

# **HYCISUN<sup>®</sup>**

**REF HS0501A**



**FFP2 Mask**  
**Non Medical**  
**EN149: 2001 + A1: 2009**

## 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

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

### Mittelwert der Rohluft

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

### Mittelwerte der Masken

Maske	Partikel [µm]					Abscheidegrad [%]				
	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

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

# EU Type Examination Certificate

This is to certify that:

Sunbeam International GmbH  
Schumanstr. 12  
Würselen  
52146  
Germany

Holds Certificate Number:

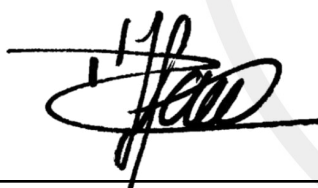
CE 750475

In respect of:

**Respiratory protective devices - Filtering half masks to protect against particles -  
To EN 149:2001+A1:2009  
Model: HYGISUN HS0501A.**

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 Hagenaaars, Managing Director

First Issued: 2021-06-09

Latest Issue: 2021-06-09

Effective Date: 2021-06-09

Expiry Date: 2026-06-09

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# EU Type Examination Certificate

No. CE 750475

## Product Specification

<b>Product Type:</b>	Filtering half masks to protect against particles.
<b>Model:</b>	HYGISUN HS0501A.
<b>Product description:</b>	<p>The particulate respirator is designed to protect against solid and non-volatile liquid particles.</p> <p>The masks are a single size, non-sterile, non-valved product held on the face by a pair of elasticated ear loops.</p> <p>The masks are intended for single shift use as denoted by the classification symbol NR.</p>
<b>Technical specification:</b>	EN 149:2001+A1:2009 – Respiratory Protective Devices - Filtering half masks to protect against particles.
<b>EN 149 classification:</b>	FFP2 NR.

First Issued: 2021-06-09  
Latest Issue: 2021-06-09

Effective Date: 2021-06-09  
Expiry Date: 2026-06-09

Page: 2 of 3

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](#).

BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands  
A member of BSI Group of Companies.

# EU Type Examination Certificate

No. CE 750475

## Certificate Administration Details

Technical File reference: TCF.02.

## Certificate Amendment Record:

Issue date	Comments	BSI Review Number
June 2021	First issue under PPE Regulation (EU) 2016/425. Product initially Certified as a "Covid-19" mask by BSI, Certificate CE 730303 refers.	2797:2021:3339407

## Certificate validity

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspect of the overall processes 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 750476.

First Issued: 2021-06-09

Latest Issue: 2021-06-09

Effective Date: 2021-06-09

Expiry Date: 2026-06-09

Page: 3 of 3

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A member of BSI Group of Companies.

# 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:

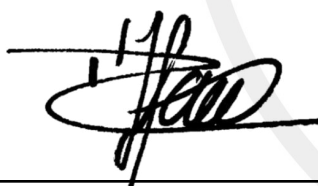
CE 750476

In respect of:

**For the manufacture of respiratory protective devices -  
Filtering half masks to protect against particles - To EN 149:2001+A1:2009.**

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 Hagenaaers, Managing Director

First Issued: 2021-06-09

Latest Issue: 2021-06-09

Effective Date: 2021-06-09

Expiry Date: 2026-06-09

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

No. CE 750476

## Model produced 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:

<b>Product type:</b>	Respiratory protective device – Filtering half masks to protect against particles.
<b>Model:</b>	HYGISUN HS0501A.
<b>Technical Specification:</b>	EN 149:2001+A1:2009 – Respiratory Protective Devices - Filtering half masks to protect against particles.
<b>EN 149 classifications:</b>	FFP2 NR.

## Certificate Administration Details:

### Certificate Amendment Record:

Issue date	Comments	BSI Review No.
June 2021	First issue. Referenced product initially Certified as a "Covid-19" mask by BSI, with the associated BSI issued Module C2 Certificate CE 730304.	2797:21:3339408

### 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: 2021-06-09

Effective Date: 2021-06-09

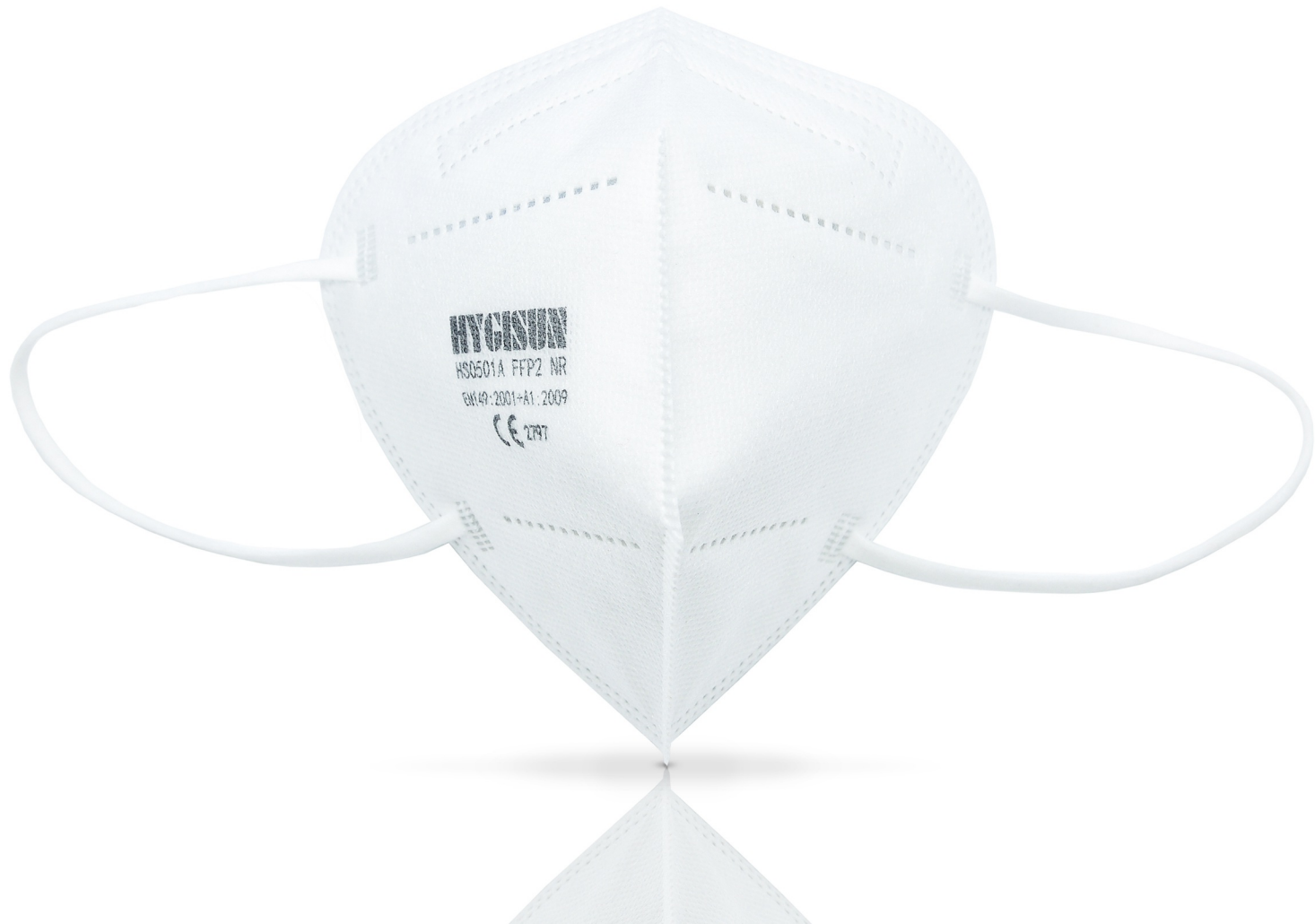
Latest Issue: 2021-06-09

Expiry Date: 2026-06-09

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A member of BSI Group of Companies.



**HYGNIUM**

HS0501A FFP2 NR

EN149:2001+A1:2009

CE 2797

**HYGASUN**

HS0501A FFP2 NR

EN149:2001+A1:2009

CE 2797

**persönliche Schutzmaske**

**PERSONAL PROTECTIVE MASK**

1Stück/ Piece

12 Stück/ piece

产品名称	FFP2个人防护口罩可作为医疗防护使用
Product Name	FFP2 personal protective mask (for medical protection)
执行标准	EN149:2001 + A1:2009
Standard	EN149:2001 + A1:2009
产品规格	16x10.5厘米
Product Size	16x10.5cm
材质	30%熔喷无纺布+TPPE+活性炭
Material	30% melt-blown nonwoven fabric + TPPE + activated carbon
产品颜色	白色
Product Color	white
质检员	
Checklist	
生产日期	

**PT-CATEGORIA DI RESPIRAZIONE**

**INSTRUZIONI**

**Pada:** Este produto atende à classificação de respiratório de filtro mecânico FFP2 de acordo com o Regulamento da Comissão Europeia em Regulação.

**Use potendially indicata contro particelle, virus, fumighe e aerosolizanti di vario tipo. Non impiegare il prodotto per uso medico.**

**Advertencia:**

- O usuário deve ser treinado e usar FFP não oferece proteção contra a contaminação por agentes infecciosos.
- A utilização do produto sem seguir devidamente as instruções ou utilizar de maneira diversa sem capacitação como resultado da engenharia e fabricação alteradas pode ter efeitos adversos na saúde.
- A máscara deve ser usada apenas se houver uma emergência declarada.
- Solicite e mantenha fechada ao Solução e misture se ela estiver quente.
- Não deve ser usado durante o transporte.
- O uso prolongado pode causar irritação da pele e dos olhos.
- Utilizar e armazenar corretamente.
- Não expira: a face externa deve ser limpa.
- Evitar a exposição aos seguintes fatores:
- 1. Exposição a materiais corrosivos e gases tóxicos.
- 2. Exposição a produtos inflamáveis.
- 3. Exposição a líquidos que cause danos físicos.
- 4. Não lavar a máscara com água quente e detergente.
- 5. Não colocar a peça para secar no sol.
- 6. Não reutilizar.
- 7. Não lavar a máscara antes de ser reusada desinfetada, lavada e seca.

Jaseo de Ebro FFP2

**Qualified Certificate - 1 PCS**



# 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
377	洛阳科利德科技有限公司 Luoyang Kelide Technology Co., Ltd.	91410306MA44H8X31L	German Mask: EURL
378	仙桃市平峰救生设备有限公司 Xiatao Pingfeng Life Saving Equipment Co., Ltd.	91429081MA4H9A90L9P	CE
379	湖南云想生活电子商务有限公司 Hunan Dreaming Cloud E-Commerce CO., Ltd	91430105MA4LAAUW8C	CE
380	连云港晟瑞医疗用品有限公司 Lianyungang Shengrui Medical Supplies Co., Ltd.	91320724MA4900367H	CE
381	南京海思医疗器械有限公司 Nanjing Hoesy Medical Apparatus and Instruments Co., Ltd.	91320113MA209F2D54B	CE
382	江苏昌盛服饰有限公司 Jiangsu Changsheng Clothing Co., Ltd	91320921MA1N90UE2B	CE

## 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.

**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*

(Surname, Name)

Quality Manager

Hunan Dreaming Cloud E-Commerce CO., Ltd.



# 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
<b>Job number:</b> 3220780 Job type: Testing Samples Submitted Start Date: 27/05/2020 Test type: Type Sample ID: 10190222 <b>Registration:</b> CE 730303 Scheme: Positive pressure RPE Protocol: PP123 Scheme Manager: 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	
	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
<b>7.7 Practical performance</b> 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.  <i>2 test subjects, masks tested 'As received'</i>	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
<b>7.9 Leakage</b> <b>7.9.1 Total inward leakage</b>  <i>5 test subjects, masks tested 'As received'</i>	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
<b>7.9 Leakage</b> <b>7.9.2 Penetration of filter material</b> <i>3 test samples masks tested 'As received', for NaCl (Sodium Chloride) and PO (Paraffin oil), 3min test</i>	Testing shall be done in accordance with 8.11	6% for both PO and NaCl	Pass
<b>7.12 Carbon dioxide content of the inhalation air</b> <i>3 test samples, masks tested 'As received'</i>	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
<b>7.16 Breathing resistance</b> <i>3 test samples, masks tested 'As received'</i>	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
<b>Appendix A - Test Panel Data</b>			
<b>Product Photographs</b>			

## 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

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

CLAUSE	REQUIREMENTS	ASSESSMENT
7.7	<p><b>Practical performance</b></p> <p>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.</p> <p>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.</p> <p>Test in accordance with clause 8.4 of the standard.</p> <p><b>Testing in accordance with BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers</b></p> <p><i>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:</i></p> <p><i>a) head harness comfort; b) security of fastenings; c) field of vision; d) any other comments reported by the wearer on request.</i></p>	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
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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).

Test in accordance with clause 8.7 of the standard.

Pass

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

Sample	Pre-test condition	Dead space CO <sub>2</sub> (%)	
		Limit	Measured
14	AR	< 1.0	0.48
15	AR		0.50
16	AR		0.52

# Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
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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

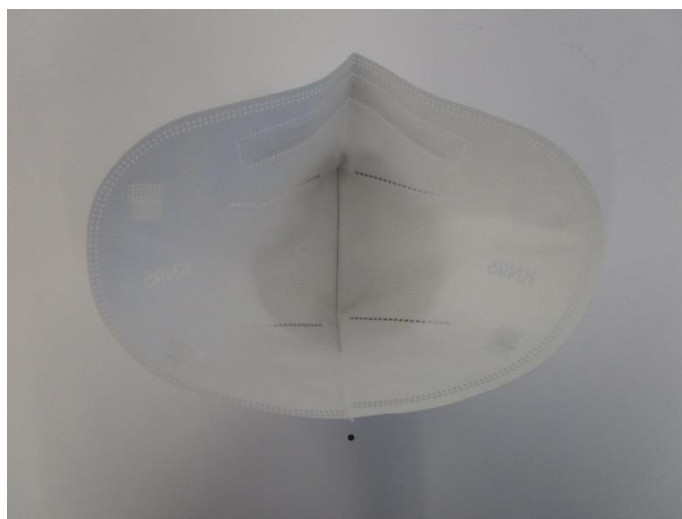
## Product photographs.



Front view



Side View



Inside View

\*\*\*End of Report\*\*\*