FFP2 MASK

NON MEDICAL EN149:2001+A1:2009

Foldable Particulate Respirator

High filtration efficiency
Low respitatiory resistance
More comfortable to wear

HYGISUN

REF HS0501A

20PCS

② SINGLE USE

CE 2797

FFP2 Mask

NON MEDICAL EN149:2001+A1:2009

⚠ IMPORTANT : The respiratory protection mask FFP2 is designed to protect from pollen, virus, industrial dust.

⚠ WICHTIG:Die Atemschutzmaske FFP2 schützt vor Pollen, Virus und Industriestaub.

APPLICATION :
It is used in the Protection industry for dust generation during construction, dust prevention, metal casting, stone mining, electronics,pharmaceutical, physical processing and grinding, which has good protection against sandstorm, haze and PM2.5. Can effectively protect pollen allergy, virus transmission, etc.

Expiration Date:
The storage temperature is -20 ~ 28 °C, the storage is moderate ≤ 80%,The validity period is 3 years in the dry indoor environment.

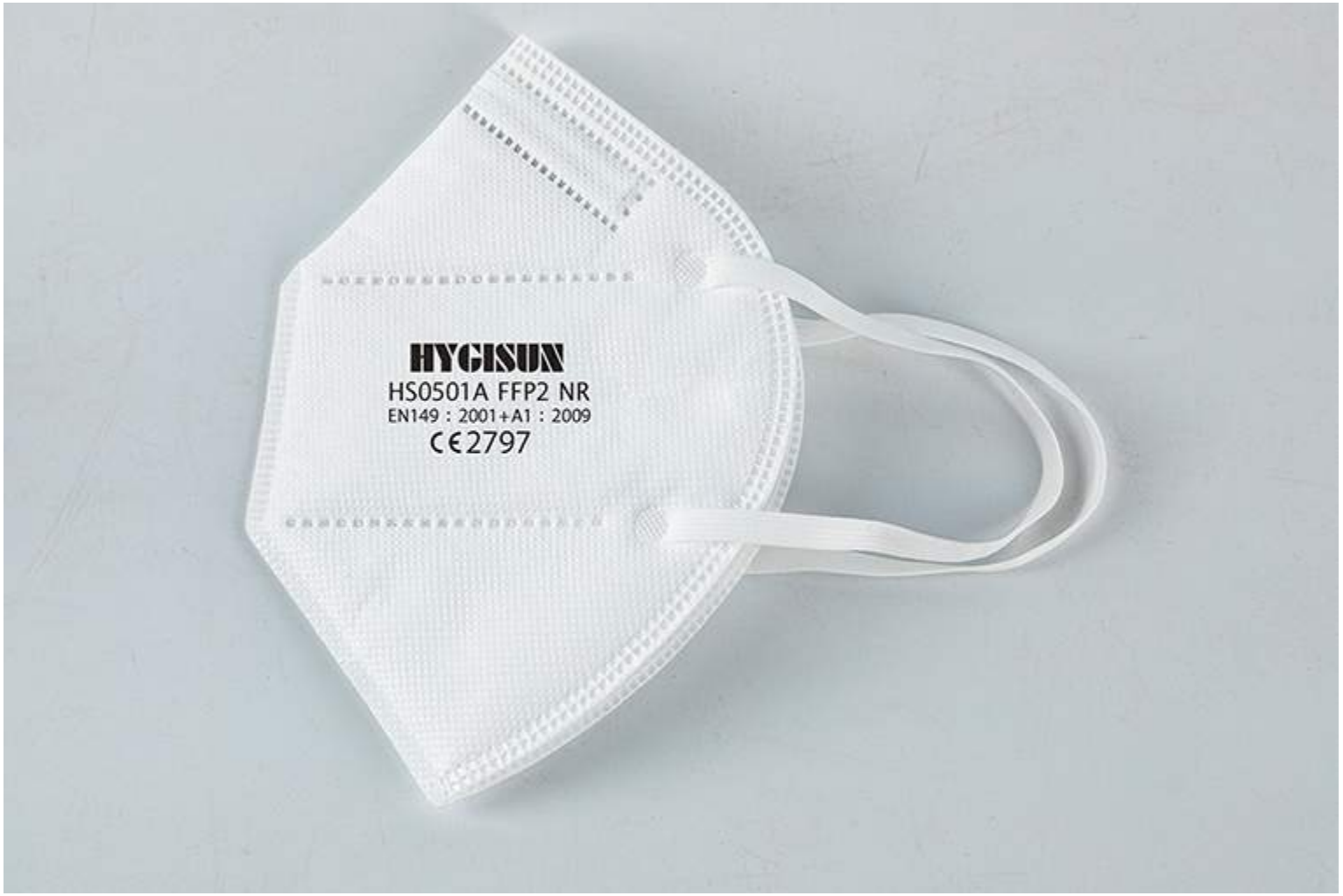
MANUFACTURER:Hunan Browning Cloud-E Commerce CO., Ltd
ADDRESS: Block 1, Smart Tech Park, 57# Wangqing Avenue, Changsha Economic and Technological Development Zone, Changsha, Hunan, China

Sanhenn International GmbH, Schanenstr. 12
57462 Wilnsdorf, Germany

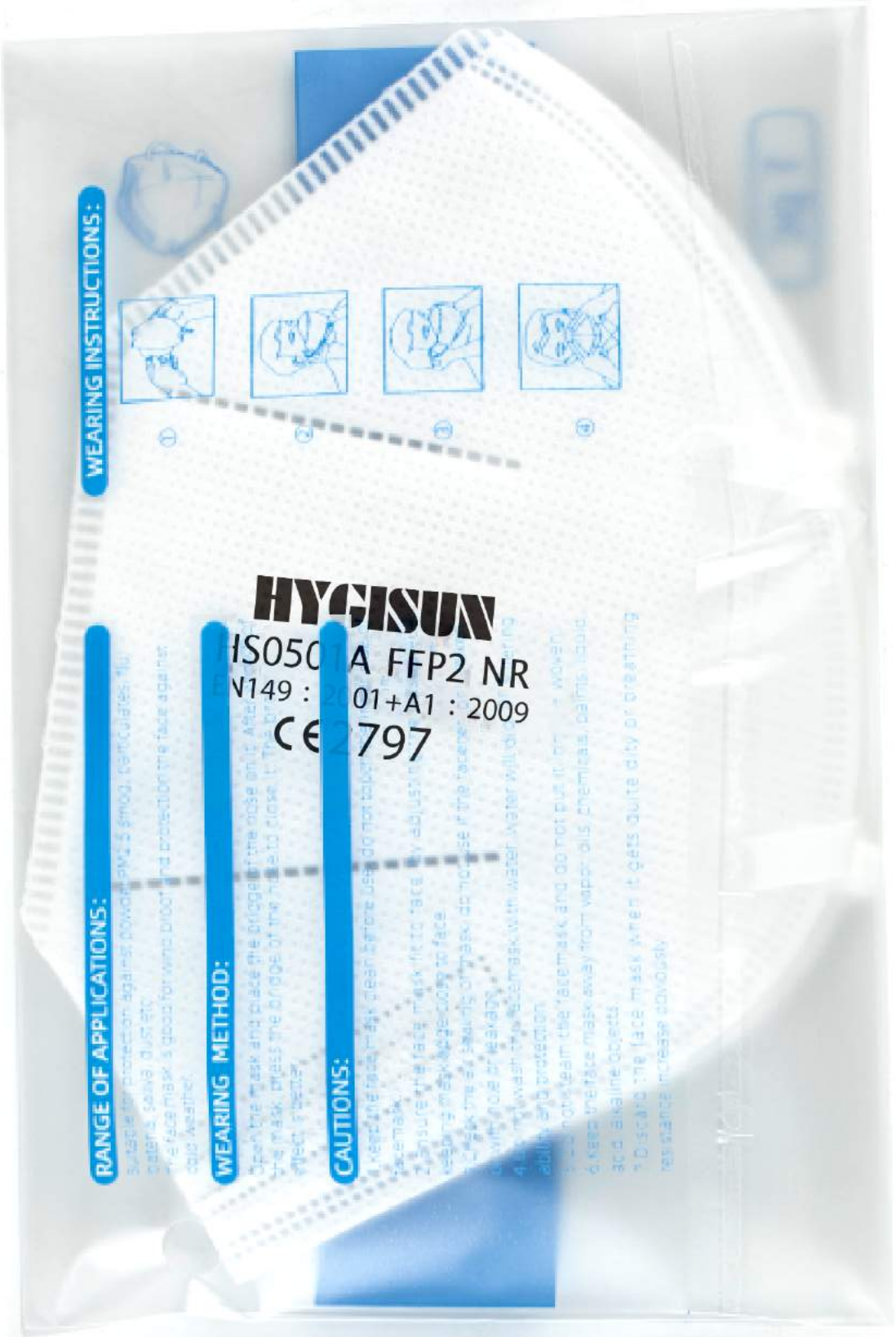
4 260678 530003


FFP2 MASK
NON MEDICAL EN149:2001+A1:2009
Foldable Particulate Respirator
Atemschutzmaske
Gegen Feinstaub
Faltbar
HYGISUN
REF RS0501A
20PCS
SINGLE USE
CE 2797
FFP2 Mask
NON MEDICAL EN149:2001+A1:2009


FFP2 MASK
NON MEDICAL EN149:2001+A1:2009
Foldable Particulate Respirator
HYGISUN
REF HS0501A
High filtration efficiency
Low respitatiory resistance
More comfortable to wear
20PCS
SINGLE USE
CE 2797
FITTING INSTRUCTIONS
FFP2 Mask
NON MEDICAL EN149:2001+A1:2009
HYGISUN
HS0501A FFP2 NR
EN149 : 2001+A1 : 2009
CE 2797
PERSONAL PROTECTIVE MASK
1 pc


HYGISUN
HS0501A FFP2 NR
EN149 : 2001+A1 : 2009
CE2797


PERSONAL PROTECTIVE MASK
1 pc


WEARING INSTRUCTIONS :
HYGISUN
HS050 A FFP2 NR
N149 : 01+A1 : 2009
CE 2797
RANGE OF APPLICATIONS:
WEARING METHOD:
CAUTIONS:

LOW RESISTANCE

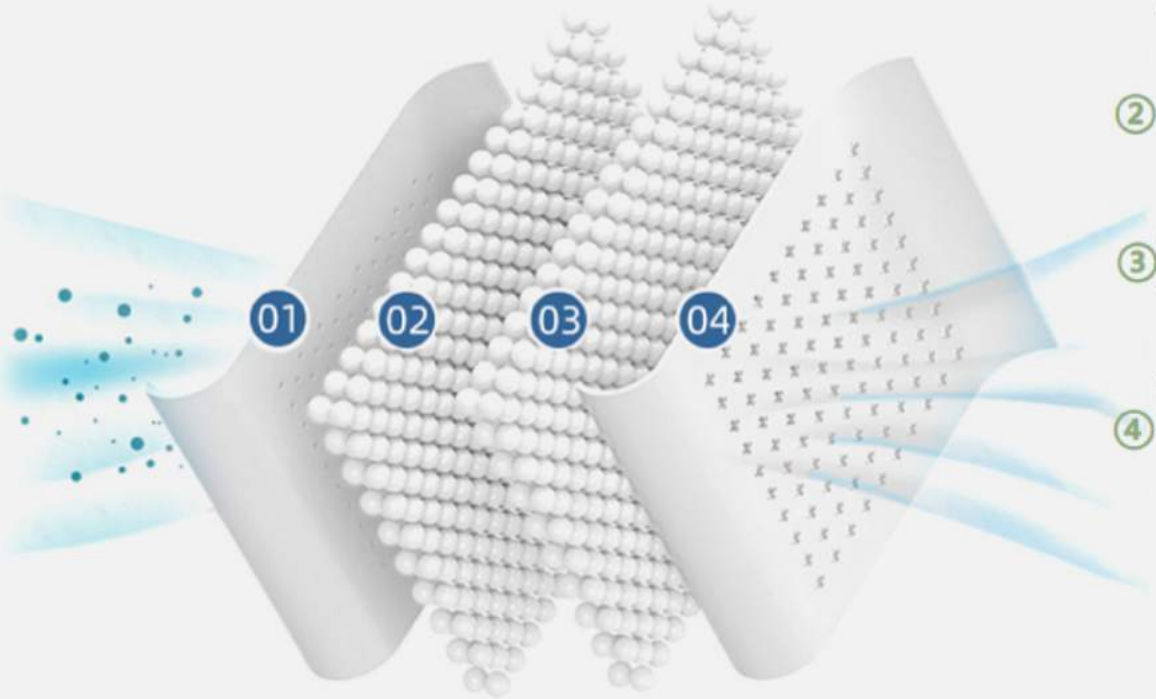
PARTICLE PREVENTION

ANTI DROPLET

GOOD VENTILATION

4-layers for filtration

Multi-layers with more than 95% filtration efficient



① **Outer layer: 65gsm SS non-woven fabric**

Thick waterproof fiber, block the big particulates

② **Inner layer 1: 25gsm melt-blown fabric**

Effective static adsorption for filter the micro-particulates

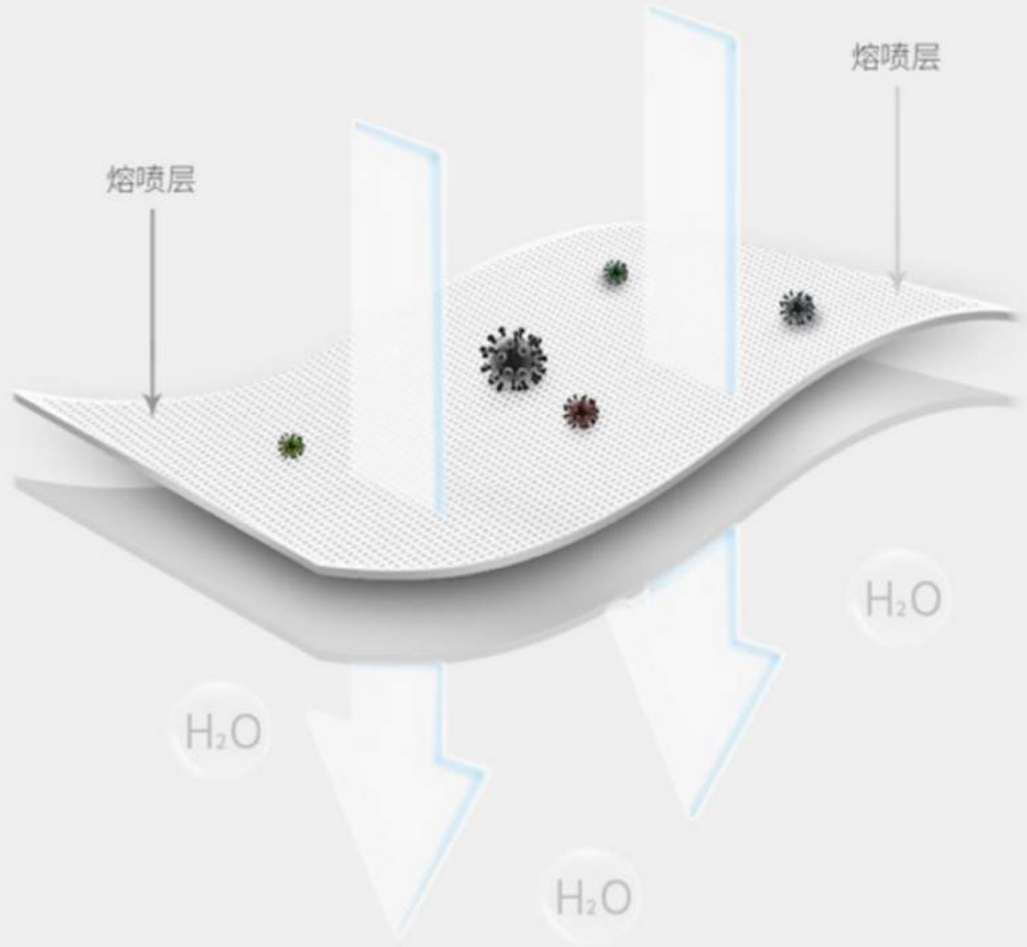
③ **Inner layer 2: 25gsm melt-blown fabric**

Anti-microbial with nanometer level material

skin-friendly layer: 50gsm SS non-woven fabric

④ skin-friendly and free allergic

Melt-blownfabric
layer bring a better protection



High effective filtration

Block the 0.3um level particulates

Filtration rate higher than 95%

SKIN-FRIENDLY LAYER

Non-woven fabric layer, free allergic

Stretchy betl with extention kit

Width belt, feel free on wearing

Physical weld point

Free glue and free HCHO

DEKRA Testing and Certification GmbH
Standort Essen
Persönliche Schutzausrüstungen

Adlerstraße 29
45307 Essen, Germany

Tel +49.201.52319-0
Fax +49.201.52319-401
E-Mail CPA@dekra.com

Prüfbericht / *Test report*
No. 3418690.10-CPA Revision 2

Prüfgegenstand *Testsubject*	Corona SARS-CoV-2 Atemschutzmaske *Corona SARS-CoV-2 respiratory protective mask*
Modell *Type*	HS0501A (FFP2 Mask)
Hersteller *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
Prüfgrundlage *Test requirement*	Prüfgrundsatz für Corona SARS-Cov-2 Pandemie Atemschutzmasken Rev. 1 vom 26.03.2020 *Testing principle for Corona SARS-CoV-2 pandemic respiratory masks rev. 1 of 2020-03-26*
Prüfergebnis *Test result*	Die Pandemie Atemschutzmaske entspricht den Corona SARS-CoV-2 Prüfanforderungen. *The pandemic respiratory protective mask does meet the Corona SARS-CoV-2 test requirements.*
Datum *Date of issue*	08.07.2020

Dieser Bericht besteht aus 16 Seiten. *This report consists of 16 pages.*

DEKRA Testing and Certification GmbH, Handwerkstraße 15, 70565 Stuttgart
Zertifizierungsstelle *Certification Body*: Dinnendahlstraße 9, 44809 Bochum
Telefon +49.234.3696-400, Fax +49.234.3696-401, DTC-Certification-body@dekra.com

Veranlassung / *Reason*

Auftragseingang *Date of order*	27/05/2020
Auftraggeber *Applicant*	Sunbeam International GmbH Schumanstraße 12 52146 Würselen, Germany
Importeur *Importer*	Sunbeam International GmbH Schumanstraße 12 52146 Würselen, Germany
Eingang der Prüfmuster *Date of receipt of test item*	29/05/2020
Prüfzeitraum *Date (s) of performance of tests*	29/05/2020 – 17/06/2020
Prüfstandort *Test location*	DEKRA Testing and Certification GmbH Persönliche Schutzausrüstungen Adlerstraße 29, 45307 Essen, Germany

Zusammenfassung der Prüfung / *Summary of Testing*

Prüfung *Test*		**bestanden** *pass*	**nicht bestanden** *fail*	**nicht anwendbar** *not applicable*
2.2	Sichtprüfung / *Visual inspection*	✓		
2.3	Anlegeprüfung / *Donning test*	✓		
2.4	Durchlass des Filtermediums / *Penetration of the filter medium*	✓		
2.5	Ausatemventil(e) / *Exhalation valve(s)*			✓
2.6	Atemwiderstand / *Breathing resistance*			
2.6.1	CPA ohne Ventil / *CPA without valve*	✓		
2.6.2	CPA mit Ventil / *CPA with valve*			✓
2.7	Kennzeichnung und Informationen des Herstellers / *Marking and manufacturer's information*	✓		

N/T Nicht getestet oder geprüft / *Not tested or checked*

Bemerkung / *Remarks*:

Die Prüfung gilt als „bestanden“, wenn der ermittelte Messwert kleiner oder gleich dem vorgegebenen Grenzwert ist. Mögliche Erklärungen zu „nicht bestandenen“ oder nicht durchgeführten Prüfungen können dem Glossar am Ende dieses Prüfberichts entnommen werden.

The test is considered as a “pass” if the measured value is less or equal to the limit.

Possible explanations for "failed" or not performed tests can be found in the glossary at the end of this test report.

DEKRA Testing and Certification GmbH

(Dr. Spittler)

Prüfingenieur/ *Test engineer*

Inhaltsverzeichnis / *Table of contents*

0 Revision

Dieser Prüfbericht ersetzt den Prüfbericht Nr./ *This test report replaces test report no.*

- 3418690.10-CPA Revision 1 (06/07/2020)

Begründung der Revision 1 / *Reason for revision 1:*

- Die Prüfberichtsnummer wurde korrigiert. / *The test report number has been corrected.*:

  3418690.10-CPA Revision 1

Begründung der Revision 2 / *Reason for revision 2:*

- Die Herstellerinformationen auf Seite 1 wurden korrigiert. / *The manufacturer information on page 1 has been corrected.*:

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

- Die Auftraggeber und Importeur informationen auf Seite 2 wurden korrigiert. / *The applicant and importer information on page 2 have been corrected.*:

  Sunbeam International GmbH
  Schumanstraße 12
  52146 Würselen

1 Bezug der Prüfergebnisse / *Reference of the test results*

Die in diesem Bericht aufgeführten Ergebnisse beziehen sich ausschließlich auf die untersuchten Prüfmuster.
The results listed in this report refer only to the tested samples.
Für die Prüfung wurden folgende Dokumente zugrunde gelegt:
The following documents were taken as a basis for the tests:

1	Verpackung / *packaging*
2	Gebrauchsanweisung / *user manual*

Die folgende Maske wurde geprüft / *The following mask was tested:*

Umverpackung / *outer packaging*

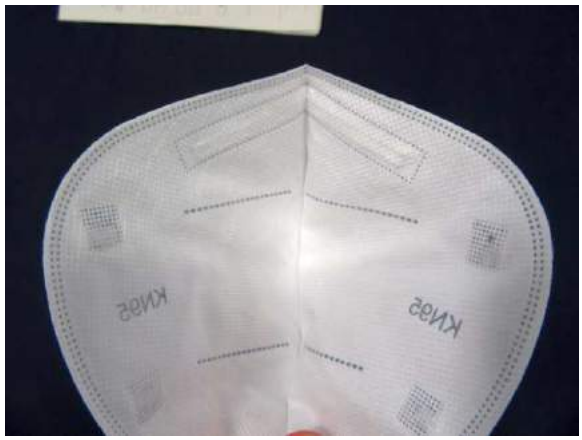
Umverpackung / *outer packaging*

Umverpackung / *outer packaging*

Umverpackung / *outer packaging*

Seitenansicht / *side view*

Seitenansicht / *side view*

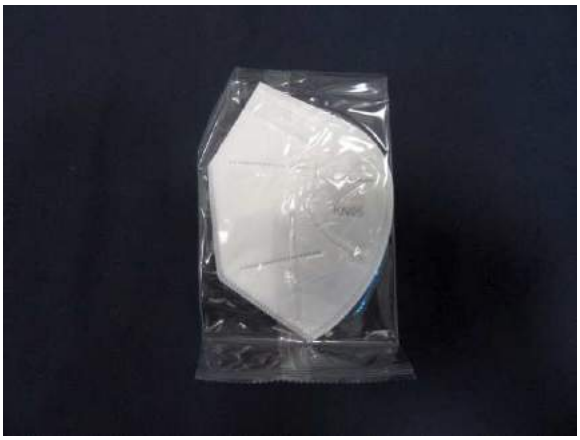


Innenansicht / *inner view*

Frontansicht / *front view*

Verpackung / *packaging*

Einzelverpackung / *single packaging*



Einzelverpackung / single packaging

2 Prüfergebnisse / *Test results*

A Prüfgrundsatz für Corona SARS-Cov-2 Pandemie Atemschutzmasken / *Testing principle for Corona SARS-CoV-2 pandemic respiratory masks*

Die nachfolgenden Ziffern entsprechen den Abschnitten des Prüfgrundsatzes für Corona SARS-Cov-2 Pandemie Atemschutzmasken.

The following numbers correspond to the paragraphs of the testing principle for Corona SARS-CoV-2 pandemic respiratory masks.

2 Anforderungen und Prüfungen / *Requirements and tests*

2.1 Übersicht der Prüfungen / *Overview of tests*

Prüfung *Test*	**Abschnitt EN 149:2001+A1:2009** *Section EN 149:2001+A1:2009*
Sichtprüfung *Visual inspection*	--
Anlegeprüfung *Donning test*	8.4.1
Durchlass des Filtermediums *Flow rate through the filter medium*	8.11
Ausatemventil-Durchströmung *Exhalation valve flow*	8.3.4
Atemwiderstand (Geräte ohne Ventil) *Breathing resistance (valveless devices)*	8.9.2 + 8.9.3
Atemwiderstand (Geräte mit Ventil) *Breathing resistance (valved devices)*	8.9.2 + 8.9.3
Konditionierung *Conditioning*	**Abschnitt EN 149:2001+A1:2009** *Section EN 149:2001+A1:2009*
Temperaturkonditionierung *Temperature conditioning*	8.3.2 nur *only* a)
Gebrauchssimulation *Simulation of wearing*	8.3.1

2.2 **Sichtprüfung** / *Visual inspection*

CPA müssen zum Verkauf so verpackt angeboten werden, dass sie gegen mechanische Beschädigung und Verunreinigung vor dem Gebrauch geschützt sind.
When supplied for purchase, the CPA must be packed in such a way that they are protected against mechanical damage and contamination prior to their use.

Ergebnis: *test result:*	Die Verpackung schützt die Maske vor mechanischer Beschädigung und Verunreinigungen. *The package protects the mask from mechanical damage and contamination.*	**bestanden** *pass*	**nicht bestanden** *fail*
		✓	

2.3 **Anlegeprüfung** / *Donning test*

Die CPA muss leicht an- und abgelegt werden können. Die Kopfbänderung muss kräftig genug sein, um die CPA in Position zu halten. Die CPA muss einen Dichtsitz am Gesicht der Testperson gewährleisten. Bei einem Trageversuch dürfen keine offensichtlichen Undichtigkeiten im Bereich der Dichtlinie der Maske erkennbar sein. Bei der Beatmung durch eine Testperson dürfen keine Luftströmungen, die durch Undichtigkeiten in der Dichtlinie (schlechte Anpassung an das Gesicht) entstehen, wahrnehmbar sein.
Putting on and removing the CPA must be done easily. The head straps must be strong enough to keep the CPA in place. The CPA must ensure a close fit at the face of the test person. When carrying the mask in a test, no obvious leakage along the sealing line of the mask shall be recognisable. When the test person uses the mask for breathing, no air flow shall be noticeable which is caused by leakage in the sealing line (poor facial fit).

Ergebnis: *test result:*	Die Kopfbänderung besteht aus dünnen flexiblen Bändern und die CPA konnte leicht angelegt und abgenommen werden. *The headgear consists of thin flexible straps and the CPA was easy to put on and take off.*	**bestanden** *pass*	**nicht bestanden** *fail*
		✓	

Ergebnis: *test result:*	Die Kopfbänderung ist kräftig genug, um die CPA in Position zu halten. *The headgear is strong enough to hold the CPA in place.*	**bestanden** *pass*	**nicht bestanden** *fail*
		✓	

Ergebnis: *test result:*	Bei einem Trageversuch waren keine offensichtlichen Undichtigkeiten im Bereich der Dichtlinie der CPA erkennbar oder bei einer Beatmung in Form von Luftströmungen wahrnehmbar. *During a wearing test, no obvious leaks were detected in the area of the sealing line of the CPA or were perceptible in the form of air currents during ventilation.*	**bestanden** *pass*	**nicht bestanden** *fail*
		✓	

2.4 Durchlass des Filtermediums / *Penetration of the filter medium*

Der Durchlass des Filters der CPA wird mit Paraffinöl mit 95 l/min geprüft. Es müssen insgesamt drei Muster der CPA geprüft werden. Die drei Muster werden wie folgt konditioniert: Temperaturkonditionierung nur bei hoher Temperatur und Gebrauchssimulation mit feuchter Beatmung für 20 Minuten. Die Prüfung erfolgt nach EN 149:2001+A1:2009 Abschnitt 8.11 mit der Prüfung des Durchlasses nach EN 13274-7:2008 Abschnitt 5.1 und 5.2. Der Durchlass der CPA aller drei Muster muss ≤ 6,0 % sein.

The penetration through the filter of the CPA is tested using paraffin oil at 95 l/min. In total, three samples of the CPA have to be tested. The three samples will be conditioned as follows: temperature conditioning only at high temperature, and simulation of wearing with moist respiration for 20 minutes. The test is carried out in accordance with section 8.11 of EN 149:2001+A1:2009 with the filter penetration according to EN 13274-7:2008 clause 5.1 and 5.2. The penetration of the CPA of all three samples must be ≤ 6.0 %.

Tabelle I Ergebnisse beim Kurztest (3 min) / *Table I Results during short test (3 min)*

Probe *Sample*[1]	**Konditionierung** *Conditioning*	**Durchlassgrad bei 95 l/min Paraffinöl** *Penetration at 95 l/min Paraffine oil* **[%]**	
		Anforderung *Requirement*	**Ergebnis** *Test result*
01	T.C. + S.W.	≤ 6,0	1,5
02	T.C. + S.W.		1,4
03	T.C. + S.W.		1,3

[1] Vom Prüflabor verwendete Bezeichnung. *Designation used by the testing laboratory.*
T.C.: Temperatur konditioniert / *Temperature conditioned*
S.W.: Gebrauchssimulation / *Usage simulation*

2.5 **Ausatemventil(e)** / *Exhalation valve(s)*

Die CPA darf ein oder mehrere Ausatemventil(e) haben. Sie müssen in jeder Lage richtig funktionieren. Die Prüfung muss nach EN 149:2001+A1:2009 Abschnitt 8.9.1 erfolgen. Falls ein Ausatemventil(e) vorhanden ist, muss es (müssen sie) nach einem 30 s dauernden kontinuierlichen Ausatemstrom von 300 l/min weiter richtig funktionieren. Die Prüfung erfolgt während der Messung des Atemwiderstandes. Wenn das Gehäuse des Ausatemventils am Maskenkörper befestigt ist wird mit einer gefühlten Kraft von 10 N per Hand an dem Ausatemventil bzw. an dessen Gehäuse gezogen. Löst sich das Ventil, gilt die Prüfung als nicht bestanden.
The CPA may have one or more exhalation valves; these must work properly in any position. The test has to be carried out in accordance with section 8.9.1 of EN 149:2001+A1:2009. If one or more exhalation valves are in place, they must continue to work properly after a continuous exhalation flow of 300 l/min for 30 s. The test is carried out during the measurement of the breathing resistance. Once the casing of the exhalation valve has been fastened to the mask body, the exhalation valve or its casing is manually pulled with a felt force of 10 N. If the valve comes loose, the test is deemed as not passed.

Ergebnis: *test result:*	Die CPA beinhaltet kein(e) Ausatemventil(e). *The CPA does not include (an) exhalation valve(s).*	**bestanden** *pass*	**nicht bestanden** *fail*
		✓	

2.6 **Atemwiderstand** / *Breathing resistance*

Die Atemwiderstände gelten für CPA mit und ohne Ventil(e).

The breathing resistance requirements apply to valved and valveless CPA.

2.6.1 **CPA ohne Ventil** / *CPA without valve*

Geprüft werden zwei CPA nach der Temperaturkonditionierung und der Gebrauchssimulation mit feuchter Beatmung für 20 Minuten. Die Prüfung erfolgt in Anlehnung an EN 149:2001+A1:2009 Abschnitt 8.9. Der Ausatemwiderstand wird in der Lage geradeaus sehend geprüft.

Der Atemwiderstand bei der Einatmung bei 95 l/min muss bei allen Mustern ≤ 3,0 mbar sein.

Der Atemwiderstand bei der Ausatmung bei 160 l/min muss bei allen Mustern ≤ 3,0 mbar sein.

2 CPA are tested after the temperature conditioning and the simulation of wearing with moist respiration for 20 minutes. The test is carried out following section 8.9 of EN 149:2001+A1:2009. The exhalation resistance is tested in the position "looking straight ahead".

The breathing resistance for inhalation at 95 l/min must be ≤ 3.0 mbar at all samples.

The breathing resistance for exhalation at 160 l/min must be ≤ 3.0 mbar at all samples.

Tabelle II Ergebnisse der Einatemwiderstandsmessungen bei 95 l/min
Table II Results of inhalation resistance measurements at 95 l/min

Probe *Sample*[1]	**Konditionierung** *Conditioning*	**Einatemwiderstand** *Inhalation resistance* **[mbar]**	
		Anforderung *Requirement*	**Ergebnis** *Test result*
04	T.C. + S.W.	≤ 3,0	1,4
05	T.C. + S.W.		1,7

[1] Vom Prüflabor verwendete Bezeichnung / *Designation used by the testing laboratory.*
T.C.: Temperaturkonditioniert / *Temperature conditioned*
S.W.: Gebrauchssimulation / *Usage simulation*

Tabelle III Ergebnisse der Ausatemwiderstandsmessungen bei 160 l/min
Table III Results of exhalation resistance measurements at 160 l/min

Probe *Sample*[1]	**Konditionierung** *Conditioning*	**Ausatemwiderstand** *Exhalation resistance* **[mbar]**	
		Anforderung *Requirement*	**Ergebnis** *Test result*
04	T.C. + S.W.	≤ 3,0	2,2
05	T.C. + S.W.		2,5

[1] Vom Prüflabor verwendete Bezeichnung. / *Designation used by the testing laboratory.*
T.C.: Temperaturkonditioniert / *Temperature conditioned*
S.W.: Gebrauchssimulation / *Usage simulation*

Gemessen in der ersten definierten Lage des Prüfkopfes / *Measured in the first defined position of the test head:*
geradeaussehend / *facing directly ahead*

2.7 Kennzeichnung und Informationen des Herstellers / *Marking and manufacturer's information*

Die Kennzeichnung der CPA oder der kleinsten Verpackungseinheit soll dokumentiert werden, sodass eindeutig erkennbar ist, welche CPA vorliegt.

The marking of the CPA or the smallest packing unit must be documented so that it becomes unmistakeably clear which CPA is provided.

Ergebnisse / *Test Results*		
	bestanden *pass*	**nicht bestanden** *fail*
Die CPA oder die kleinste Verpackungseinheit muss mit den folgenden Informationen gekennzeichnet sein: *The marking of the CPA or the smallest packing unit must contain the following information:*		
a) Name, Warenzeichen und/oder andere Angaben zur Identifikation des Herstellers; *a) Name, trademark and/or other details identifying the manufacturer;*	✓	
b) Typidentische Kennzeichnung (Nummer, Modell oder Ähnliches) *b) Marking identifying the type (number, model or similar)*	✓	
Informationen müssen jeder CPA oder der kleinsten Verpackungseinheit beigelegt sein. Die Informationen können in Textform oder beispielsweise in Piktogrammen dargestellt werden. Die Informationen müssen mindestens Angaben enthalten zu: *Information must be supplied with each CPA or smallest packing unit. This information can be displayed either as text or as pictograms, for example. The information must also provide at least details on:*		
a) Sitz sowie richtiges An- und Ablegen; *a) Fit and correct putting on and removing of the mask;*	✓	
b) Hinweise zur Verwendung *b) Instruction on its use*	✓	

B Glossar /*Glossary*

2.2 **Sichtprüfung** / *Visual inspection*

Die Verpackung schützt die Maske nicht vor mechanischer Beschädigung und Verunreinigungen:

- Keine Verpackung vorhanden
- Verpackung ist ein offener und/oder nicht wiederverschließbarer Kunststoffbeutel
- Masken wurden lose in einem Pappkarton geliefert

The package does not protect the mask from mechanical damage and contamination:

- *No packaging supplied*
- *Packaging is an open and/or non-reclosable plastic bag*
- *Masks were delivered loose in a cardboard box*

2.3 **Anlegeprüfung** / *Donning test*

Offensichtliche Undichtigkeiten im Nasenbereich der CPA:

- Konstruktion Nasenbügel (Länge, Breite, Stärke, Material)
- Schnitt der Maske
- Verwendetes Maskenmaterial (Steifigkeit)
- Bänderung nicht stark genug

Obvious leaks in the area of the nose of the CPA:

- *Nose clip construction (length, width, thickness, material)*
- *Shape of the mask*
- *Mask material used (stiffness)*
- *Headgear not strong enough*

Offensichtliche Undichtigkeiten im Kinnbereich der CPA:

- Schnitt der Maske
- Verwendetes Maskenmaterial (Steifigkeit)
- Bänderung nicht stark genug
- Bänderung zu stark

Obvious leaks in the area of the chin of the CPA:

- *Shape of the mask*
- *Mask material used (stiffness)*
- *Headgear not strong enough*
- *Headgear too strong*

Offensichtliche Undichtigkeiten im Wangenbereich der CPA:

- Schnitt der Maske
- Verwendetes Maskenmaterial (Steifigkeit)
- Bänderung nicht stark genug

Obvious leaks in the area of the cheek of the CPA:

- *Shape of the mask*
- *Mask material used (stiffness)*
- *Headgear not strong enough*

Begründungen für nicht durchgeführte Prüfung:

- Starker Eigengeruch der Maske:
  Verwendete Materialien könnten ein Risiko für den Benutzer darstellen
- Partikel lösen sich von der Maske:
  Ablösende Partikel könnten ein Risiko für den Benutzer darstellen
- Atemwiderstand der Maske zu hoch (siehe 2.6):
  Zu hohe körperliche Belastung für den Benutzer

Reasons for not performed tests:

- *Strong inherent smell of the mask:*
  Materials used could be a risk for the user
- *Particles detach from the mask:*
  Detaching particles could be a risk to the user
- *Breathing resistance of the mask too high (see 2.6):*
  Too high physical stress for the user

2.4 **Durchlass des Filtermediums** / *Penetration of the filter medium*

Verwendetes Material ist im geprüften Aufbau nicht geeignet

(Materialwechsel kann negativen Einfluss auf **A**temwiderstand und/oder Anlegeversuch haben)

Material used is not suitable in the tested setup

(Change of material can have a negative influence on breathing resistance and/or donning test)

2.6 **Atemwiderstand** / *Breathing resistance*

Verwendetes Material erzeugt zu hohen Atemwiderstand

(Materialwechsel kann negativen Einfluss auf Filterdurchlass und/oder Anlegeversuch haben)

Material used is causing too high breathing resistance

(Change of material can have a negative influence on the penetration of the filter medium and/or donning test).

2.7 Kennzeichnung und Informationen des Herstellers / *Marking and manufacturer's information*

Name, Warenzeichen oder andere Angaben zur Identifikation des Herstellers (nicht bestanden):

- Keinerlei Angaben zum Hersteller
- Warenzeichen / Marke können keine eindeutige Informationen über die Produktionsstätte liefern (z.B. Markeninhaber ist nicht Hersteller und/oder hat mehrere Produktionsstätten)
- Angaben auf Maske, kleinster Verpackungseinheit und/oder Umverpackung unterscheiden sich von einander
- Nur Informationen zum Importeur verfügbar
- Informationen nicht in Deutsch oder Englisch verfügbar

Name, trademark or other information identifying the manufacturer (fail):

- *No information about the manufacturer*
- *Trademark / brand cannot provide clear information about the production site (e.g. brand owner is not the manufacturer and/or has several production sites)*
- *Information on mask, smallest packaging unit and/or packaging differ from each other*
- *Only information about the importer available*
- *Information not available in German or English*

Typidentische Kennzeichnung (Nummer, Modell oder Ähnliches) (nicht bestanden):

- KN95 und FFP2 (ohne jeden Zusatz) sind Klassifizierungen der Maske und keine Modellbezeichnungen (Beispiel für eine gültige Modellbezeichnung: Marke ABC Atemschutzmaske KN95/FFP2)
- Angaben auf Maske, kleinster Verpackungseinheit und/oder Umverpackung unterscheiden sich von einander
- Informationen nicht in Deutsch oder Englisch verfügbar

Marking identifying the type (number, model or similar) (fail):

- *KN95 and FFP2 (without any addition) are classifications of the mask and not type description (Example of a valid type description: Brand ABC respiratory mask KN95/FFP2)*
- *Information on mask, smallest packaging unit and/or packaging differ from each other*
- *Information not available in German or English*

Sitz sowie richtiges An- und Ablegen (nicht bestanden):

- Keinerlei Angaben
- Vorhandene Piktogramme nicht ausreichend
- Beschreibung zum An- und Ablegen der Maske nicht passend zum Maskentyp
- Beschreibung zum An- und Ablegen der Maske nicht vollständig/nicht eindeutig
- Informationen nicht in Deutsch oder Englisch verfügbar

Fit and correct putting on and removing of the mask (fail):

- *No information*
- *Existing pictograms not sufficient*
- *Description for putting on and removing of the mask not suitable for the mask type*
- *Description for putting on and removing of the mask not complete/not clear*
- *Information not available in German or English*

Hinweise zur Verwendung (nicht bestanden):

- Falsche, irreführende oder nicht validierte Angaben zur Wiederverwendbarkeit, Verwendungsdauer und Haltbarkeit der Maske
- Aussage: „Maske kann gereinigt werden"
- Gefährliche Aussagen zum Verwendungsbereich

Instructions for use (not fail):

- *Incorrect, misleading or non-validated information on the reusability, duration of use and durability of the mask*
- *Statement: „Mask can be cleaned"*
- *Dangerous statements regarding the scope of use*

Bewertung der Konformität von Corona SARS-Cov-2 Pandemie Atemschutz (CPA) nach dem Prüfgrundsatz für Corona SARS-Cov-2 Pandemie Atemschutzmasken Revision 1
Evaluation of the conformity of corona sars-cov-2 pandemic respiratory protection (CPA) according to the testing principle for corona sars-cov-2 pandemic respiratory protection masks revision 1

Berichtsnummer *Report number*	3418690.10-CPA Revision 2
Prüfgegenstand *Test subject*	Corona SARS-CoV-2 Atemschutzmaske *Corona SARS-CoV-2 respiratory protective mask*
Modell *Type*	HS0501A (FFP2 Mask)
Hersteller *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
Importeur *Importer*	Sunbeam International GmbH Schumanstraße 12 52146 Würselen, Germany

Die Anforderungen des Prüfgrundsatzes sind *The requirements of the test principle are*	✓ Erfüllt *Fulfilled*

Die technische Wirksamkeit des oben genannten Produkts ist im Rahmen der Empfehlung (EU) 2020/403 der Europäischen Kommission vom 13. März 2020 über Konformitätsbewertungs- und Marktüberwachungsverfahren im Kontext der COVID-19 Bedrohung zu vermuten.
The technical efficiency of the above-mentioned product is to be presumed within the framework of the European Commission Recommendation (EU) 2020/403 of 13th March 2020 on conformity assessments and market surveillance procedures in the context of the COVID-19 risk.

Der Prüfgrundsatz kann unter der Website der ZLS eingesehen werden.
The test principle can be accessed under the ZLS website.

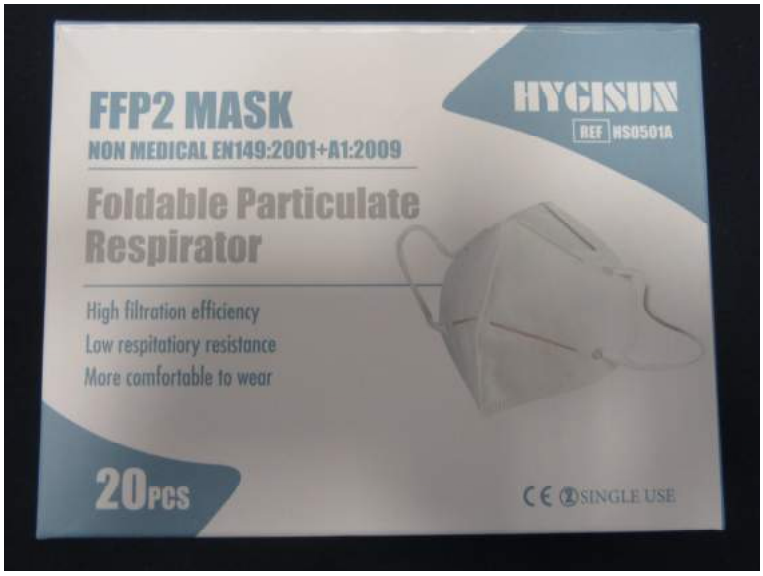
Diese Bewertung ist gültig vom 08.07.2020 bis 08.07.2021.
This evaluation of conformity is valid from 2020-07-08 until 2021-07-08.

DEKRA Testing and Certification GmbH
Bochum, 2020-07-08

Jörg-Timm Kilisch
Geschäftsführer *Managing Director*

DEKRA Testing and Certification GmbH, Handwerkstraße 15, 70565 Stuttgart
Zertifizierungsstelle: Dinnendahlstraße 9, 44809 Bochum,
Telefon +49.234.3696-400, Fax +49.234.3696-401, DTC-Certification-body@dekra.com

HS0501A (FFP2 Mask)



DEKRA Testing and Certification GmbH, Handwerkstraße 15, 70565 Stuttgart
Zertifizierungsstelle: Dinnendahlstraße 9, 44809 Bochum,
Telefon +49.234.3696-400, Fax +49.234.3696-401, DTC-Certification-body@dekra.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
Job type:	Testing Samples Submitted	Schumanstr. 12
Start Date:	27/05/2020	Würselen
Test type:	Type	52146
Sample ID:	10190222	Germany
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		
			Walking	Walking with head side to side	Walking with head up & down	Walking and talking	Walking	Average	
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). 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_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

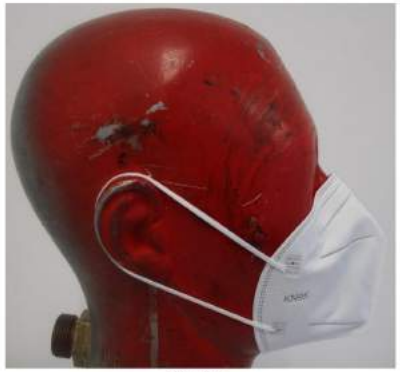
Appendix A. – Test Panel Data

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

Latest Issue: 2020-07-03

Effective Date: 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

Latest Issue: 2020-07-03

Effective Date: 2020-07-03

Expiry Date: 2021-07-03

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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
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

The 3rd Party Certificate of

FDA Medical Device Registration

Note:

This file is Not being issued by FDA. We, EUT, as the 3rd party, produce it, intended to facilitate customer display & transmit information. The following contents, FDA registered Facility/Owner/Operator &FDA listing Medical Device, are excerpted from database at www.fda.gov.

Establishment:

Hunan Dreaming Cloud E-Commerce CO., Ltd

Block 1, Smart Tech Park, 57# Huangxing Avenue, Changsha Economic and Technological Develo

Zone, Changsha, Hunan, China 41000

Registration Number / FEI Number*:

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set.

Status: **Active**

Date of Registration Status: **2020**

Owner/Operator

Hunan Dreaming Cloud E-Commerce CO., Ltd

Block 1, Smart Tech Park, 57# Huangxing Avenue, Changsha Economic and Technological Development Zone, Changsha, Hunan, China 41000

Owner/Operator Number: 10070835

Official Correspondent

Contact Name: Edward Zhao Vice General Manager

Block 1, Smart Tech Park, 57# Huangxing Avenue, Changsha Economic and Technological Development Zone, Changsha, Hunan, China 41000

Tel: +86- 731-82070608 E-mail: info@mesin.cn

Devices Listing Information

Proprietary Name	Product Codes	Device Class	Listing Number	Establishment Operations
Disposable Respirator Mask	LYU	1	D393932	Manufacturer

Please careful protect your **Listing Number.**

Professional FDA Registration Services, by Guangzhou UTT Testing Service Co., Ltd.

FDA CERTIFICATE NUM: UTT20APR134C

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

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

White list of China's mask export

动态更新：取得国外标准认证...

	Luoyang Kenjian Technology Co.,Ltd.	
388	仙桃市仟腾救生设备有限公司 Xiantao Qianteng Life Saving Equipment Co.,Ltd.	91429004MA49AH0L5F
389	武冈市协众医疗器械有限公司 [illegible] Xiezhong Medical Equipment [illegible]	91430581MA4R4KQG1F
390	湖南云想生活电子商务有限公司 Hunan Dreaming Cloud E-Commerce CO., Ltd	91430105MA4LAAUW8C
[illegible]	[illegible] Lianyungang Meishun Medical Supplies Co., Ltd.	91320724596900367H
392	南京海尼医疗器械有限公司 Nanjing Honney Medical Apparatus and Instruments Co.,Ltd.	91320118MA20W2X949
393	江苏岛瀛服饰有限公司 Jiangsu Daoying Clothing Co., Ltd	91320921MA1N9GUH28
394	江苏南方卫材医药股份有限公司 Jiangsu Nanfang Medical Co.,Ltd	91320400250815683R
395	启东正茂新材料有限公司 Qidong ZhengMao New Material Co.,LTD	91320681MA20P9095L
396	江西鲍斯高服饰有限公司 Jiangxi Baosi Clothing Co.,Ltd	91361029MA384PJHXY
397	江西威仕特生物科技有限公司 Jiangxi VST Biotechnology Co., Ltd	91440300692523901R
398	青州尧王制药有限公司 Qingzhou Yaowang Pharmaceutical Co., Ltd.	91370781613582541Q
399	烟台沃德麦克斯纳米科技有限公司 Yantai World-max Nanotechnology co., Ltd	91370600MA3MNP0F9B
400	青岛德润防护用品有限公司 Qingdao Derun Protective Equipment Co.,ltd.	91370282MA3RPHKX7A
401	山东星宇手套有限公司 Shandong Xingyu Gloves Co., Ltd.	913707857741816OX7
402	升欣（上海）纺织品科技有限公司 Shengxin (Shanghai) Textile Technology Co., LTD	9131011669580205XY
403	上海威尔逊光电仪器有限公司 Wilson Instruments (SHA) Co., Ltd.	91310230632150402H
404	上海威抗医疗用品有限公司	91310113MA1GP609XY

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

Ouyang, Zhouya

Quality Manager

Hunan Dreaming Cloud E-Commerce CO., Ltd.