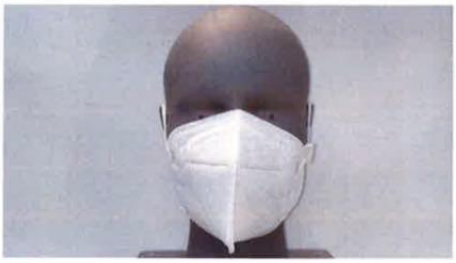
10. Abbildung



Die hier aufgeführten Prüfergebnisse beziehen sich auf die geprüften Objekte.
Eine Aussage über die Gleichmäßigkeit der Produktion lässt sich hieraus nicht ableiten.

Institut für Arbeitsschutz – IFA –
Im Auftrag

Dipl.-Ing. Judith Krisinger

Sachbearbeiter

Benedikt Brenner

Inspectie SZW
Ministerie van Sociale Zaken en Werkgelegenheid

> Retouradres Postbus 90801 2509 LV Den Haag

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t.a.v. De heer H Cai
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3047 BJ ROTTERDAM

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Medewerker afd.
Inspectieondersteuning

T +31 (0)70 333 6383

Onze referentie
2010243/01

Datum 4 juni 2020
Betreft Afhandeling inspectie

Geachte heer Cai,

Op woensdag 3 juni 2020 brachten de heer R.W van de Spoel (FIOD) en ondergetekende een inspectiebezoek aan Colorfone. Tijdens deze inspectie, gericht op de naleving van het Warenwetbesluit Persoonlijke beschermingsmiddelen en Directive 2016/425 en 2020/403, zijn geen overtredingen geconstateerd.

Hoogachtend,

M.A.M. Hek
Inspecteur Markttoezicht Productveiligheid Inspectie SZW