HYGISUN®

REF HS0501A

FFP2 Mask

Non Medical

EN149: 2001+A1: 2009


FFP2-MASKE
PERSÖNLICHE SCHUTZMASKE EN149:2001+A1:2009
Faltbare Partikel
-Atemschutzmaske
Hohe Filtrationseffizienz
Geringer Atemwiderstand
Bequem zu tragen
HYGISUN®
REF HS0501A
Schwarz/Black
6Stück
Einmalgebrauch
CE 2797

Bedienungsanleitung

Nehmen Sie die Maske an den Ohrschlaufen in die Hand und drücken Sie diese mit dem Bügel auf den Nasenrücken gegen Ihr Gesicht, während Sie die Ohrschlaufen hinter Ihren Ohren positionieren.

Formen Sie den Bügel mit beiden Händen in die Form Ihrer Nase.

Testen Sie die Passform. Nehmen Sie beide Hände über die Atemschutzmaske und atmen Sie kräftig aus. Wenn Luft um Ihre Nase strömt, ziehen Sie den Bügel fester.

Hinweis zur Verwendung:

- Bitte verwenden Sie dieses Produkt nicht in der Nähe einer Feuerquelle.
- Da es sich bei diesem Produkt um eine Einwegmaske handelt, kann es nicht durch Waschen wiederverwendet werden.
- Von hohen Temperaturen und Luftfeuchtigkeit fernhalten und an einem sauberen Ort aufbewahren.
- Persönliche Schutzmaske, Nicht medizinisch.
- Verwenden Sie einzeln verpackte Produkte, sobald diese ausgepackt sind.


FFP2-MASK
PERSONAL PROTECTIVE MASK EN149:2001+A1:2009
Foldable Particulate Respirator
High filtration efficiency
Low respitatiory resistance
More comfortable to wear
HYGISUN®
REF HS0501A
Schwarz/Black
6PCS
Single Use
CE 2797
FFP2 Maske


FFP2 Maske
EN149:2001+A1:2009
WICHTIG: Die Atemschutzmaske FFP2 schützt vor Pollen, Viren und Industriestaub.
ANWENDUNG:
Die Maske wird in der Schutzindustrie bei Staubentwicklung, während des Baus zur Staubverhütung, beim Metallguss, Steinabbau, in der Elektronik, Pharmazie, der physikalischen Verarbeitung und beim Schleifen verwendet und bietet einen guten Schutz gegen Sandstürme, Durst und PM2.5. Kann wirksam vor Pollenallergien, Virusübertragung usw. schützen.
VERFALLSDATUM:
Lagertemperatur: -20~38°C, Lagerfeuchtigkeit ≤ 80%, Haltbarkeit: 2 Jahre in trockenen Innenräumen.
Hunan Dreaming Cloud E-Commerce CO., Ltd
Block 7, Smart Tech Park, 577F Huangxing Avenue, Changsha Economic and Technological Development Zone, Changsha, Hunan, China
EC REP
Sunbeam International GmbH
Schumastr. 12, 52146 Würselen, Germany
4 260676 530485
FFP2 MASK
Grau


HYGISAN
HS0501A FFP2 NR
EN149:2001+A1:2009
2797

Hunan Dreaming Cloud E-Commerce CO., Ltd
Block 1, Smart Tech Park, 57# Huangxing Avenue, Changsha Economic and Technological Development Zone,Changsha, Hunan, China

EU-KONFORMITÄTSERKLÄRUNG

Diese Konformitätserklärung wurde unter der alleinigen Verantwortung des Herstellers

Hunan Dreaming Cloud E-Commerce CO., Ltd.

Block 1, Smart Tech Park, 57 # Huangxing Avenue, Changsha Economic and Technological Development Zone, Changsha, Hunan, China

ausgestellt.

EG-Vertreter: Sunbeam International GmbH, Schumanstr.12, Würselen 52146 Deutschland

Hiermit wird erklärt, dass die folgende persönliche Schutzausrüstung (PSA)

Produktbeschreibung: HYGISUN Partikelfilter-Halbmaske

Produktmodell (e): HS0501A 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.: CE 730303 (Ausstellungsdatum: 03/07/2020)

herausgegeben von BSI Group Niederlande BV

John M. Keynesplein 9, 1066 EP, Amsterdam, Niederlande (Notified Body No. 2797)

und entspricht den Verfahren in Modul C2 der Verordnung (EU) 2016/425 unter der Überwachung der BSI Group The Netherlands BV (Notified Body Nr. 2797), auf die auf dem vom BSI ausgestelltem Zertifikat CE 730304 (Ausstellungsdatum: 03/07/2020) verwiesen wird.

Changsha, China, 07.04.2020

Ouyang Zhouya

(Nachname Name)

Qualitätsmanager

Hunan Dreaming Cloud E-Commerce CO., Ltd.

Hunan Dreaming Cloud E-Commerce CO., Ltd.
Block 1, Smart Tech Park, 57# Huangxing Avenue, Changsha Economic and Technological Development Zone, Changsha, Hunan, China

EU DECLARATION OF CONFORMITY

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

Hunan Dreaming Cloud E-Commerce CO., Ltd.

Block 1, Smart Tech Park, 57# Huangxing Avenue, Changsha Economic and Technological Development Zone, Changsha, Hunan, China

EC Representative: Sunbeam International GmbH, Schumanstr.12, Würselen 52146 Germany:

hereby declaring the following Personal Protective Equipment (PPE)

Product Description: HYGISUN Particulate Filtering Half Mask

Product Model/s: HS0501A 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.: CE 730303 (Issue Date: 03/07/2020)

issued by

BSI Group The Netherlands B.V.

John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands (Notified Body No. 2797)

and is/are in conformance with procedures set out in Module C2 of Regulation (EU) 2016/425 under the surveillance of BSI Group The Netherlands B.V.(Notified Body No. 2797), referenced on BSI issued Certificate CE 730304 (Issue Date: 03/07/2020).

Changsha, China, 04/07/2020

Ou Yang Zhou Ya

(Surname, Name)

Quality Manager

Hunan Dreaming Cloud E-Commerce CO., Ltd.

Test Report No.: 244275321a 001

Client: **SUNBEAM INTERNATIONAL GMBH**

Contact Information: Schumanstr. 12, 52146 Würselen, Germany

Contact Person: Edward Zhao

Sample Description As Declared :

No. Of Sample	80pcs
Product Description	Personal Protective Respirator Mask
Colour	White
Style No.	HS0501A
Manufacture	Hunan Dreaming Cloud E-Commerce Co., Ltd.
Test Type	Partial test
Product Type	Single shift use only
Claimed Classification	FFP2

Sample obtaining method: Sending by customer

Condition at delivery: *Test item complete and undamaged.*

Sample Receiving date: 2020-10-28 & 2020-12-01

Delivery condition: *Apparent good, Samples tested as received*

Test Period: 2020-10-28 to 2020-11-13 & 2020-12-01 to 2020-12-07

Place of testing: *Textiles laboratory Shanghai*

Test Specification:
EN 149:2001 + A1:2009 Respiratory Protective Devices – Filtering Half Masks to Protect against particles- Requirements, testing, marking

Test Result
Please refer to next page

For and on behalf of

TÜV Rheinland (Shanghai) Co., Ltd.

Candy Jiang

2020-12-07 Candy Jiang/ Section Manager

Date *Name/Position*

Sample information is provided by customer. Test result is drawn according to the kind and extent of tests performed. This test report relates to the above mentioned test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any safety mark on this or similar products. "Decision Rule" document announced in our website (https://www.tuv.com/landingpage/en/qm-gcn/) describes the statement of conformity and its rule of enforcement for test results are applicable throughout this test report

Summary of test results

Clause	Item	M001
7.3	Visual inspection	N/R
7.4	Package	M
7.5	Material	M
7.6	Cleaning and disinfection	N/A
7.7	Practical performance	M
7.8	Finish of parts	M
7.9.1	Leakage	M
7.9.2	Penetration of filter material	M
7.10	Compatibility with skin	M
7.11	Flammability	M
7.12	Carbon dioxide content of the inhalation air	M
7.13	Head harness	M
7.14	Field of vision	M
7.15	Exhalation valve(s)	N/A
7.16	Breathing Resistance	M
7.17	Clogging	N/A
7.18	Demountable parts	M
9	Marking	N/R
10	Information to be supplied by the manufacturer	N/R

Note : M = Meet Performance Standard
N/R = Not Request
N/A = Not Applicable
F = Below Performance Standard
* = No Submitted Information
M# = Refer to result page

Material list

Material No.	Material	Color/Pattern	Location
M001	Whole Product	White	Personal Protective Respirator Mask

1. Visual inspection

Test method : EN 149:2001+A1:2009 Clause 8.2

Clause	Item	M001
7.3	The visual inspection shall also include the marking and the information supplied by the manufacturer.	N/R
7.4	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.	Pass
7.5	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.	Pass
	After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the face piece or straps.	Pass
	When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	Pass
	Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Pass
7.8	Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs	Pass
7.18	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.	Pass

Remark:
N/A: Due to no relevent information/material
N/R: Due to not request

2. Practical performance

Test method : EN 149:2001+A1:2009 Clause 8.4 & 8.5

Clause	Item	M001
7.7	Wearing	Pass
7.7	Walking test	Pass
7.7	Work simulation test	Pass
7.10	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	Pass
7.13	The head harness shall be designed so that the particle filtering half mask can be donned and removed easily. The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position and be capable of maintaining total inward leakage requirements for the device	Pass
7.14	The field of vision is acceptable if determined so in practical performance tests	Pass

Remark:
N/A: Due to no relevent information/material
N/R: Due to not request

3. Leakage

Test method : EN 149:2001+A1:2009 Clause 8.5
Requirement : FFP2:
At least 46 out of the 50 individual exercise results for total inward leakage ≤11%
At least 8 out of the 10 individual wearer arithmetic means for the total inward leakage ≤ 8%

M001								
Subject	Condition	Specimen No.	Leakage (%)					
			Walk	Head Side/side	Head Up/down	Talk	Walk	Mean
BM	As received	1	6.820	6.858	8.681	6.160	6.471	6.998
ACH		2	6.217	6.743	8.947	8.174	6.003	7.217
ML		3	6.369	6.586	7.298	7.943	6.967	7.033
LLC		4	6.483	7.124	8.832	7.335	7.067	7.368
DG		5	7.124	6.336	8.432	8.143	6.521	7.311
SG	After conditioning	6	5.632	6.821	7.964	8.148	6.883	7.090
YL		7	7.643	7.211	8.143	8.621	6.964	7.716
KQ		8	6.845	7.004	7.962	8.047	7.012	7.374
KXH		9	6.431	6.225	8.921	8.882	7.062	7.504
YY		10	6.119	7.821	8.679	9.021	5.803	7.489
Conclusion		Pass						

Facial Dimension Of Subject (mm)										
Subject	BM	ACH	ML	LLC	DG	SG	YL	KQ	KXH	YY
Face length	135	127	120	120	130	135	115	120	130	130
Face width	160	159	133	140	145	155	135	135	155	165
Face Depth	130	122	115	115	132	132	118	115	120	143
Mouth Width	52	55	52	50	50	55	48	50	52	50

4. Flammability

Test method : EN 149:2001+A1:2009 Clause 8.6
Requirement : ≤5s

M001				
Item	Condition	Specimen No	Test results	Conclusion
Afterflame time (s)	As received	1	1.1	Pass
		2	1.3	
	After conditioning	3	1.4	
		4	1.3	

5. Carbon Dioxide Content Of The Inhalation Air

Test method : EN 149:2001+A1:2009 Clause 8.7
Requirement : ≤1%

M001.						
Item	Condition	Test results				Conclusion
Content (%)	As received	Specimen 1	Specimen 2	Specimen 3	Mean	Pass
		0.62	0.63	0.64	0.63	

6. Breathing Resistance

Test method : EN 149:2001+A1:2009 Clause 8.9

Requirement : FFP2:
Inhalation: 30l/min: ≤0.7mbar
Inhalation: 95l/min: ≤2.4mbar
Exhalation: 160l/min:≤3.0mbar

M001																
Flow rate (l/min)		Resistance (mbar)														
As received		Specimen 1					Specimen 2					Specimen 3				
		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
Inhalation	30	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4
	95	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.2	1.2	1.2	1.2	1.2
Exhalation	160	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4
Simulated wearing treatment		Specimen 4					Specimen 5					Specimen 6				
		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
Inhalation	30	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4
	95	1.4	1.4	1.4	1.4	1.4	1.3	1.3	1.3	1.3	1.3	1.4	1.4	1.4	1.4	1.4
Exhalation	160	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.4	2.4	2.4	2.4	2.4
Temperature conditioned		Specimen 7					Specimen 8					Specimen 9				
		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
Inhalation	30	0.3	0.3	0.3	0.3	0.3	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4
	95	1.3	1.3	1.3	1.3	1.3	1.2	1.2	1.2	1.2	1.2	1.3	1.3	1.3	1.3	1.3
Exhalation	160	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3
Conclusion		Pass														

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

7. Penetration Of Filter Material

Test method : EN 149:2001+A1:2009 Clause 8.11
Requirement : FFP2:≤6%

M001			
Aerosol	Condition	Specimen No.	Penetration (%)
Sodium chloride Penetration	As received	1	0.003
		2	0.001
		3	0.001
	Simulated wearing treatment	4	0.006
		5	0.007
		6	0.010
	Mechanical strength + Temperature conditioned @ Exposure test of 120mg	7	0.017
		8	0.017
		9	0.117
Paraffin oil Penetration	As received	10	0.031
		11	0.043
		12	0.018
	Simulated wearing treatment	13	0.132
		14	0.241
		15	0.167
	Mechanical strength + Temperature conditioned @ Exposure test of 120mg	16	0.531
		17	0.862
		18	0.863
Conclusion	Pass		

Photo:


Persönliche Schutzmaske
PERSONAL PROTECTIVE MASK
1Stück/ Piece

END -

General Terms and Conditions of Business of TÜV Rheinland in Greater China

1. Scope

1.1 These General Terms and Conditions of Business of TÜV Rheinland in Greater China ("GTCB") is made between the client and one or more member entities of TÜV Rheinland in Greater China as applicable as the case may be ("TÜV Rheinland"). The Greater China hereof refers to Mainland China, Hong Kong and Taiwan.The client hereof includes:

(i) a natural person capable to form legally binding contracts under the applicable laws who concludes the contract not for the purpose of a daily use;

(ii) the incorporated or unincorporated entity duly organized, validly existing and capable to form legally binding contracts under the applicable law.

1.2 The following terms and conditions apply to agreed services including consultancy services, information, deliveries and similar services as well as ancillary services and other secondary obligations provided within the scope of contract performance.

1.3 Any standard terms and conditions of the client of any nature shall not apply and shall hereby be expressly excluded. No standard contractual terms and conditions of the client shall form part of the contract even if TÜV Rheinland does not explicitly object to them.

1.4 In the context of an ongoing business relationship with the client, this GTCB shall also apply to future contracts with the client without TÜV Rheinland having to refer to them separately in each individual case.

2. Quotations

Unless otherwise agreed, all quotations submitted by TÜV Rheinland can be changed by TÜV Rheinland without notice prior to its acceptance and confirmation by the other party.

3. Coming into effect and duration of contracts

3.1 The contract shall come into effect for the agreed terms upon the quotation letter of TÜV Rheinland or a separate contractual document being signed by both contracting parties, or upon the works requested by the client being carried out by TÜV Rheinland. If the client instructs TÜV Rheinland without receiving a quotation from TÜV Rheinland (quotation), TÜV Rheinland is, in its sole discretion, entitled to accept the order by giving written notice of such acceptance (including notice sent via electronic means) or by performing the requested services.

3.2 The contract term starts upon the coming into effect of the contract in accordance with article 3.1 and shall continue for the term agreed in the contract.

3.3 If the contract provides for an extension of the contract term, the contract term will be extended by the term provided for in the contract unless terminated in writing by either party with a six-week notice prior to the end of the contractual term.

4. Scope of services

4.1 The scope and type of the services to be provided by TÜV Rheinland shall be specified in the contractually agreed service scope of TÜV Rheinland by both parties. If no such separate service scope of TÜV Rheinland exists, then the written confirmation of order by TÜV Rheinland shall be decisive for the service to be provided.

4.2 The agreed services shall be performed in compliance with the regulations in force at the time the contract is entered into.

4.3 TÜV Rheinland is entitled to determine, in its sole discretion, the method and nature of the assessment unless otherwise agreed in writing or if mandatory provisions require a specific procedure to be followed.

4.4 On execution of the work there shall be no simultaneous assumption of any guarantee of the correctness (proper quality) and working order of either tested or examined parts nor of the installation as a whole and its upstream and/or downstream processes, organisations, use and application in accordance with regulations, nor of the systems on which the installation is based. In particular, TÜV Rheinland shall assume no responsibility for the construction, selection of materials and assembly of installations examined, nor for their use and application in accordance with regulations, unless these questions are expressly covered by the contract.

4.5 In the case of inspection work, TÜV Rheinland shall not be responsible for the accuracy or checking of the safety programmes or safety regulations on which the inspections are based, unless otherwise expressly agreed in writing.

4.6 If mandatory legal regulations and standards or official requirements for the agreed service scope change after conclusion of the contract, with a written notice to the client, TÜV Rheinland shall be entitled to additional remuneration for resulting additional expenses.

4.7 The services to be provided by TÜV Rheinland under the contract are agreed exclusively with the client. A contract of third parties with the services of TÜV Rheinland, as well as making available of and justifying confidence in the work results (test reports, test results, expert reports, etc.) is not part of the agreed services. This also applies if the client passes on work results - in full or in extracts - to third parties in accordance with clause 11.4.

5. Performance periods/dates

5.1 The contractually agreed periods/dates of performance are based on estimates of the work involved which are prepared in line with the details provided by the client. They shall only be binding if being confirmed as binding by TÜV Rheinland in writing.

5.2 If binding periods of performance have been agreed, these periods shall not commence until the client has submitted all required documents to TÜV Rheinland.

5.3 Articles 5.1 and 5.2 also apply, even without express approval by the client, to all extensions of agreed periods/dates of performance not caused by TÜV Rheinland.

5.4 TÜV Rheinland is not responsible for a delay in performance, in particular if the client has not fulfilled his duties to cooperate in accordance with clause 6.1 or has not done so in time and, in particular, has not provided TÜV Rheinland with all documents and information required for the performance of the service as specified in the contract.

5.5 If the performance of TÜV Rheinland is delayed due to unforeseeable circumstances such as force majeure, strikes, business disruptions, governmental regulations, transport obstacles, etc., TÜV Rheinland is entitled to postpone performance for a reasonable period of time which corresponds at least to the duration of the hindrance plus any time period which may be required to resume performance.

6. The client's obligation to cooperate

6.1 The client shall guarantee that all cooperation required on its part, its agents or third parties will be provided in good time and at no cost to TÜV Rheinland.

6.2 Design documents, supplies, auxiliary staff, etc. necessary for performance of the services shall be made available free of charge by the client. Moreover, collaborative action of the client must be undertaken in accordance with legal provisions, standards, safety regulations and accident prevention instructions. And the client represents and warrants that:

a) it has required statutory qualifications;

b) the product, service or management system to be certified complies with applicable laws and regulations; and

c) it doesn't have any illegal and dishonest behaviours or is not included in the list of Enterprises with Serious Illegal and Dishonest Acts of People's Republic of China.

If the client breaches the aforesaid representations and warranties, TÜV Rheinland is entitled to i) immediately terminate the contract/order without prior notice; and ii) withdraw the issued testing report/certificates if any.

6.3 The client shall bear any additional cost incurred on account of work having to be redone or being delayed as a result of late, incorrect or incomplete information provided by or lack of proper cooperation from the client. Even where a fixed or maximum price is agreed, TÜV Rheinland shall be entitled to charge extra fees for such additional expense.

7. Prices

7.1 If the scope of performance is not laid down in writing when the order is placed, invoicing shall be based on costs actually incurred. If no price is agreed in writing, invoicing shall be made in accordance with the price list of TÜV Rheinland valid at the time of performance.

7.2 Unless otherwise agreed, work shall be invoiced according to the progress of the work.

7.3 If the execution of an order extends over more than one month and the value of the contract or the agreed fixed price exceeds €2,500.00 or equivalent value in local currency, TÜV Rheinland may demand payments on account or in instalments.

8. Payment terms

8.1 All invoice amounts shall be due for payment without deduction on receipt of the invoice. No discounts and rebates shall be granted.

8.2 Payments shall be made to the bank account of TÜV Rheinland as indicated on the invoice, stating the invoice and client numbers.

8.3 In cases of default of payment, TÜV Rheinland shall be entitled to claim default interest at the applicable short term loan interest rate publicly announced by a reputable commercial bank in the country where TÜV Rheinland is located. At the same time, TÜV Rheinland reserves the right to claim further damages.

8.4 Should the client default in payment of the invoice despite being granted a reasonable grace period, TÜV Rheinland shall be entitled to cancel the contract, withdraw the certificate, claim damages for non-performance and refuse to continue performance of the contract.

8.5 The provisions set forth in article 8.4 shall also apply in cases involving returned cheques, cessation of payment, commencement of insolvency proceedings against the client's assets or cases in which the commencement of insolvency proceedings has been dismissed due to lack of assets.

8.6 Objections to the invoices of TÜV Rheinland shall be submitted in writing within two weeks of receipt of the invoice.

8.7 TÜV Rheinland shall be entitled to demand appropriate advance payments.

8.8 TÜV Rheinland shall be entitled to raise its fees at the beginning of a month if overheads and/or purchase costs have increased. In this case, TÜV Rheinland shall notify the client in writing of the rise in fees. This notification shall be issued one month prior to the date on which the rise in fees shall come into effect (period of notice of changes in fees). If the rise in fees remains under 5% per contractual year, the client shall not have the right to terminate the contract. If the rise in fees exceeds 5% per contractual year, the client shall be entitled to terminate the contract by the end of the period of notice of changes in fees. If the contract is not terminated, the changed fees shall be deemed to have been agreed upon by the time of the expiry of the notice period.

8.9 Only legally established and undisputed claims may be offset against claims by TÜV Rheinland.

9. Acceptance of work

9.1 Any part of the work result ordered which is complete in itself may be presented by TÜV Rheinland for acceptance as an instalment. The client shall be obliged to accept it immediately.

9.2 If acceptance is required or contractually agreed in an individual case, this shall be deemed to have taken place two (2) weeks after completion and handover of the work, unless the client refuses acceptance within this period stating at least one fundmental breach of contract by TÜV Rheinland.

9.3 The client is not entitled to refuse acceptance due to insignificant breach of contract by TÜV Rheinland.

9.4 If acceptance is excluded according to the nature of the work performance of TÜV Rheinland, the completion of the work shall take its place.

9.5 If the client was unable to make use of the time windows provided for within the scope of a certification procedure for auditing/performance by TÜV Rheinland and the certificate is therefore to be withdrawn (e.g. performance of surveillance audits), TÜV Rheinland is entitled to immediately charge a lump-sum compensation of 10% of the order amount as compensation for expenses. The client reserves the right to prove that the TÜV Rheinland has incurred no damage whatsoever or only a considerably lower damage than the above lump sum.

9.6 Insofar as the client has undertaken in the contract to accept services, TÜV Rheinland shall also be entitled to charge lump-sum damages in the amount of 10% of the order amount as compensation for expenses if the service is not called within one year after the order has been placed. The client reserves the right to prove that the TÜV Rheinland has incurred no damage whatsoever or only a considerably lower damage than the above mentioned lump sum.

10. Confidentiality

10.1 For the purpose of these terms and conditions, "confidential information" means all information, documents, images, drawings, know-how, data, samples and project documentation which one party (the "disclosing party") hands over, transfers or otherwise discloses to the other party (the "receiving party"), and the confidential information created during performance of work by TÜV Rheinland, including product testing data, defects, conformity to the technical standard and related reports. Confidential information also includes paper copies and electronic copies of such information. Confidential information is expressly not the data and know-how collected, compiled or otherwise obtained by TÜV Rheinland (non-personal) within the scope of the provision of services by TÜV Rheinland. TÜV Rheinland is entitled to store, use, further develop and pass on the data obtained in connection with the provision of services for the purposes of developing new services, improving services and analysing the provision of services.

10.2 The disclosing party shall mark all confidential information disclosed in written form as confidential before passing it onto the receiving party. The same applies to confidential information transmitted by e-mail. If confidential information is disclosed orally, the receiving party shall be appropriately informed in advance and the disclosing party shall confirm in writing the confidentiality nature of the information within five working days of oral disclosure. Where the disclosing party fails to do so within the stipulated period, the receiving party shall not take any confidentiality obligations hereunder towards such information.

10.3 All confidential information which the disclosing party transmits or otherwise discloses to the receiving party and which is created during performance of work by TÜV Rheinland:

a) may only be used by the receiving party for the purposes of performing the contract, unless expressly otherwise agreed in writing by the disclosing party;

b) may not be copied, distributed, published or otherwise disclosed by the receiving party, unless this is necessary for fulfilling the purpose of the contract or TÜV Rheinland is required to pass on confidential information, inspection reports or documentation to the government authorities, judicial court, accreditation bodies or third parties that are involved in the performance of the contract;

c) must be treated by the receiving party with the same level of confidentiality as the receiving party uses to protect its own confidential information, but never with a lesser level of confidentiality than that which is reasonably required.

10.4 The receiving party may disclose any confidential information received from the disclosing party only to those of its employees who need this information to perform the services required for the contract. The receiving party undertakes to oblige these employees to observe the same level of secrecy as set forth in this confidentiality clause.

10.5 Information for which the receiving party can furnish proof that:

a) it was generally known at the time of disclosure or has become general knowledge without violation of this confidentiality clause by the receiving party; or

b) it was disclosed to the receiving party by a third party entitled to disclose this information; or

c) the receiving party already possessed this information prior to disclosure by the disclosing party; or

d) the receiving party developed it itself, irrespective of disclosure by the disclosing party, shall not be deemed to constitute "confidential information" as defined in this confidentiality clause.

10.6 All confidential information shall remain the property of the disclosing party. The receiving party hereby agrees to immediately (i) return all confidential information, including all copies, to the disclosing party, and/or (ii) on request by the disclosing party, to destroy all confidential information, including all copies, and confirm the destruction of this confidential information to the disclosing party in writing, at any time if so requested by the disclosing party but at the latest and without special request after termination or expiry of the contract. This does not extend to include reports and certificates prepared for the client solely for the purpose of fulfilling the obligations under the contract, which shall remain with the client. However, TÜV Rheinland is entitled to make file copies of such reports, certificates and confidential information that forms the basis for preparing these reports and certificates in order to evidence the correctness of its results and for general documentation purposes required by laws, regulations and the requirements of working procedures of TÜV Rheinland.

10.7 From the start of the contract and for a period of three years after termination or expiry of the contract, the receiving party shall maintain strict secrecy of all confidential information and shall not disclose this information to any third parties or use it for itself.

11. Copyrights and rights of use, publications

11.1 TÜV Rheinland shall retain all exclusive copyrights in the reports, expert reports/opinions, test reports/results, results, calculations, presentations etc. prepared by TÜV Rheinland, unless otherwise agreed by the parties in a separate agreement. As the owner of the copyrights, TÜV Rheinland is free to grant others the right to use the work results for individual or all types of use ("right of use")

11.2 The client receives a simple, unlimited, non-transferable, non-sublicensable right of use to the contents of the work results produced within the scope of the contract, unless otherwise agreed by the parties in a separate agreement.The client may only use such reports, expert reports/opinions, test reports/results, results calculations, presentations etc. prepared within the scope of the contract for the contractually agreed purpose.

11.3 The transfer of right of use of the generated work results regulated in clause 11.2. of the GTCB is subject to full payment of the remuneration agreed in favour of TÜV Rheinland.

11.4 The client may use work results only complete and unshortened. The client may only pass on the work results in full unless TÜV Rheinland has given its prior written consent to the partial passing on of work results.

11.5 Any publication or duplication of the work results for advertising purposes or any further use of the work results beyond the scope regulaed in clause 11.2 needs the prior written approval of TÜV Rheinland in each individual case.

11.6 TÜV Rheinland may revoke a once given approval according to clause 11.5 at any time without stating reasons. In this case, the client is obliged to stop the transfer of the work results immediately at his own expense and, as far as possible, to withdraw publications.

11.7 The consent of TÜV Rheinland to publication or duplication of the work results does not entitle the client to use the corporate logo, corporate design or test/certification mark of TÜV Rheinland.

12. Liability of TÜV Rheinland

12.1 Irrespective of the legal basis, to the fullest extent permitted by applicable law, in the event of a breach of contractual obligations or tort, the liability of TÜV Rheinland for all damages, losses and reimbursement of expenses caused by TÜV Rheinland, its legal representatives and/or employees shall be limited to: (i) in the case of a contract with a fixed overall fee, three times the overall fee for the entire contract; (ii) in the case of a contract for annually recurring services, the agreed annual fee; (iii) in the case of a contract expressly charged on a time and material basis, a maximum of 20,000 Euro or equivalent amount in local currency; and (iv) in the case of a framework agreement that provides for the possibility of placing individual orders, three times of the fee for the individual order under which the damages or losses have occurred. Notwithstanding the above, in the event that the total and accumulated liability calculated according to the foregoing provisions exceeds 2.5 Million Euro or equivalent amount in local currency, the total and accumulated liability of TÜV Rheinland shall be only limited to and shall not exceed the said 2.5 Million Euro or equivalent amount in local currency.

12.2 The limitation of liability according to article 12.1 above shall not apply to damages and/or losses caused by malice, intent or gross negligence on the part of TÜV Rheinland or its vicarious agents. Such limitation shall not apply to damages for a person's death, physical injury or illness.

12.3 In cases involving a fundamental breach of contract, TÜV Rheinland will be liable even where minor negligence is involved. For this purpose, a "fundamental breach" is breach of a material contractual obligation, the performance of which permits the due performance of the contract. Any claim for damages for a fundamental breach of contract shall be limited to the amount of damages reasonably foreseen as a possible consequence of such breach of contract at the time of the breach (reasonably foreseeable damages), unless any of the circumstances described in article 12.2 applies.

12.4 TÜV Rheinland shall not be liable for the acts of the personnel made available by the client to support TÜV Rheinland in the performance of its services under the contract, unless such personnel made available is regarded as vicarious agent of TÜV Rheinland. If TÜV Rheinland is not liable for the acts of the personnel made available by the client under the foregoing provision, the client shall indemnify TÜV Rheinland against any claims made by third parties arising from or in connection with such personnel's acts.

12.5 Unless otherwise contractually agreed in writing, TÜV Rheinland shall only be liable under the contract to the client.

12.6 The limitation periods for claims for damages shall be based on statutory provisions.

12.7 None of the provisions of this article 12 changes the burden of proof to the disadvantage of the client.

13. Export control

13.1 When passing on the services provided by TÜV Rheinland or parts thereof to third parties in Greater China or other regions, the client must comply with the respectively applicable regulations of national and international export control law.

13.2 The performance of a contract with the client is subject to the proviso that there are no obstacles to performance due to national or international foreign trade legislations or embargos and/or sanctions. In the event of a violation, TÜV Rheinland shall be entitled to terminate the contract with immediate effect and the client shall compensate for the losses incured thereof by TÜV Rheinland.

14. Data protection notice

TÜV Rheinland processes personal data of the client for the purpose of fulfilling this contract. In addition, TÜV Rheinland also processes the data for other legal purposes in accordance with the relevant legal basis. The personal data of the client will only be disclosed to other natural or legal persons if the legal requirements are met. This also applies to transfers to third countries. The personal data will be deleted immediately as soon as a corresponding reason for deletion arises. Data subjects may exercise the following rights: right of information, right of rectification, right of deletion, right of processing limitation, right of objection, right of data transferability. In addition, persons concerned by the data processing have the right to revoke their consent at any time with effect for the future, as well as the right to file a complaint with the competent data protection supervisory authority. For further details on the processing of personal data by TÜV Rheinland as the person responsible or contract processor, please refer to the respective data protection information. You can contact the Group Data Protection Officer of TÜV Rheinland by e-mail at datenschutz@de.tuv.com or by post at the following address: TÜV Rheinland AG, c/o Group Data Protection Officer, Am Grauen Stein, 51105 Cologne, Germany.

15. Test material: transport risk and storage

15.1 The risk and costs for freight and transport of documents or test material to and from TÜV Rheinland as well as the costs of necessary disposal measures shall be borne by the client.

15.2 Any destroyed and otherwise worthless test material will be disposed of by TÜV Rheinland for the client at the expense of the client, unless otherwise agreed.

15.3 Undamaged test material shall be stored by TÜV Rheinland for four (4) weeks after completion of the test. If a longer storage period is desired, TÜV Rheinland charges an appropriate storage fee.

15.4 After the expiry of the 4 weeks or any longer period agreed upon, the test material will be disposed of by TÜV Rheinland for the client for a fee in accordance with clause 15.2.

16. Termination of the contract

16.1 Notwithstanding clause 3.3 of the GTCB, TÜV Rheinland and the client are entitled to terminate the contract in its entirety or, in the case of services combined in one contract, each of the combined parts of the contract individually and independently of the continuation of the remaining services with six (6) months' notice to the end of the contractually agreed term.

16.2 For good causes, TÜV Rheinland may consider giving a written notice to the client to terminate the contract which includes but not limited to the following:

a) the client does not immediately notify TÜV Rheinland of changes in the conditions within the company which are relevant for certification or signs of such changes;

b) the client misuses the certificate or certification mark or uses it in violation of the contract;

c) in the event of several consecutive delays in payment (at least three times);

d) a substantial deterioration of the financial circumstances of the client occurs and as a result the payment claims of TÜV Rheinland under the contract are considerably endangered and TÜV Rheinland cannot reasonably be expected to continue the contractual relationship.

16.3 In the event of termination with written notice by TÜV Rheinland for good cause, TÜV Rheinland shall be entitled to a lump-sum claim for damages against the client if the conditions of a claim for damages exist. In this case, the client shall owe 15% of the remuneration to be paid until the end of the fixed contract term as lump-sum compensation. The client reserves the right to prove that there is no damage or a considerably lower damage, TÜV Rheinland reserves the right to prove a considerably higher damage in individual cases.

16.4 TÜV Rheinland is also entitled to terminate the contract with written notice if the client has not been able to make use of the time windows for auditing /service provision provided by TÜV Rheinland within the scope of a certification procedure and the certificate therefore has to be withdrawn (for example during the performance of monitoring audits). Clause 16.3 applies accordingly.

17. Partial invalidity, written form, place of jurisdiction and dispute resolution

17.1 All amendments and supplements must be in writing in order to be effective. This also applies to amendments and supplements to this clause 17.1.

17.2 Should one or several of the provisions under the contract and/or these terms and conditions be or become ineffective, the contracting parties shall replace the invalid provision with a legally valid provision that comes closest to the content of the invalid provision in legal and commercial terms.

17.3 Unless otherwise stipulated in the contract, the governing law of the contract and these terms and conditions shall be chosen following the rules as below:

a) if TÜV Rheinland in question is legally registered and existing in the People's Republic of China, the contracting parties hereby agree that the contract and these terms and conditions shall be governed by the laws of the People's Republic of China.

b) if TÜV Rheinland in question is legally registered and existing in Taiwan, the contracting parties hereby agree that the contract and these terms and conditions shall be governed by the laws of Taiwan.

c) if TÜV Rheinland in question is legally registered and existing in Hong Kong, the contracting parties hereby agree that the contract and these terms and conditions shall be governed by the laws of Hong Kong.

17.4 Any dispute in connection with the contract and these terms and conditions or the execution thereof shall be settled friendly through negotiations. Unless otherwise stipulated in the contract, if no settlement or no agreement in respect of the extension of the negotiation period can be reached within two months of the arising of the dispute, the dispute shall be submitted:

a) in the case of TÜV Rheinland in question being legally registered and existing in the People's Republic of China, to China International Economic and Trade Arbitration Commission (CIETAC) to be settled by arbitration under the Arbitration Rules of CIETAC in force when the arbitration is submitted. The arbitration shall take place in Beijing, Shanghai, Shenzhen or Chongqing as appropriately chosen by the claiming party.

b) in the case of TÜV Rheinland in question being legally registered and existing in Taiwan, to Chinese Arbitration Association Taipei Branch to be arbitrated in accordance with its then current Rules of Arbitration. The arbitration shall take place in Taipei.

c) in the case of TÜV Rheinland being legally registered and existing in Hong Kong, to Hong Kong International Arbitration Centre (HKIAC) to be settled by arbitration under the HKIAC Administered Arbitration Rules in force when the Notice of Arbitration is submitted in accordance with these rules. The arbitration shall take place in Hong Kong.

The decision of the relevant arbitration tribunal shall be final and binding on both parties. The arbitration fee shall be borne by the losing party.

May 2019

TÜV Rheinland (Shanghai) Co., Ltd., Shanghai TüV Rheinland Building, No. 177 , Lane 777, West Guangzhong Road, Jing'an District,
Shanghai, 200072, P.R.China
Tel +86 21 6108 1188 Fax +86 21 6108 1099 Mail: service-gc@tuv.com Web: www.tuv.com

Test Report 3220780.

Sunbeam International GmbH

Introduction.

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

Job/Registration Details		Client Details
Job number:	3220780	Sunbeam International GmbH Schumanstr. 12 Würselen 52146 Germany
Job type:	Testing Samples Submitted	
Start Date:	27/05/2020	
Test type:	Type	
Sample ID:	10190222	
Registration:	CE 730303	
Scheme:	Positive pressure RPE	
Protocol:	PP123	
Scheme Manager:	Nathan Shipley	

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

Approved For Issue	
	Issue Date: 17 June 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 26 May 2020 and the testing was started on 27 May 2020.

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

Test Samples.

Sample ID	ER Number	Description
1 to 19	10190222	Model: HYGISUN HS0501A FFP2

Description of Test Samples.

Sample Description
COVID-19 masks for use by healthcare workers: Model: HYGISUN HS0501A FFP2

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	
RF1	1 AR	OK	OK	OK	None	Pass
AH1	2 AR	OK	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. Pass

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).

Table B: Clause 7.9.1 - Total inward leakage

Test candidate	Sample	Pre test condition	Inward Leakage (%)						Assessment
			A	B	C	D	E	Average	
			Walking	Walking with head side to side	Walking with head up & down	Walking and talking	Walking		
GR1	3	AR	3.07	3.90	3.05	2.07	3.01	3.02	Pass
BH2	4	AR	4.76	6.77	6.65	6.33	6.29	6.16	Pass
JT1	5	AR	0.44	0.58	0.57	0.44	0.61	0.53	Pass
JS2	6	AR	10.08	0.58	0.68	0.33	0.47	2.43	Pass
BH1	7	AR	3.28	0.83	5.05	3.08	4.64	3.38	Pass

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	0.330
9	AR			0.409
10	AR			0.234

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	1.125
12	AR			1.202
13	AR			2.496

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	0.48
15	AR		0.50
16	AR		0.52

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	0.42
18	AR			0.47
19	AR			0.40
17	AR	95	< 2.4	1.33
18	AR			1.50
19	AR			1.26

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	2.05
18	AR			2.40
19	AR			1.98

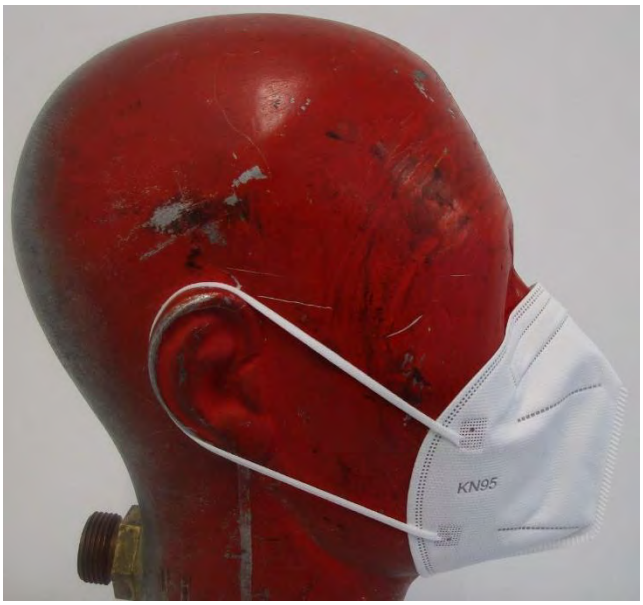
Appendix A. – Test Panel Data

Test Candidate	Facial Dimensions (mm)					Sex
	Length of face	Width of face	Face depth	Width of mouth	Head Circumference	
RF1	104	122	121	55	549	Male
AH1	108	124	130	46	570	Male
GR1	124	145	126	49	590	Male
BH2	124	148	120	51	595	Male
JT1	130	140	118	44	589	Male
JS2	126	142	125	57	575	Male
BH1	120	126	120	58	565	Male

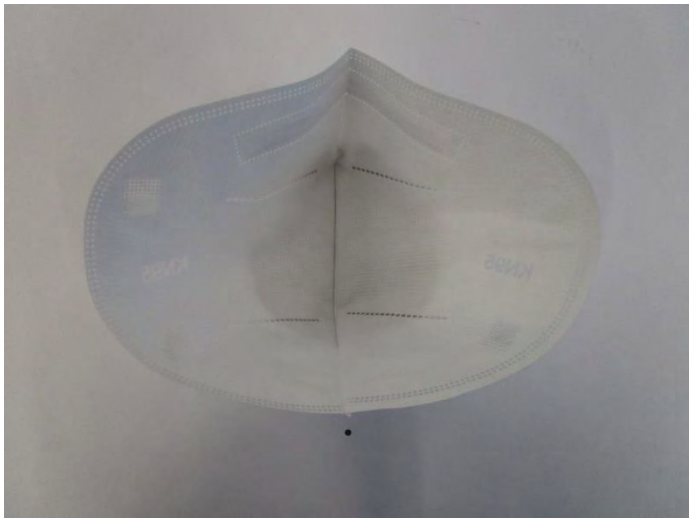
Note: All candidates were clean shaven

Product photographs.

Front view



Side View



Inside View

End of Report

EU Type Examination Certificate

This is to certify that:

Sunbeam International GmbH
Schumanstr. 12
Würselen
52146
Germany

Holds Certificate Number: CE 730303

In respect of:

Model HYGISUN HS0501A Face mask
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: 2020-07-03

Effective Date: 2020-07-03

Latest Issue: 2020-07-03

Expiry Date: 2021-07-03

PRODUCTS
RvA C 646

...making excellence a habit.™

EU Type Examination Certificate

No. CE 730303

Product Specification

Product Name:	Particulate Respirator.
Product Type:	Particulate filtering half masks for use by Healthcare professionals.
Model:	**HYGISUN HS0501A.**
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: 2020-07-03
Latest Issue: 2020-07-03

Effective Date: 2020-07-03
Expiry Date: 2021-07-03

EU Type Examination Certificate

No. CE 730303

Certificate Administration Details

Technical File Reference: Sunbeam International GmbH, TCF.01, V0 dated 28/06/2020.

Certificate Amendment Record:

Issue date	Comments	BSI Review No.
July 2020	First issue.	2797:20:3220783

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 730304.

First Issued: 2020-07-03
Latest Issue: 2020-07-03

Effective Date: 2020-07-03
Expiry Date: 2021-07-03

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

This is to certify that:

Sunbeam International GmbH
Schumanstr. 12
Würselen
52146
Germany

Holds Certificate Number: CE 730304

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: 2020-07-03

Effective Date: 2020-07-03

Latest Issue: 2020-07-03

Expiry Date: 2021-07-03

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 730304

Product manufactured by:

Hunan Dreaming Cloud E-Commerce CO., Ltd
Block 1, Smart Tech Park,
57# Huangxing Avenue,
Changsha Economic and Technological Development Zone,
Changsha,
Hunan,
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:	HYGISUN HS0501A 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: 2020-07-03
Latest Issue: 2020-07-03

Effective Date: 2020-07-03
Expiry Date: 2021-07-03

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

No. CE 730304

Certificate Administration Details:

Certificate Amendment Record and BSI internal Review relating to this Certificate

Issue date	Comments	BSI Review No.
July 2020	First issue.	2797:20:3220784

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: 2020-07-03
Latest Issue: 2020-07-03

Effective Date: 2020-07-03
Expiry Date: 2021-07-03

HYBETA
HYGIENE · BERATUNG · TECHNISCHE ANALYSEN

Bestimmung des Abscheidegrades von neuen Masken **Prüfbericht: HYBETA_NM_0346**

Datum der Prüfung: 27.07.2020

Auftraggeber

Sunbeam International GmbH
Daniel Cmelak
Schumannstraße 12
52146 Würselen

Auftragnehmer

HYBETA GmbH
Nevinghoff 20
48147 Münster

Prüfgegenstand

HYGISUN
Ref. HSO501A
FFP2 Mask
EN 149:2001 + A1:2009
CE 2797

Messumfang

Es liegen fünf neue Masken vor.

Bestimmung des Abscheidungsgrades

Zur Bestimmung des Abscheidungsgrades werden die Masken in eine Messvorrichtung eingespannt und je Maske drei Partikelmessungen á einer Minute durchgeführt. Betrachtet werden hierbei die Partikelgrößen 0,3 µm, 0,5 µm, 1,0 µm, 3,0 µm und 5,0 µm.

Größere Partikel können Tröpfchen repräsentieren, die als Infektionsquelle bei Tröpfcheninfektionen eine entscheidende Rolle spielen. Die kleinen Partikel sind relevant, wenn Aerosole als Infektionsquelle in Frage kommen. Eine eindeutige Definition der Größe von relevanten Tröpfchen und Aerosolen liegt nicht vor.

Bei der Partikelprüfung wird der Abscheidegrad der Masken für die oben aufgeführten Partikelgrößen ermittelt und gegen die in der Rohluft vorhandene Konzentration verglichen.Für die Bewertung der Ergebnisse gibt es keine normative oder andere regulative Grundlage und kann somit nur subjektiv erfolgen. Die Werte wurden in Anlehnung an die DIN EN 149:2009-08 Tabelle 1 gewählt. Dort ist der maximale Durchlass des Prüfaerosols
·bei FFP2-Masken mit 6 % (=94 % Abscheidegrad Filtermedium)
·bei FFP3-Masken mit 1 % (=99 % Abscheidegrad Filtermedium)
definiert. KN95-Masken werden mit einem Abscheidegrad von 95 % des Filtermediums bewertet.

Die Bewertung der Ergebnisse liegt allein beim Auftraggeber. Eine Bewertung eines Ausatemventils wird nicht vorgenommen.

Die Prüfung des Abscheidegrades von luftgetragenen Partikeln ist lediglich eine orientierende Messung und ersetzt keine Prüfung der Masken nach DIN EN 149.

Mittelwert der Rohluft

	Partikel [µm]				
Maske	*0,3*	*0,5*	*1*	*3*	*5*
Rohluft	908.701	404.296	196.362	1.872	219

Mittelwerte der Masken

	Partikel [µm]					Abscheidegrad [%]				
Maske	*0,3*	*0,5*	*1*	*3*	*5*	*0,3*	*0,5*	*1*	*3*	*5*
N1	65.257	5.092	257	0	0	92,8%	98,7%	99,9%	100,0%	100,0%
N2	70.493	4.454	208	0	0	92,2%	98,9%	99,9%	100,0%	100,0%
N3	82.946	4.706	211	0	0	90,9%	98,8%	99,9%	100,0%	100,0%
N4	73.281	3.874	238	0	0	91,9%	99,0%	99,9%	100,0%	100,0%
N5	65.353	3.397	139	0	0	92,8%	99,2%	99,9%	100,0%	100,0%

Rohdaten Abscheidegrad

Messgegenstand	Zeit	Messpunkt	Probe-nahmezeit(s)	Volumen (FT3)	0.3	0.5	1.0	3.0	5.0
rohluft	27.07.2020 14:06	6	60	1.00	814265	418700	206764	2179	331
rohluft	27.07.2020 14:07	6	60	1.00	803527	407939	202122	1989	209
rohluft	27.07.2020 14:08	6	60	1.00	862703	455790	227171	2337	201
n1	27.07.2020 14:09	7	60	1.00	62804	4991	258	0	0
n1	27.07.2020 14:10	7	60	1.00	64414	4917	255	0	0
n1	27.07.2020 14:11	7	60	1.00	68554	5367	257	0	0
n2	27.07.2020 14:13	8	60	1.00	64105	4282	222	1	0
n2	27.07.2020 14:14	8	60	1.00	69867	4341	200	0	0
n2	27.07.2020 14:15	8	60	1.00	77507	4740	202	0	0
n3	27.07.2020 14:16	9	60	1.00	82058	4821	212	0	0
n3	27.07.2020 14:17	9	60	1.00	82124	4555	216	0	0
n3	27.07.2020 14:18	9	60	1.00	84656	4743	205	0	0
rohluft	27.07.2020 14:20	10	60	1.00	984953	405505	195319	1880	253
rohluft	27.07.2020 14:21	10	60	1.00	993760	415693	199958	1879	227
rohluft	27.07.2020 14:22	10	60	1.00	983745	409910	196663	1841	177
n4	27.07.2020 14:23	11	60	1.00	73053	3792	240	0	0
n4	27.07.2020 14:24	11	60	1.00	73285	3873	225	0	0
n4	27.07.2020 14:25	11	60	1.00	73506	3957	249	0	0
n5	27.07.2020 14:27	12	60	1.00	65178	3346	156	0	0
n5	27.07.2020 14:28	12	60	1.00	65271	3369	124	0	0
n5	27.07.2020 14:29	12	60	1.00	65611	3477	136	0	0
rohluft	27.07.2020 14:30	13	60	1.00	879762	338728	159920	1371	175
rohluft	27.07.2020 14:31	13	60	1.00	936114	399278	192779	1758	200
rohluft	27.07.2020 14:32	13	60	1.00	919476	387118	186565	1614	200