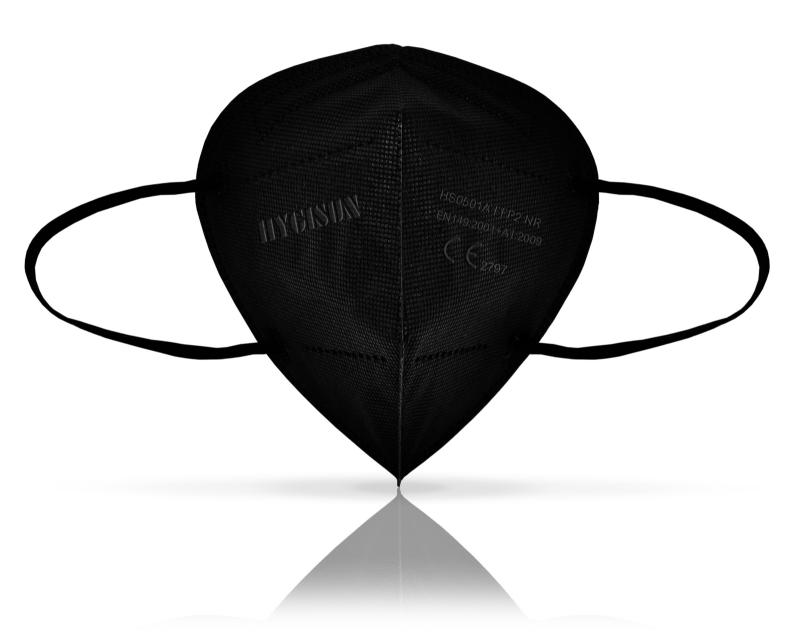
HYGISUN

REF HS0501A



FFP2 Mask Non Medical

EN149: 2001+A1: 2009



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



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



Testen Sie die Passform. Nehmen Sie beide Hände

atmen Sie kräftig aus. Wenn Luft um Ihre Nase strömt, ziehen Sie den Bügel fester.

Hinweis zur Verwendung:

Produkt nicht in der Nähe einer

- 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

- Verwenden Sie einzeln verpackte Produkte, sobald diese ausgepackt sind.











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, 07.04.202

Ouyang Zhouya

(Nachname Name)

Qualitätsmanager

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

(Surname, Name)

Quality Manager

Hunan Dreaming Cloud E-Commerce CO., Ltd.

() Wany Thou

取得国外标准认证或注册的非医用口罩生产企业清单 Name List of Non-Medical Use Face Masks Companies with

序 号 No.	生产企业 Company	统一社会信用代码 Uniform Social Credit Code	国外注册认证情况 Status of Certification / Authorization in Other Countires
977	非形外列維外使有限公司 Lonyang Kelijian Technology Co.,Ltd.	91410500MA401BXVIII	German Mark EUA
378	公共市市路款主义各生限公司 Xianton Qianteng Life Sering Equipment Co.,Ltd.	93H29OHHMA49ABOLSF	CE
379	湖南云想生活电子商务有限公司 Hunan Dreaming Cloud E-Commerce CO., Ltd	91430105MA4LAAUW8C	СЕ
380	建分泌表用医疗用品有限企用 Linnyungang Meidhun Modlerd Supplies Co., Ltd.	91320724596800367H	CE
	京市海北區行基础市联合司 Sheijing Housey Medical Apparatus and Instruments On,Ltd.	91320136MA20W230948	CE CE
582	江京岛速度等有限公司 Sangan Daoying Clothing Co., Ltd	91100921MATNIGUE28	cz





Test Report No.: 244275321a 001 Page 1 of 7

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: Test Result

EN 149:2001 + A1:2009 Respiratory Protective Devices – Filtering Half Masks Please refer to next page to Protect against particles- Requirements, testing, marking

For and on behalf of

TÜV Rheinland (Shanghai) Co., Ltd.

2020-12-07 Candy Jiang/ Section Manager

Croy Jiang

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



Page 2 of 7

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 F = Below Performance Standard

Material list

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



Page 3 of 7

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.						
	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					
7.5	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										
		Chaoiman	Leakage (%)								
Subject	Condition	Specimen No.	Walk	Head Side/side	Head Up/down	Talk	Walk	Mean			
BM		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	As received	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		6	5.632	6.821	7.964	8.148	6.883	7.090			
YL	Λ £ £ 6 	7	7.643	7.211	8.143	8.621	6.964	7.716			
KQ	After	8	6.845	7.004	7.962	8.047	7.012	7.374			
KXH	conditioning	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				
	As received	1	1.1					
Afterflame time	As received	2	1.3	Pass				
(s)	After conditioning	3	1.4					
	After conditioning	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 (0/)	As resolved	Specimen 1	Specimen 2	Specimen 3	Mean	Door			
Content (%)	As received	0.62	0.63	0.64	0.63	Pass			



Page 5 of 7

6. Breathing Resistance

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

FFP2:

Requirement Inhalation: 30l/min: ≤0.7mbar

Inhalation: 95l/min: ≤2.4mbar Exhalation: 160l/min:≤3.0mbar

	M001															
Flow rate (I	/min)		Resistance (mbar)													
A a receive	,		Sp	ecime	n 1			Sp	ecime	n 2			Sp	ecime	n 3	
As receiv	eu	Α	В	С	D	Е	Α	В	C	D	Е	Α	В	С	D	Е
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
IIIIaiation	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			Specimen 4				Specimen 5			Specimen 6						
wearing trea	tment	Α	В	С	D	Е	Α	В	O	D	Е	Α	В	С	D	Е
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
IIIIaiation	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
Temperat	ure		Sp	ecime	n 7			Sp	ecime	n 8			Sp	ecime	n 9	
condition	ed	Α	В	С	D	Е	Α	В	O	D	Е	Α	В	С	D	Е
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
IIIIaiation	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



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7. Penetration Of Filter Material

Test method : EN 149:2001+A1:2009 Clause 8.11

Requirement : FFP2:≤6%

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



Page 7 of 7

Photo:





END -

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

- 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 goljicable as the case may be ("TÜV Rheinland"). The Greater China has goljicable as the Maniland China, Hong Kong and Talwan. The client hereof refers to Maniland China, Hong Kong and Talwan. The client hereof includes: a natural person capable to form legally brinding contracts under the applicable leave Mic concludes the contract not for the purpose of a daily specificable with the concludes the contract not for the purpose of a daily specificable with the concludes the contract not for the purpose of a daily specificable with the concludes the contract not for the purpose of a daily specificable with the concludes the contract not for the purpose of a daily specificable with the concludes the contract of the form the contract of t
- substitute teams who do until color the character of the component of the character of unincorporated entity duly organized, vailed yeating and capable to form legally binding contracts under the applicable law. The following team and conditions agily to agreed services including an accordance of the contract of the contract of the contract performance. Any standard terms and conditions of the client of any nature shall not apply and shall hereby be expressly excluded. No standard contractable terms and conditions of the client of any nature shall not apply and shall hereby be expressly excluded. No standard contractable terms and conditions of the client of any nature shall not apply and shall hereby be expressly excluded. No standard contractable terms and conditions of the contract dear contract and the contract and the contract of the contract of the contract of an ongoing business relationship with the client. this GTCB shall also apply to future contracts with the client without TUV Rheinland having to refer to them separately in each individual case. 1.2

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.

- vorming into effect and outration of contracts.

 The contract shall come into effect for the agreed terms upon the quotatic letter of TUV Rheinland or a separate contractual document being signed both contracting panties, or upon the works requested by the client being representation of the contract o
- contract.
 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. 3.3

- 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. In so 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.

- intent the written contribution or of order by 1 UV intensinan state to excesse by the contribution or of order by 1 UV intensinan state to excesse the three agreed are contributed in compliance with the regulations in force at the time the contract is entered into.

 TUV 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.

 The provisions require a specific procedure to be followed.

 The provisions require a specific procedure to be followed.

 The provisions require a specific procedure to be followed.

 The provisions require a specific procedure 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 he installation is 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.

 The case of impection work TÜV Rheinland shall not be responsible for
- 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
- the accusary of checking on the salety programmes of salety regulations or writing.

 Incidence in the salety in the sal

Performance periods/dates

- 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 beliefly agreed periods/dates of performance are based on estimates of the work involved which are prepared in line with the details beliefly growthmed as binding by TÜV Rheinland in writing.
 5. If binding periods of performance have been agreed, these periods shall not commence until the client has submitted all required documents to TÜV 10. A felicie 6.5 In 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 in not responsible for a delay in performance, in particular if the client has not fulfilled his daties to cooperate in accordance with clause 6.1 Rheinland with all documents and information required for the performance of the service as specified in the contract.

 5.51 the performance of TÜV Rheinland is delayed due to unforeseeable cricicumstances such as force majeure, strikes, business directions in extractions of the service as specified in the contract.

 6. The clients obtained to drugting the performance.

 6. The clients obtained in cooperate.

The client's obligation to cooperate

- 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.
- 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, safely regulations and accident prevention instructions. And the client represents and warrants have

- b) the product, service or management system to be certified complies with applicable laws and regulations; and
- 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.
- Reclient 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.
- 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, TUV Rheinland shall be entitled to charge extra fees for such additional expense.

- 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 a greed in writing, invoicing shall be made in accordance with the price list of TUV Prinelland vasid at the time of performance. TuV Prinelland vasid at the time of performance, and appeals of the work of the work.

 If the execution of an order extends over more than one month and the value of the confract or the agreed fixed price exceeds C.250.00 or equivalent. 7.1
- of the work.

 If the execution of an order extends over more than one month and the value of the contract or the agreed fixed price exceeds e2,500.00 or equivalent value in local currency, TÜV Rheinland may demand payments on account or in instalments.

- All invoice amounts shall be due for payment without deduction on receipt of the invoice. No discounts and rebates shall be granted. The property of the property of the property of the property of the on the invoice, stating the invoice and client numbers. In cases of default of payment, TÜV Rheinland shall be entitled to claim default interest at the applicable short term loan interest rate publicly. 8.3
- unced by a reputable commercial bank in the country where TÜV land is located. At the same time, TÜV Rheinland reserves the right to 8.4
- Rhehland is located. At the same time, I by I well-hand is located. At the same time, I by I well-hand is located that there damages. Should the client default in payment of the invoice despite being granted a reasonable grace period. TUV Rheniland shall be entitled to cancel the contract, withdraw the certificate, claim damages for non-performance and The provisions set of thin larticle & I shall also apply in cases involving returned chaques, cessation of payment, commencement of insolvency

- of assets.

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

 TUV Rheinland shall be entitled to demand appropriate advance payments. TUV Rheinland shall be entitled to stem is fises at the beginning of a month of the control of the c

- Acceptance of work

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

 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
 stating at least one fundmental breach of contract by TUY Rheinland.

 cellent is not entitled to refuse acceptance due to insignificant breach of
 contract by TUY Rheinland.

 consistence is excluded according to the nature of the work performance of TÜV
 her interest of the cellent is a made to make the cellent was under to make use of the entitled

 election was under to make use of the other amount as compensation to the
 scope of a certification procedure for auditing-performance by TÜV
 Rheinland and the certificate is therefore to be withdrawn (e.p. performance
 of surveillance audits). TÜV Rheinland is entitled to immediately charge a
 tump-sum compensation of 10% of the order amount as compensation to

 for as the client has undersident in the contract to accept services, TÜV
 Rheinland and lais obe entitled to charge lump-sum damage in the amount
 of 10% of the order amount as compensation to respense if the service is
 reserves the right to prove that the TÜV Rheinland has langed in the amount
 of 10% of the order amount as compensation to respense if the service is
 reserves the right to prove that the TÜV Rheinland has incurred no damage
 whatsoewer or only a considerably lower damage than the above lump or the properties of these terms and conditions, "confidential information" means all

- 10. Confidential of these terms and conditions, "confidential information" means all information in the propose of these terms and conditions, "confidential information" means all project documentation which one party (the "disclosing party") hands over, and the confidential information rested during party (by the disclosing party") hands over, and the confidential information created during performance of work by TVV. Rheinland, including product testing data, defects, conformity to the technical standard and related reports. Confidential information confidential consideration or confidential information. Confidential confidential information confidential continual confidential confidential confidential confidential confid

- work by TÜV Phinishand.

 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.

 may only be used by the receiving party withing by the disclosing party.

 The property of the purpose of the contract of the purpose of the contract or TÜV Phenishand is required to pass on confidential information, inspection reports or documentation to the government authorities, judicial court, accordation bodies or third parties that are involved in the contract or TÜV Phenishand is required to pass on confidential information, inspection reports or documentation to the government authorities, judicial court, accordation bodies or third parties that are involved in the unit of the party was to protect to won confidential information, to never with a lesser level of confidentially than that which is reasonably required.

 The disclosing party only to bose of its employees who need this information be disclosing party only to bose of its employees who need this information be perform the services required for the confidential pricates with a lesser level of confidentially than that which is reasonably required.

 The disclosing party only to bose of its employees who need this information be performed to the confidential pricates by the receiving party undertakes to oblige these employees to observe the same level of secrecy as set furth in this confidentially clause by the receiving party undertakes to oblige these employees to observe the same level of secrecy as etc. the transfer of the pricate of the pr

Copyrights and rights of use, publications

10.6

- Copyrights and rights of use, publications
 TÜV Rheinland shall retain all exclusive copyrights in the reports, expert
 reports/opinion, set reports/results, results, calculations, presentations etc.
 pregnared by TÜV Rheinland, unless otherwise agreed by the parties in a
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Liability of TÜV Rheinland

- 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 inability accludated according to the foregoing provisions exceeds 2.5 Million Euro or equivalent amount in local currency, the total and not exceed the second of the control of the foregoing the foregoing the foregoing the total and not according to add 5.5 Million Euro or equivalent amount in local currency. The limitation of liability according to article 12.1 above shall not apply to damages and/or tosses caused by malco, iterator or gross negligence on the part of TIV Rheinfand or its vicenous agents. Such imitation shall not apply to loss the second of the
- available by the client to support TOV Rheinland in the performance of its services under the contract, urless such personnel make available is such contract, and the contract of the subsequence of the contract of the cont

- on the services provided by TÜV Rheinland or parts thereof to third s in Greater China or other regions, the client must comply with the ctively applicable regulations of national and international export
- assing on the services provided by TUV 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 formance of a contract with the client is subject to the provision that there are no obstacles to performance due to national or international foreign trade legislations or embargos and/or soantions. In the event of a voision, TUV Rheinland shall be entitled to terminate the contract with immediate effect and the client talk compensate for the losses incured thereof by TUV

Data protection notice

TÜV Rhieriland processes personal data of the client for the purpose of fulfilling this contract, in addition, TÜV Rhieriland also processes the data for other things the contract the purpose of fulfilling this contract, and the processes the data for other data of the client will only be disclosed to other natural or legal persons if the legal requirements are met. This also applies to transfer to third countries. The personal data will be deleted immediately as soon as a corresponding reason for deletion arises. Deletion size, but also place to transfer to the deletion arises. Deletion size, the personal data will be deleted in mediately as one as a corresponding reason for deletion arises. Deletion size, the deletion size of the contract of the deletion size of the dele

- 15.1The 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.

 stroyed and otherwise worthless test material will be disposed of by TÜV

 Rheinland for the client at the expense of the client, unless otherwise
- Rheinland for the client at the expense of the client, unless otherwise agree.
 15.3Undamaged 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.
 15.4After 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 § 5.2.

- 16.1 Notwithstanding clause 3.3 of the GTCB, TUV 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 independingly of the contractually agreed term.

 16.2For of serminate the contract which includes but not client to the client to tend the contractually agreed term.

 16.2For of serminate the contract which includes but not climited to the following:

 a) the client does not immediately notify TUV Rheinland of changes in the conditions within the company which are relevant for contributions or signs of such changes:

 b) the client measures the certificate or certification or signs of such

- b) the client misuses the certificate or certification mark or uses it in violation or the contract.

 c) in the event of several conscavitive dialiga in pawner (at least three incep);

 d) a use a revent of several conscavitive dialiga in pawner (at least three incep);

 d) a use of the contract of the financial circumstances of the client occurs and considerably endangered and TÜV Rheinland under the contract are as a return of the contract are considerably endangered and TÜV Rheinland cannot reasonably be expected to continue the contractual relationship, leaded for good cause. The Rheinland shall be entitled to a lump sum claim for damages against the client of the conditions of a claim for damages exist. In this case, the certification of the fixed contract trans a lump-sum compressation. The client reserves the right to Rheinland reserves the right to prove a considerably higher damage in individual cases.
- Rheirland reserves the right to prove a considerably higher damage in individual cases, einland is also entitled to terminate the contract with written notice if the clien has not been able to make use of the time windows for auditing /service provision provided by TUV 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. 16.4TÜV Rhei

- invalidity, written form, place of jurisdiction and dispute resolution
 All amendments and appdementar met be in writing in order to be effective. The alload populses to immediate that supplements on the class 9 7.1.
 Should one or several of the provisions under the contract and/or these terms and conditions be or become intellective, the contracting parties shall replace the immedia provisions with a legally valid provision that comes closest to the context of the invalid provision in legal and commercial berns.

 The context of the invalid provision in legal and commercial berns.

 The context of the invalid provision in legal and commercial berns.

 The context of the invalid provision in legal and commercial berns.

 The context of the invalid provision is placed by the context of the context and these terms and conditions shall be chosen following the rules as below: in TUV Rhenizand 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 Howard and existing in Howard, the contracting parties hereby agree that the contract and these terms and conditions shall be governed by the laws of Howard and existing in Howard Knopt.

 If TUV Rhenizand in question is legally registered and existing in Howard Knopt.

 The contracting parties hereby agree that the contract and these terms and conditions shall be governed by the laws of Howard Royal Andrews and the contract and these terms and conditions shall be governed by the laws of Howard Royal Andrews and the contracting parties hereby agree that the contract and these terms and conditions shall be governed by the laws of Howard Knopt.

 The contracting parties hereby agree that the contract and these terms and conditions on the execution thereof shall be settled thready through negotiations of the expectation of the regulation period can be extended within two monthas of the artist and the settlem of the howard and the settlem of

- Notice of Arbitration is submitted in accordance with these rules. The arbitration shall take place in Hong Kong. cision of the relevant arbitration tribunal shall be final and binding on both parties. The arbitration fee shall be borne by the losing party.



Test Report 3220780.

Sunbeam International GmbH



Introduction.

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

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

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

Approved For Issue	
201/2	
	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

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' 7.9 Leakage	Test method clause Testing shall be done in accordance with 8.4.	Requirement 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.	Assessment Pass
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' 7.9 Leakage 7.9.1 Total inward leakage 5 test subjects, masks tested 'As		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	Pass
7.9 Leakage 7.9.1 Total inward leakage 5 test subjects, masks tested 'As			
7.9.1 Total inward leakage acceptage			
	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
	Testing shall be done in accordance with 8.11	6% for both PO and NaCl	Pass
7.12 Carbon dioxide content of Te	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
	Festing 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			





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



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

and after the test, comments on the following shall be recorded:

comments reported by the wearer on request.

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

CLAUSE	REQUIREMENTS	ASSESSMEN ⁻
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.	Pass
	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	

Table A: Practical performance

Table Al Tractical performance								
Test Sample			Comments					
		Sample	Head harness comfort	Security of fastenings	Field of vision	Any other comments	Assessment	
	RF1	1 AR	OK	OK	OK	None	Pass	
	AH1	2 AR	OK	OK	OK	None	Pass	

a) head harness comfort; b) security of fastenings; c) field of vision; d) any other

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

			Inward Leakage (%)						
Test	Cample	Pre test	Α	В	С	D	Е		
candidate	Sample	condition	Walking	Walking with head side to side	Walking with head up & down	Walking and talking	Walking	Average	Assessment
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

I GID C C C C G	<u> </u>	nam emeriae penetration test		
Sample	Pre-test	Flow through filter (I/min)	Penetra	ation (%)
number	condition	Flow through filter (I/min)	Limit	Actual
8	AR			0.330
9	AR	95	< 6	0.409
10	AR			0.234

Table D: Clause 8.11 - Paraffin oil penetration test

Sample	Pre-test	Flow through filter (I/min)	Penetra	ation (%)
number	condition	Flow tillough filter (i/fillin)	Limit	Actual
11	AR			1.125
12	AR	95	< 6	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).

Test in accordance with clause 8.7 of the standard.

Pass

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

Cample	Due took sondition	Dead spac	e CO ₂ (%)
Sample	Pre-test condition	Limit	Measured
14	AR		0.48
15	AR	< 1.0	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.

Pass

The breathing resistances shall meet the requirements of FFP2; 30l/min – 0.7mbar (inhale), 95l/min – 2.4mbar (inhale), 160l/min – 3.0mbar (exhale)

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

Cample	Pre-test	st Continuous flow	Inhalation resistance (mbar)		
Sample	condition	(l/min)	Limit	Measured	
17	AR			0.42	
18	AR	30	< 0.7	0.47	
19	AR			0.40	
17	AR			1.33	
18	AR	95	< 2.4	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

Cample	Pre-test	Continuous flow	Exhalation resistance (mbar)		
Sample	condition	(l/min)	Limit	Measured	
17	AR			2.05	
18	AR	160	< 3.0	2.40	
19	AR			1.98	



Appendix A. – Test Panel Data

Test	Facial Dimensions (mm)						
Candidate	Length of face	Width of face	Face depth	Width of mouth	Head Circumference	Sex	
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):

Previous Notified Body: BSI 0086

First Issued: 2020-07-03 Latest Issue: 2020-07-03 Drs. Dave Hagenaars, Managing Director

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

Page: 1 of 3

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This certificate has been issued by and remains the property of BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands and should be returned immediately upon request. To check its validity telephone +31 20 3460780. An electronic certificate can be authenticated online.

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

Page: 2 of 3

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

Page: 3 of 3

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To check its validity telephone +31 20 3460780. An electronic certificate can be authenticated online.







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):

Previous Notified Body: BSI 0086

First Issued: 2020-07-03 Latest Issue: 2020-07-03 Drs. Dave Hagenaars, Managing Director

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

Page: 1 of 3

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

Page: 2 of 3

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To check its validity telephone +31 20 3460780. An electronic certificate can be authenticated online.

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

Page: 3 of 3

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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

Prüfgegenstand

HYGISUN

Ref. HSO501A

FFP2 Mask

EN 149:2001 + A1:2009

CE 2797

Auftragnehmer

HYBETA GmbH

Nevinghoff 20

48147 Münster

Messumfang

Es liegen fünf neue Masken vor.





Bestimmung des Abscheidungsgrades

Prüfbericht: HYBETA_NM_0346

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

- ·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 <u>orientierende Messung</u> und <u>ersetzt keine Prüfung der Masken nach DIN EN 149</u>.

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

Prüfbericht: HYBETA_NM_0346

			Probe-	Volumen					
Messgegenstand	Zeit	Messpunkt	nahmezeit(s)	(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