# HYGISUN®

REF HS0501A

# FFP2 Maske / FFP2 Mask

## Persönliche Schutzmaske

## Personal Protective Mask


CE 2797

EN 149: 2001+A1: 2009

# CARTON DIMENSION ( FFP2 - White - 20er )

HYGISUN®

| 1 PC/OPP | 20 PCS/box | 1000 PCS/carton | 20000 PCS/pallet |
|---|---|---|---|

EAN: 4260676530003

CE 2797


FFP2-MASKE
PERSÖNLICHE SCHUTZMASKE EN149:2001+A1:2009
HYGISUN®
REF HS0501A
Faltbare Partikel
-Atemschutzmaske
Hohe Filtrationseffizienz
Geringer Atemwiderstand
Bequem zu tragen
HYGISUN
HS0501A FFP2 NR
EN149 : 2001+A1 : 2009
CE 2797
20Stück
Einmalgebrauch
CE 2797

# Bedienungsanleitung
# Fitting instructions

Nehmen Sie die Maske an den Ohrschlaufen in die Hand und drücken Sie diese mit dem Bügel auf den Nasenrücken gegen Ihr Gesicht, während Sie die Ohrschlaufen hinter Ihren Ohren positionieren.
Take the mask by the ear loops in your hand and press it against your face with the strap on the bridge of your nose while you position the ear loops behind your ears.

Formen Sie den Bügel mit beiden Händen in die Form Ihrer Nase.
Shape the nose clip into the shape of your nose with both hands.

Testen Sie die Passform. Nehmen Sie beide Hände über die Atemschutzmaske und atmen Sie kräftig aus. Wenn Luft um Ihre Nase strömt, ziehen Sie den Bügel fester.
Test the correct fit. Put both hands over the respirator and exhale forcefully. When air flows out around your nose, press the nose clip tighter.

## HINWEIS ZUR VERWENDUNG: / NOTICE FOR USE:

- Bitte verwenden Sie dieses Produkt nicht in der Nähe einer Feuerquelle.
Please do not use this product near fire sources.
- Da es sich bei diesem Produkt um eine Einwegmaske handelt, kann es nicht durch Waschen wiederverwendet werden.
As this product is a disposable mask, it cannot be reused through washing.
- Von hohen Temperaturen und Luftfeuchtigkeit fernhalten und an einem sauberen Ort aufbewahren.
Keep it away from high temperature and humidity and keep it in clean place.
- Persönliche Schutzmaske, Nicht medizinisch.
personal protective mask, non-medical.
- Verwenden Sie einzeln verpackte Produkte, sobald diese ausgepackt sind.
Use individually packaged products as soon as they are unpacked.


FFP2-MASK
PERSONAL PROTECTIVE MASK EN149:2001+A1:2009
Foldable Particulate Respirator
High filtration efficiency
Low respitatiory resistance
More comfortable to wear
HYGISUN®
REF HS0501A
HYGISUN
HS0501A FFP2 NR
EN149 : 2001+A1 : 2009
CE 2797
20PCS
Single Use
CE 2797


FFP2 Maske
EN149:2001+A1:2009
WICHTIG: Die Atemschutzmaske FFP2 bietet Schutz vor Pollen, Viren und Industriestaub.
IMPORTANT: The respiratory protection mask FFP2 is designed to protect from pollen, virus and industrial dust.
ANWENDUNG: / APPLICATION:
Die Maske wird in der Schutzindustrie bei Staubentwicklung, während des Baus zur Staubverhütung, beim Metallguss, Steinabbau, in der Elektronik, Pharmazie, der physikalischen Verarbeitung und beim Schleifen verwendet und bietet einen guten Schutz gegen Sandstürme, Dunst und PM2.5. Kann wirksam vor Pollenallergien, Virusubertragung usw. schützen.
It is used in the industry for dust generation during construction, dust prevention, metal casting, stone mining, electronics, pharmaceutical, physical processing and grinding. It also offers good protection against sandstorms, haze and PM2.5. Can effectively protect pollen allergy, virus transmission, etc.
VERFALLSDATUM: / EXPIRATION DATE:
Lagertemperatur: -20~38°C, Lagerfeuchtigkeit ≤80%, Haltbarkeit: 2 Jahre in trockenen Innenräumen.
The storage temperature is -20~38°C, the storage is moderate ≤80%, The validity period is 2 year in the dry indoor environment.
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 REP
Sunbeam International GmbH
Schumanstr. 12, 52146 Würselen, Germany
PZN: 16865038
4 260676 530003


HYGISUN®
FFP2 Maske
Nicht medizinisch EN149:2001+A1:2009
FFP2-MASKE
Nicht medizinisch EN149:2001+A1:2009
Faltbare Partikel
-Atemschutzmaske
Hohe Filtrationseffizienz
Geringer Atemwiderstand
Bequem zu tragen
20 Stück
HYGISUN®
REF HS0501A


FFP2-MASK
Foldable Particulate Respirator
High filtration efficiency
Low respiratory resistance
More comfortable to wear
20pcs
Single Use
LOT:20201025-01-A
PD:2020/10/25
MHD/BBD:2022/10/24
CE 2797


Persönliche Schutzmaske
PERSONAL PROTECTIVE MASK
1Stück/ Piece


Persönliche Schutzmaske
PERSONAL PROTECTIVE MASK
1Stück/ Piece

# HYGISUN

## QUALIFIED CERTIFICATE

| | |
|---|---|
| 产品名称 | FFP2个人防护口罩(不作为医疗防护使用) |
| Product Name | FFP2 personal protective mask.(For personal protective only) |
| 执行标准 | EN149:2001 + A1:2009 |
| Standard | EN149:2001 + A1:2009 |
| 产品规格 | 16×10.5厘米 |
| Product Size | 16×10.5CM |
| 材质 | 30%熔喷布+70%无纺布 |
| Material | 30% MELT-BLOWN FABRIC+70% NON-WOVEN FABRIC |
| 质检员 | |
| Checker | |
| 生产日期 | |
| Date | QC:01 |
| 生产批号 | PD: SEE ON PACKAGE |
| Lot code | LOT: SEE ON PACKAGE |
| 使用周期 | 一次性 |
| Usege count | Single use |
| 有效期 | 2年 |
| Period of validity | 2 years |
| 生产企业 | 湖南云想生活电子商务有限公司 |
| Manufacturer | Hunan Dreaming Cloud E-Commerce CO., Ltd |
| 生产地址 | 长沙经济技术开发区黄兴大道南段57号星为创芯园1栋501号 |
| Address | Block 1, Smart Tech Park, 57# Huangxing Avenue, Changsha Economic and Technological Development Zone, Changsha, Hunan, China |

QUALITY PASSED
检验 合格
HUNANDREAMINGCLOUDE-COMMERCECO.,LTD

储存条件：本品应储存温度-20~38℃，储存湿度≤80%避光干燥的室内环境下，通风良好，无腐蚀性气体的清洁环境内，如贮存不当导致发霉变质禁用。

STORAGE CONDITIONS AND METHODS: The storage temperature is -20~38℃, and the relative humidity is not more than 80%. Well-ventilated and clean environment without corrosive gas, please do not use if the product gets mildewed or deteriorated due to improper storage.

本产品为个人防护用品，不作为医疗防护使用

THIS PRODUCT IS UNDER PERSONAL PROTECTIVE EQUIPMENT DIRECTIVE (PPE) FOR PERSONAL PROTECTIVE ONLY

MADE IN CHINA

HYGISUN

## ANLEITUNG

**Norm:**

Dieses Produkt entspricht der Norm EN149:2001 + A1:2009 für Atemschutzgeräte – Halbmaske zur Filterung zum Schutz vor Partikeln. Diese Filtermasken sind gemäß der Verordnung der Europäischen Kommission (EU) 2016/425 über PSA als Persönliche Schutzausrüstung in der Kategorie III eingestuft und entsprechend gekennzeichnet

**Bestimmungsgemäße Verwendung:**

Die Staubmaske ist als Kategorie FFP 2 eingestuft. Sie schützt vor Partikeln, Nebel, Rauch und Aerosolen auf Ölbasis. Die Verpackung schützt die Maske vor der Verwendung. Schützt wirksam vor Pollen. Die Maske kann nur zum persönlichen Schutz verwendet werden, nicht für medizinische Zwecke. Maske nicht bei der Brandbekämpfung und in explosionsgefährdeten Bereichen nutzen.

**Dichtsitztest**

1.Bedecken Sie die Maske vorsichtig mit beiden Händen ohne den Dichtsitz zu verändern.
2.stark Ausatmen;
3.Bei einer Leckage im Nasenbereich, den Nasenbügel neu anpassen. Dichtsitzprüfung wiederholen.
4.Bei einer Leckage am Maskenrand, den Sitz der Bänder überprüfen und anpassen. Dichtsitzprüfung wiederholen.

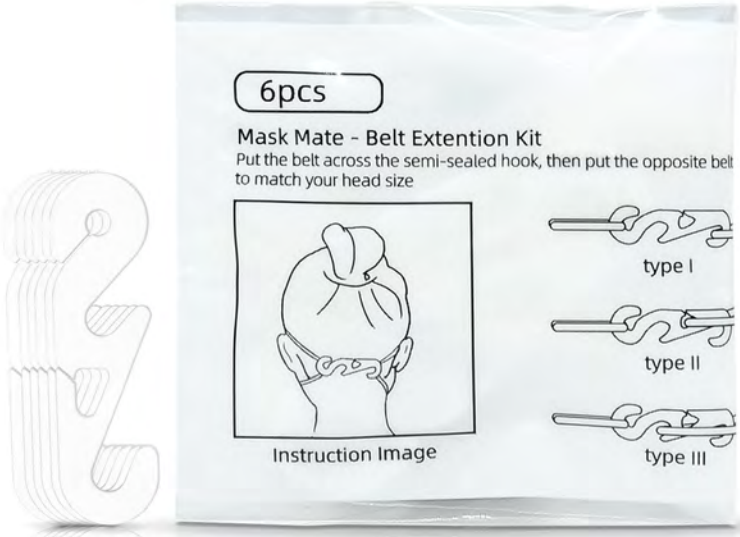
Wenn Sie KEINEN richtigen Dichtsitz erreichen können, betreten Sie NICHT den Gefahrenbereich. Informieren Sie ihren Vorgesetzten.

**Warnungen und Einschränkungen:**

- Vergewissern Sie sich immer, dass das Produkt:
  Geeignet ist für die Anwendung;
  Korrekt angelegt ist;
  Während des gesamten Aufenthalts im Gefahrenbereich getragen wird;
  Ersetzt wird, wenn notwendig.
- Richtige Auswahl, Schulung, Gebrauch und gegebenenfalls Reinigung sind die Voraussetzungen dafür, dass das Produkt den Anwender vor bestimmten luftgetragenen Gefahrstoffen schützt.
- Die Nichtbefolgung aller Anweisungen zur Anwendung der Maske und/oder die Fehlbenutzung während des Aufenthaltes im Gefahrenbereich kann die Gesundheit des Anwenders beeinträchtigen und zu schweren Erkrankungen oder Dauerschäden führen.
- Beachten Sie bei der Auswahl und richtigen Anwendung nationale Bestimmungen und alle mitgelieferten Informationen.
- Vor Gebrauch muss der Anwender, in Übereinstimmung mit den nationalen Regeln, in der funktionsgerechten Handhabung geschult sein.
- Dieses Produkt schützt nicht vor Gasen und Dämpfen.
- Verwenden Sie die Maske nicht in Umgebungen mit weniger als 19,5% Sauerstoff
- Verwenden Sie die Masken nicht in Umgebungen mit unbekannten Gefahrstoffen oder Konzentrationen, die die zulässigen Höchstwerte übersteigen.
- Verwenden Sie die Maske nicht, wenn Gesichtshaare im Bereich des Dichtrandes einen korrekten Dichtsitz der Maske verhindern.
- Verlassen Sie sofort den belasteten Bereich, wenn:
  a) Das Atmen schwer fällt.
  b) Schwindel oder andere Beschwerden auftreten.
  c) Die Maske beschädigt wird.
  d) Geruch oder Geschmack des Gefahrstoffs oder eine Reizung auftritt.
- Entsorgen und ersetzen Sie die Maske, wenn sie beschädigt ist, der Atemwiederstand stark erhöht ist oder am Ende einer Schicht.
- Die Maske darf niemals verändert oder repariert werden.
- Die Maske ist zum einmaligen Gebrauch vorgesehen und ist danach entsprechend der nationalen Vorgaben zu entsorgen.

**Transport und Lagerung:**

Die Partikelmasken haben eine Lagerdauer von 2 Jahren. Das Ende der Lagerdauer ist auf der Verpackung angegeben. Vergewissern Sie sich vor Gebrauch immer, dass das Produkt noch innerhalb der Lagerdauer liegt. Das Produkt sollte sauber, trocken und im Temperaturbereich von -20°C bis +38°C bei einer maximalen rel. Luftfeuchtigkeit von 80% gelagert werden. Für Lagerung
und Transport die Originalverpackung verwenden. Nicht direkter Sonnenstrahlung aussetzen.


6pcs
Mask Mate - Belt Extention Kit
Put the belt across the semi-sealed hook, then put the opposite belt
to match your head size
Instruction Image
type I
type II
type III


HYGIENIUM
HS0501A FFP2 NR
EN149:2001+A1:2009
CE 2797

# 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 | [illegible] Luoyang Kaijun Technology Co.,Ltd. | [illegible] | [illegible] |
| 378 | [illegible] Xianlian Qiandeng Life Saving Equipment Co.,Ltd. | [illegible] | 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 | [illegible] Linyangang Meishun Medical Supplies Co., Ltd. | [illegible] | CE |
| 381 | [illegible] Nanjing Hesuny Medical Apparatus and Instruments Co.,Ltd. | [illegible] | CE |
| 382 | [illegible] Fangpai Dunying Clothing Co., Ltd | [illegible] | 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 750475 (Ausstellungsdatum: 09/06/2021)**

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 750476 (Ausstellungsdatum: 09/06/2021) verwiesen wird.

Changsha, China, 10.06.2021

OuYang Zhouya

OuYang Zhouya

(Nachname Name)

Qualitätsmanager

Hunan Dreaming Cloud E-Commerce CO., Ltd.

# 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 Hagenaars, Managing Director

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

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



PRODUCTS
RvA C 646

...making excellence a habit.™

# EU Type Examination Certificate

No. CE 750475

**Product Specification**

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

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

# 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

# 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 Hagenaars, Managing Director

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

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



PRODUCTS
RvA C 646

...making excellence a habit.™

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

No. CE 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:

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

**Certificate Administration Details:**

**Certificate Amendment Record:**

| Issue date | Comments | BSI Review No. |
|---|---|---|
| June 2021 | First issue.<br>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
Latest Issue: 2021-06-09

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

# Test Report 3339405.

## Sunbeam International GmbH.

# Introduction.

This report has been prepared by D. Key and relates to the activity detailed below:

| Job/Registration Details | | Client Details |
|---|---|---|
| Job number: | 3339405 | Sunbeam International GmbH<br>Schumanstr. 12<br>Würselen<br>52146<br>Germany |
| Job type: | Testing samples submitted | |
| Start Date: | 17/01/2021 | |
| Test type: | Type | |
| Sample ID: | 10195243 | |
| Registration: | CE 730303 | |
| Scheme: | Negative 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: 22 March 2021 |

# Objectives.

This is an independent Type Test evaluation to BS EN 149:2001+A1:2009. This report covers the gap testing from the BSI COVID-19 filtering face piece technical specification, for COVID-19 masks for use by healthcare workers.
See BSI Test Report 3220780 for the BSI COVID-19 filtering face piece technical specification test results.

# Product Scope.

Respiratory protective device- Filtering half masks to protect against particles.

# Report Summary.

The samples were received on 18 December 2020 and the testing was started on 17 January 2021.

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

## Test Samples.

| Sample ID | ER Number | Description |
|---|---|---|
| 1 to 37 | 10195243 | Model: HYGISUN HS0501A FFP2 NR |

## Description of Test Samples.

| Sample Description |
|---|
| Model: HYGISUN HS0501A FFP2 NR. Valveless vertical fold flat particle filtering half mask with elastic earloops and removable plastic earloop clip |

# Test Requirements.

BS EN 149:2001 + A1:2009
Respiratory protective devices - Filtering half masks to protect against particles.

| CLAUSE | REQUIREMENTS | ASSESSMENT |
|---|---|---|
| 7 | Requirements | - |
| 7.1 | General | - |
| 7.2 | Nominal values and tolerances | - |
| 7.3 | Visual Inspection | Pass (1) |
| 7.4 | Packaging | N/T (1) |
| 7.5 | Material | Pass |
| 7.6 | Cleaning and disinfecting | N/A (2) |
| 7.7 | Practical performance | N/T (3) |
| 7.8 | Finish of parts | Pass |
| 7.9 | Leakage | - |
| 7.9.1 | Total inward leakage | Pass (3) |
| 7.9.2 | Penetration of filter material | Pass (3) |
| 7.10 | Compatibility with skin | Pass |
| 7.11 | Flammability | Pass |
| 7.12 | Carbon dioxide content of inhalation air | N/T (3) |
| 7.13 | Head harness | Pass |
| 7.14 | Field of vision | Pass |
| 7.15 | Exhalation valves | N/A (4) |
| 7.16 | Breathing resistance | Pass (3) |
| 7.17 | Clogging | N/A (4) |
| 7.18 | Demountable parts | N/A (4) |
| 9 | Marking | N/T (1) |
| 10 | Information to be supplied by the manufacturer | N/T (1) |
| Appendix A - Test Panel Data | | |
| Product Photographs | | |

(1) Packaging, Marking and Information not assessed as requested by BSI Product Certification
(2) Single use mask
(3) See also results from BSI COVID-19 filtering face piece technical specification testing, BSI Test Report number 3220780.
(4) Not a design feature of this product

# 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: Manufacturer's Minimum Design Flow

# 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.

BS EN 149:2001 + A1:2009
Respiratory protective devices - Filtering half masks to protect against particles.

| CLAUSE | REQUIREMENTS | ASSESSMENT |
|---|---|---|
| 7.1 | General | |
| | In all tests all samples shall meet the requirements. | - |
| 7.2 | Nominal values and tolerances | |
| | Unless otherwise specified, the values stated in this European Standard are expressed as nominal values. Except for temperature limits, values, which are not stated as maxima or minima, shall be subject to a tolerance of ±5%. Unless otherwise specified, the ambient temperature for testing shall be (16 – 32) °C, and the temperature limits shall be subject to an accuracy of ± 1°C. | - |
| 7.3 | Visual Inspection | |
| | The visual inspection shall also include the marking and the information supplied by the manufacturer. | Pass (1) |
| 7.5 | Material | |
| | Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used. | Pass |
| | After undergoing the conditioning described in clause 8.3.1 of the standard none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps. | |
| | Three particle filtering half masks shall be tested. | 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 |
| | Testing shall be done in accordance with 8.2. | |
| 7.8 | Finish of parts | |
| | Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs. | Pass |
| | Testing shall be done in accordance with 8.2. | |

(1) Marking and user information were not assessed as requested by BSI Product Certification

# Test Results. (Continued)

| CLAUSE | REQUIREMENTS | ASSESSMENT |
|---|---|---|
| 7.9 | Leakage | |
| 7.9.1 | Total inward leakage<br>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.<br>The total inward leakage consists of three components: face seal leakage, exhalation valve leakage (if exhalation valve fitted) and filter penetration.<br>For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than<br>25% for FFP1<br>11% for FFP2<br>5% for FFP3<br>and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than<br>22% for FFP1<br>8% for FFP2<br>2% for FFP3<br>Testing shall be done in accordance with 8.5. | Pass (1)<br>See Table A |

Table A: Clause 7.9.1 - Total inward leakage.

| Test candidate | Sample | Pre-test condition | Inward leakage (%). | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | A | B | C | D | E | Average |
| | | | Walking | Walking with head side to side | Walking with head up & down | Walking and talking | Walking | |
| LM2 | 8 | TC | 7.2973 | 3.9167 | 5.7087 | 3.2365 | 5.1736 | 5.0666 |
| SI1 | 9 | TC | 0.2104 | 0.2047 | 0.2353 | 0.2276 | 0.1237 | 0.2003 |
| KH1 | 10 | TC | 0.2112 | 0.2296 | 0.2503 | 0.5231 | 0.6973 | 0.3823 |
| CB1 | 11 | TC | 3.0178 | 1.8510 | 8.0745 | 1.8897 | 5.6798 | 4.1025 |
| JW1 (2) | 12 | TC | 0.5893 | 0.9512 | 0.7366 | 0.4300 | 0.6535 | 0.6721 |

(1) Results for the remaining 'as received' samples are covered in BSI Test Report number 3220780 for the BSI COVID-19 filtering face piece technical specification testing.
(2) Earloop clip used.

# Test Results. (Continued)

| CLAUSE | REQUIREMENTS | ASSESSMENT |
|---|---|---|
| 7.9.2 | Penetration of filter material | |
| | The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1 | |
| | A total of 9 samples of particle filtering half masks shall be tested for each aerosol. Testing in accordance with 8.11 using the Penetration test according to EN 13274-7, shall be performed on: | Pass (1) See Tables B and C |
| | 3 samples as received, | |
| | 3 samples after the simulated wearing treatment described in 8.3.1. | |
| | Testing in accordance with 8.11 using the Exposure test with a specified mass of test aerosol of 120 mg, and for particle filtering devices claimed to be re-usable additionally the Storage test, according to EN 13274-7, shall be performed: | Pass (1) See Table D and E |
| | for non-re-usable devices on: | |
| | 3 samples after the test for mechanical strength in accordance with 8.3.3 followed by temperature conditioning in accordance with 8.3.2. | |
| | for re-usable devices on: | |
| | 3 samples after the test for mechanical strength in accordance with 8.3.3 followed by temperature conditioning in accordance with 8.3.2 and followed by one cleaning and disinfecting cycle according to the manufacturer's instruction. | N/A (2) |

Table B: Clause 8.11 - Sodium Chloride penetration test.

| Sample | Pre-test condition | Continuous flow (l/min) | Penetration (%) | |
|---|---|---|---|---|
| | | | Limit | Measured |
| 16 | SW | 95 | 6.0 | 0.1635 |
| 17 | SW | 95 | 6.0 | 0.1645 |
| 18 | SW | 95 | 6.0 | 0.1542 |

Table C: Clause 8.11 - Paraffin oil penetration test.

| Sample | Pre-test condition | Continuous flow (l/min) | Penetration (%) | |
|---|---|---|---|---|
| | | | Limit | Measured |
| 22 | SW | 95 | 6.0 | 1.1895 |
| 23 | SW | 95 | 6.0 | 1.9665 |
| 24 | SW | 95 | 6.0 | 1.6080 |

(1) Results for the remaining 'as received' samples are covered in BSI Test Report number 3220780 for the BSI COVID-19 filtering face piece technical specification testing.
(2) Not a design feature of this product.

# Test Results. (Continued)

| CLAUSE | REQUIREMENTS | ASSESSMENT |
|---|---|---|

7.9.2 Penetration of filter material (continued)

Table D: Clause 8.11. Exposure test Sodium Chloride.

| | Sample 28 MS TC | Sample 29 MS TC | Sample 30 MS TC |
|---|---|---|---|
| Flow through filter | 95 l/min | | |
| Elapsed time (minutes) | Measured penetration %<br>(Maximum permitted penetration 6.0 %) | | |
| 5 | 0.239798 (1) | 0.100650 (1) | 0.149081 (1) |
| 10 | 0.192890 | 0.079177 | 0.121274 |
| 15 | 0.141387 | 0.065270 | 0.096979 |
| 20 | 0.090230 | 0.052679 | 0.076271 |
| 25 | 0.056086 | 0.041193 | 0.054319 |
| 30 | 0.033608 | 0.032297 | 0.038793 |
| Result | Pass | Pass | Pass |

(1) The reading at which 5 subsequent sampling intervals showed a declining filter penetration. The testing was terminated without the 120mg exposure limit being reached, as permitted by BS EN 13274-7.

# Test Results. (Continued)

| CLAUSE | REQUIREMENTS | ASSESSMENT |
|---|---|---|

7.9.2 Penetration of filter material (continued)

Table E: Clause 8.11 Paraffin oil exposure test.

| | Sample 25 MS TC | Sample 26 MS TC | Sample 27 MS TC |
|---|---|---|---|
| Flow through filter | 95 l/min | | |
| Elapsed time (minutes) | Measured penetration %<br>(Maximum permitted penetration 6.0 %) | | |
| 3 | 2.1110 | 1.5950 | 1.9965 |
| 5 | 2.2125 | 1.6255 | 2.0845 |
| 10 | 2.4525 | 1.9880 | 2.3595 |
| 15 | 2.5900 | 1.9280 | 2.4440 |
| 20 | 2.8495 | 1.9610 | 2.5800 |
| 25 | 3.0625 | 2.0000 | 2.6650 |
| 30 | 3.2990 | 2.1675 | 2.7670 |
| 35 | 3.2725 | 2.2115 | 2.9130 |
| 40 | 3.4220 | 2.2705 | 3.0045 |
| 45 | 3.6010 | 2.3765 | 3.0950 |
| 50 | 3.6315 | 2.3965 | 3.1885 |
| 55 | 3.7715 | 2.4610 | 3.2285 |
| 60 | 3.8520 | 2.5240 | 3.3385 |
| (1) | 4.0125 | 2.5060 | 3.3755 |
| Result | Pass | Pass | Pass |

(1) A loading of 120 mg was achieved after a period of 63 minutes, 10 seconds had elapsed.

# Test Results. (Continued)

| CLAUSE | REQUIREMENTS | ASSESSMENT |
|---|---|---|
| 7.10 | Compatibility with skin | |
| | 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 |
| | Testing shall be done in accordance with 8.4 and 8.5. | |
| 7.11 | Flammability | |
| | The material used shall not present a danger for the wearer and shall not be of a highly flammable nature. | |
| | When tested, the particle filtering half mask shall not burn or not continue to burn for more than 5 seconds after removal from the flame. | Pass<br>See Table F |
| | The particle filtering half mask does not have to be usable after the test. | |
| | Testing shall be done in accordance with 8.6. | |

Table F: Clause 8.6 – Flammability.

| Sample | Area exposed | Comments |
|---|---|---|
| 34 AR | Filter material, welding. | Did not ignite. |
| 35 AR | Earloop, vertical welding. | Did not ignite. |
| 36 TC | Filter material, welding. | Did not ignite. |
| 37 TC | Earloop, vertical welding. | Did not ignite. |

| | | |
|---|---|---|
| 7.13 | Head harness | |
| | 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 |
| | Testing shall be done in accordance with 8.4 and 8.5. | |
| 7.14 | Field of vision | |
| | The field of vision is acceptable if determined so in practical performance tests. | Pass |
| | Testing shall be done in accordance with 8.4. | |

# Test Results. (Continued)

| CLAUSE | REQUIREMENTS | ASSESSMENT |
|---|---|---|
| 7.16 | Breathing resistance | |
| | The breathing resistances apply to valved and valveless particle filtering half masks and shall meet the requirements of Table 2. | |
| | Testing shall be done in accordance with 8.9. | |
| | A total of 9 valveless particle filtering half masks shall be tested:<br>3 as received, 3 after temperature conditioning in accordance with 8.3.2 and 3 after the test for simulated wearing in accordance with 8.3.1. | Pass* (1) (2)<br>See Tables G, H and I |
| | Testing shall be done in accordance with 8.9. | |
| | A total of 12 valved particle filtering half masks shall be tested: 3 as received, 3 after temperature conditioning in accordance with 8.3.2, 3 after the test for simulated wearing in accordance with 8.3.1, and 3 after the flow conditioning in accordance with 8.3.4. | N/A (3) |
| | Testing shall be done in accordance with 8.9. | |

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

| Sample | Pre-test condition | Flow (l/min) | Limit (mbar) | Measured (mbar) |
|---|---|---|---|---|
| 16 | SW | 30 | 0.7 | 0.54 |
| 17 | SW | 30 | 0.7 | 0.50 |
| 18 | SW | 30 | 0.7 | 0.53 |
| 31 | TC | 30 | 0.7 | 0.48 |
| 32 | TC | 30 | 0.7 | 0.47 |
| 33 | TC | 30 | 0.7 | 0.46 |

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

| Sample | Pre-test condition | Flow (l/min) | Limit (mbar) | Measured (mbar) |
|---|---|---|---|---|
| 16 | SW | 95 | 2.4 | 1.89 |
| 17 | SW | 95 | 2.4 | 1.87 |
| 18 | SW | 95 | 2.4 | 1.89 |
| 31 | TC | 95 | 2.4 | 1.79 |
| 32 | TC | 95 | 2.4 | 1.79 |
| 33 | TC | 95 | 2.4 | 1.72 |

(1) Results for the remaining 'as received' samples are covered in BSI Test Report number 3220780 for the BSI COVID-19 filtering face piece technical specification testing.

(2) Results for exhalation resistance are within the uncertainty of measurement, but compliance is more probable than non-compliance.

(3) Not a design feature of this product.

# Test Results. (Continued)

| CLAUSE | REQUIREMENTS | ASSESSMENT |
|---|---|---|
| 7.16 | Breathing resistance (continued) | |

Table I: Clause 8.9 – Breathing resistance. Exhalation resistance at a continuous flow, measured in five orientations with the highest value recorded.

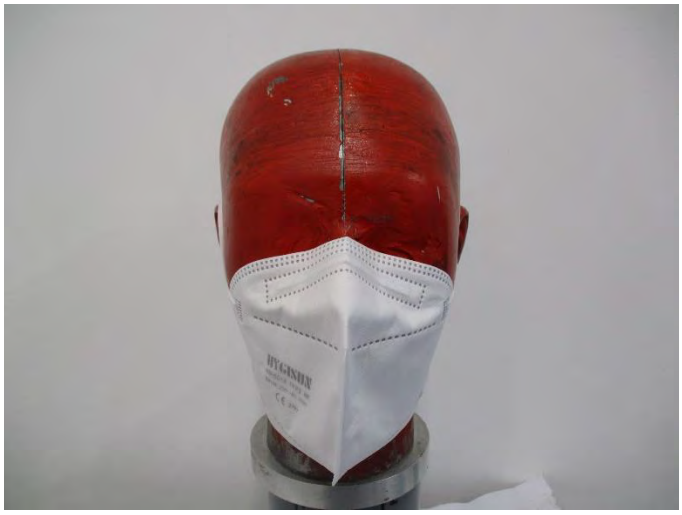
| Sample | Pre-test condition | Flow (l/min) | Limit (mbar) | Measured (mbar) |
|---|---|---|---|---|
| 16 | SW | 160 | 3.0 | 2.87 |
| 17 | SW | 160 | 3.0 | 2.96 |
| 18 | SW | 160 | 3.0 | 2.95 |
| 31 | TC | 160 | 3.0 | 2.89 |
| 32 | TC | 160 | 3.0 | 2.84 |
| 33 | TC | 160 | 3.0 | 2.79 |

# Appendix A. – Test Panel Data

| Test Candidate | Facial Dimensions (mm) | | | | | Gender |
|---|---|---|---|---|---|---|
| | Length of face | Width of face | Face depth | Width of mouth | Head Circumference | |
| JW1 | 116 | 126 | 122 | 48 | 570 | Male |
| SI1 | 121 | 135 | 142 | 48 | 575 | Male |
| LM2 | 110 | 148 | 125 | 47 | 567 | Male |
| KH1 | 112 | 142 | 115 | 60 | 585 | Male |
| CB1 | 117 | 147 | 130 | 57 | 566 | Male |

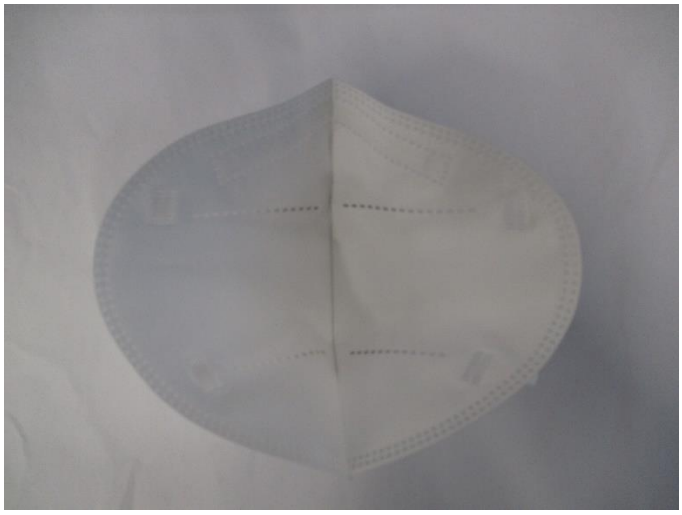
Note: All candidates were clean shaven

# Product photographs.



Front view

Side view



Inside view

*** End of Report ***

***Test Report No.:*** 244315789a 001

***Client:*** **SUNBEAM INTERNATIONAL GMBH**

***Contact Information:*** Schumanstr. 12, 52146 Würselen, Germany
Contact Person: Edward Zhao

***Sample Description As Declared:***

| | | |
|---|---|---|
| No. Of Sample | : | 80 pcs |
| Product Description | : | Personal Protective Respitator Mask |
| Product Type | : | Single shift use only |
| Material | : | - |
| Colour | : | White |
| Lot No./Batch Code | : | - |
| Buyer Name | : | - |
| Trademark | : | HYGISUN |
| Type-identifying | : | HS0501A |
| Claimed Classification | : | FFP2 NR |
| Manufacturer | : | Hunan Dreaming Cloud E-Commerce Co., Ltd. |
| Country of Origin | : | - |
| Sales Destination (Country) | : | - |
| Test Type | : | Full Test |
| Test Specification | : | EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing and Marking |
| Other Information | : | - |

***Sample Obtaining Method:*** Sending by customer

***Delivery Condition:*** Apparent good, samples tested as received

***Sample Receiving date:*** 2021-03-04 & 2021-04-21

***Testing Period:*** 2021-03-04 to 2021-04-01 & 2021-04-21 to 2021-04-27

***Place of Testing:*** Textiles laboratory Shanghai

**For and on behalf of**
**TÜV Rheinland (Shanghai) Co., Ltd.**

2021-04-30 Carmen Yan / Department Manager

*Date* *Name/Position*

## Test Report No.: 244315789a 001



**Summary of Test Results:**

| Clause | Item | Conclusion |
|---|---|---|
| 7.3 | Visual Inspection | P |
| 7.4 | Package | P |
| 7.5 | Material | P |
| 7.6 | Cleaning And Disinfection | N/A |
| 7.7 | Practical Performance | P |
| 7.8 | Finish Of Parts | P |
| 7.9.1 | Leakage | P |
| 7.9.2 | Penetration Of Filter Material | P |
| 7.10 | Compatibility With Skin | P |
| 7.11 | Flammability | P |
| 7.12 | Carbon Dioxide Content Of The Inhalation Air | P |
| 7.13 | Head Harness | P |
| 7.14 | Field Of Vision | P |
| 7.15 | Exhalation Valve(s) | N/A |
| 7.16 | Breathing Resistance | P |
| 7.17 | Clogging | N/A |
| 7.18 | Demountable Parts | N/A |
| 10 | Information To Be Supplied By The Manufacturer | P |
| 9 | Marking | P |

Note: P = Pass F = Fail
# = No Comment - = Did Not Perform
N/R = Not Request N/A = Not Applicable

**Material List:**

| Material No. | Material | Color | Location | Remark |
|---|---|---|---|---|
| M001 | Whole Product | White | Personal Protective Respitator Mask | Received on 2021.03.04 |
| M001' | Whole Product | White | Personal Protective Respitator Mask | Received on 2021.04.21 |

**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. | Pass |
| 7.4 | Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use. | Pass |
| 7.5 | Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used. | Pass |
| | After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the face piece or straps. | Pass |
| | When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse. | Pass |
| | Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer. | Pass |
| 7.8 | Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs | Pass |
| 7.18 | All demountable parts (if fitted) shall be readily connected and secured, where possible by hand. | N/A |

**Remark:**

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

## Test Report No.: 244315789a 001



**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

## Test Report No.: 244315789a 001



**Clause 7.9.1: 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 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Condition | Specimen No. | Subject | Leakage (%) | | | | | |
| | | | Walk | Head Side/Side | Head Up/Down | Talk | Walk | Mean |
| As received | 1 | BM | 4.927 | 7.304 | 9.711 | 5.581 | 2.803 | 6.065 |
| | 2 | ACH | 3.824 | 6.874 | 8.145 | 8.664 | 5.217 | 6.545 |
| | 3 | ML | 4.128 | 6.229 | 8.225 | 7.422 | 3.877 | 5.976 |
| | 4 | LLC | 3.397 | 6.785 | 8.199 | 6.357 | 4.012 | 5.734 |
| | 5 | DG | 3.981 | 6.932 | 8.902 | 7.559 | 4.331 | 6.341 |
| After conditioning | 6 | SG | 4.104 | 5.181 | 10.648 | 7.685 | 3.493 | 6.222 |
| | 7 | YL | 6.247 | 5.487 | 8.375 | 8.247 | 6.027 | 6.877 |
| | 8 | KQ | 5.525 | 6.028 | 9.084 | 8.122 | 5.021 | 6.756 |
| | 9 | KXH | 6.001 | 6.439 | 9.119 | 8.074 | 5.387 | 7.004 |
| | 10 | YY | 5.743 | 6.009 | 8.911 | 7.936 | 5.111 | 6.742 |
| Conclusion | | Pass | | | | | | |

| Facial Dimension Of Subject (mm) | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Subject | BM | ACH | ML | LLC | DG | SG | YL | KQ | KXH | YY | LL |
| Face length | 135 | 127 | 120 | 120 | 130 | 135 | 115 | 120 | 130 | 130 | 121 |
| Face width | 160 | 159 | 133 | 140 | 145 | 155 | 135 | 135 | 155 | 165 | 163 |
| Face Depth | 130 | 122 | 115 | 115 | 132 | 132 | 118 | 115 | 120 | 143 | 142 |
| Mouth Width | 52 | 55 | 52 | 50 | 50 | 55 | 48 | 50 | 52 | 50 | 45 |

**Clause 7.9.2: Penetration Of Filter Material**

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

Requirement : FFP2: ≤6%

| M001 | | | |
|---|---|---|---|
| Aerosol | Condition | Specimen No. | Penetration (%) |
| Sodium chloride Penetration | As received | 1 | 0.048 |
| | As received | 2 | 0.223 |
| | As received | 3 | 0.226 |
| | Simulated wearing treatment | 4 | 0.568 |
| | Simulated wearing treatment | 5 | 0.483 |
| | Simulated wearing treatment | 6 | 0.439 |
| | Mechanical strength + Temperature conditioned @ Exposure test of 120mg | 7 | 0.322 |
| | Mechanical strength + Temperature conditioned @ Exposure test of 120mg | 8 | 0.282 |
| | Mechanical strength + Temperature conditioned @ Exposure test of 120mg | 9 | 0.289 |
| Paraffin oil Penetration | As received | 10 | 0.566 |
| | As received | 11 | 0.536 |
| | As received | 12 | 0.521 |
| | Simulated wearing treatment | 13 | 0.586 |
| | Simulated wearing treatment | 14 | 0.623 |
| | Simulated wearing treatment | 15 | 0.637 |
| | Mechanical strength + Temperature conditioned @ Exposure test of 120mg | 16 | 0.984 |
| | Mechanical strength + Temperature conditioned @ Exposure test of 120mg | 17 | 2.392 |
| | Mechanical strength + Temperature conditioned @ Exposure test of 120mg | 18 | 1.664 |
| Conclusion | Pass | | |

**Clause 7.11: Flammability**

Test method : EN 149:2001+A1:2009 Clause 8.6

Requirement : ≤5s

| M001 | | | |
|---|---|---|---|
| Item | Condition | Specimen No. | Test results |
| Afterflame time (s) | As received | 1 | DNI |
| | As received | 2 | DNI |
| | After conditioning | 3 | DNI |
| | After conditioning | 4 | DNI |
| Conclusion | | Pass | |

**Remark:**

DNI-Do not ignite

**Clause 7.12: Carbon Dioxide Content Of The Inhalation Air**

Test Method : EN 149:2001+A1:2009 Clause 8.7

Requirement : ≤1%

| M001 | | | |
|---|---|---|---|
| Item | Condition | Test results | |
| Content (%) | As received | Specimen 1 | 0.58 |
| | As received | Specimen 2 | 0.59 |
| | As received | Specimen 3 | 0.61 |
| | As received | Mean | 0.60 |
| Conclusion | | Pass | |

## Test Report No.: 244315789a 001



**Clause 7.16: Breathing Resistance**

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

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

| M001' | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Flow rate (l/min) | | Resistance (mbar) | | | | | | | | | | | | | | |
| As received | | Specimen 1 | | | | | Specimen 2 | | | | | Specimen 3 | | | | |
| | | A | B | C | D | E | A | B | C | D | E | A | B | C | D | E |
| Inhalation | 30 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 |
| | 95 | 1.3 | 1.3 | 1.3 | 1.3 | 1.3 | 1.4 | 1.4 | 1.4 | 1.4 | 1.4 | 1.4 | 1.4 | 1.4 | 1.4 | 1.4 |
| Exhalation | 160 | 2.0 | 2.0 | 2.0 | 2.0 | 2.0 | 2.2 | 2.2 | 2.2 | 2.2 | 2.2 | 2.2 | 2.2 | 2.2 | 2.2 | 2.2 |
| Simulated wearing treatment | | Specimen 4 | | | | | Specimen 5 | | | | | Specimen 6 | | | | |
| | | A | B | C | D | E | A | B | C | D | E | A | B | C | D | E |
| Inhalation | 30 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 |
| | 95 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.4 | 1.4 | 1.4 | 1.4 | 1.4 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 |
| Exhalation | 160 | 2.4 | 2.4 | 2.4 | 2.4 | 2.4 | 2.3 | 2.3 | 2.3 | 2.3 | 2.3 | 2.3 | 2.3 | 2.3 | 2.3 | 2.3 |
| Temperature conditioned | | Specimen 7 | | | | | Specimen 8 | | | | | Specimen 9 | | | | |
| | | A | B | C | D | E | A | B | C | D | E | A | B | C | D | E |
| Inhalation | 30 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 |
| | 95 | 1.4 | 1.4 | 1.4 | 1.4 | 1.4 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 |
| Exhalation | 160 | 2.3 | 2.3 | 2.3 | 2.3 | 2.3 | 2.4 | 2.4 | 2.4 | 2.4 | 2.4 | 2.2 | 2.2 | 2.2 | 2.2 | 2.2 |
| 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

**Marking**

Test Method: EN 149:2001+A1:2009 Clause 9

| M001 | |
|---|---|
| **9.1 Packaging** | |
| The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent. | |
| 9.1.1 The name, trademark or other means of identification of the manufacturer or supplier. | Present |
| 9.1.2 Type-identifying marking. | Present |
| 9.1.3 Classification<br>The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D. | Present |
| 9.1.4 The number and year of publication of this European Standard. | Present |
| 9.1.5 At least the year of end of shelf life. The end of shelf life may be informed by a pictogram as shown in Figure 12a, where yyyy/mm indicates the year and month. | Present |
| 9.1.6 The sentence 'see information supplied by the manufacturer', at least in the official language(s) of the country of destination, or by using the pictogram as shown in Figure 12b. | Present |
| 9.1.7 The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d. | Present |
| 9.1.8 The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D". ID This letter shall follow the classification marking preceded by a single space. | N/A |
| **9.2 Particle filtering half mask** | |
| Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following: | |
| 9.2.1 The name, trademark or other means of identification of the manufacturer or supplier. | Present |
| 9.2.2 Type-identifying marking. | Present |
| 9.2.3 The number and year of publication of this European Standard. | Present |
| 9.2.4 Classification<br>The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D. | Present |
| 9.2.5 If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the classification marking preceded by a single space. | N/A |
| 9.2.6 Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified. | N/A |

**Remark:**

1. The evaluation is based on artwork.
2. N/A: Not applicable

**Information To Be Supplied By The Manufacturer**

Test Method: EN 149:2001+A1:2009 Clause 10

| M001 | |
|---|---|
| 10.1 Information supplied by the manufacturer shall accompany every smallest commercial available package | Present |
| 10.2 Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination | Present |
| 10.3 The information supplied by the manufacturer shall contain all information necessary for trained and qualified persons on | |
| - application/limitations | Present |
| - the meaning of any colour coding | N/A |
| - checks prior to use | Present |
| - donning, fitting | Present |
| - use | Present |
| - maintenance (e.g. cleaning, disinfecting), if applicable | N/A |
| - storage | Present |
| - the meaning of any symbols/pictograms used | Present |
| of the equipment | |
| 10.4 The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added | Present |
| 10.5 Warning shall be given against problems likely to be encountered, for example: | |
| - fit of particle filtering half mask (check prior to use) | Present |
| - it is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal | Present |
| - air quality (contaminants, oxygen deficiency) | Present |
| - use of equipment in explosive atmosphere | Present |
| 10.6 The information shall provide recommendations as to when the particle filtering half mask shall be discarded | Present |
| 10.7 For devices marked "NR", a warning shall be given that the particle filtering half mask shall not be used for more than one shift | Present |

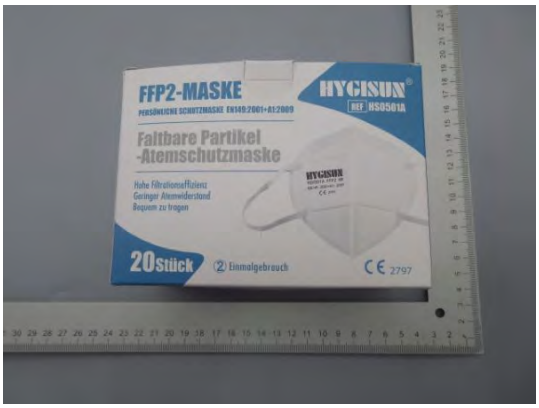
**Remark:**

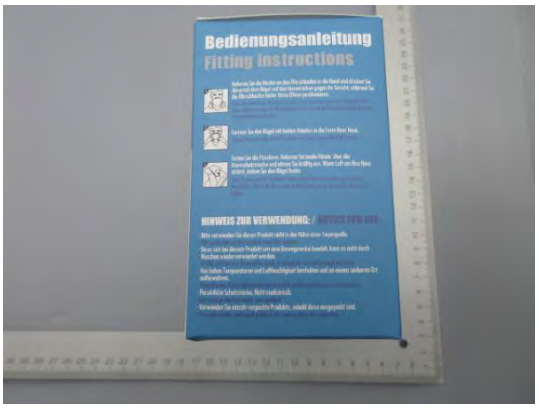
1. The evaluation is based on artwork.
2. N/A: Not applicable

Photo(s):

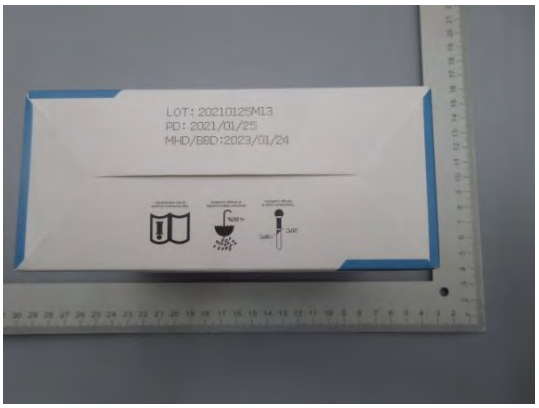

FFP2 MASK
HYGISUN
Foldable Particulate Respirator
20Pcs
Single Use
CE 2797


FFP2 Maske
EN149:2001+A1:2009


FFP2-MASKE
HYGISUN
Faltbare Partikel -Atemschutzmaske
20Stück
Einmalgebrauch
CE 2797

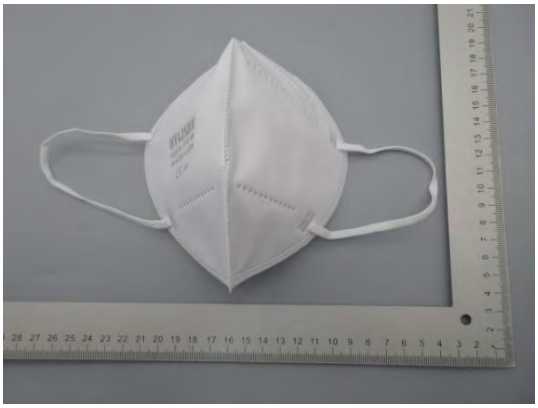

Bedienungsanleitung
Fitting instructions


HYGISUN
FFP2 Maske
PERSÖNLICHE SCHUTZMASKE EN149:2001+A1:2009


LOT: 20210125M13
PD: 2021/01/25
MHD/BBD:2023/01/24

**Photo(s):**


Persönliche Schutzmaske
PERSONAL PROTECTIVE MASK




HYGISUN
HS0501A FFP2 NR
EN149:2001+A1:2009
CE 2797

- END -

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

**1. Scope**

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

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

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

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

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

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

**2. Quotations**

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

**3. Coming into effect and duration of contracts**

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

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

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

**4. Scope of services**

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

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

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

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

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

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

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

**5. Performance periods/dates**

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

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

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

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

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

**6. The client's obligation to cooperate**

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

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

a) it has required statutory qualifications;

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

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

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

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

**7. Prices**

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

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

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

**8. Payment terms**

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

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

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

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

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

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

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

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

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

**9. Acceptance of work**

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

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

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

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

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

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

**10. Confidentiality**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**11. Copyrights and rights of use, publications**

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

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

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

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

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

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

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

**12. Liability of TÜV Rheinland**

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

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

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

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

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

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

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

**13. Export control**

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

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

**14. Data protection notice**

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

**15. Test material: transport risk and storage**

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

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

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

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

**16. Termination of the contract**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

17.4 Any dispute in connection with the contract and these terms and conditions or the execution thereof shall be settled friendly through negotiations.

Unless otherwise stipulated in the contract, if no settlement or no agreement in respect of the extension of the negotiation period can be reached within two months of the arising of the dispute, the dispute shall be submitted:

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

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

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

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

# Module B EU Type-Examination Certificate

For the requirements of PPE Regulation 2016/425

Certificate No.: CE-PC-200323-021-01-9D

| | |
|---|---|
| **Certificate holder:** | **Medical Device Branch of Zhangzhou Easepal Industrial Co., Ltd.**<br>4th Floor of Building #7, No.228, Jiaosong Road, Taiwanese Investment Zone, Zhangzhou, Fujian, China |
| **Product:** | **Particle Filtering Half Mask**<br>Detailed product description listed in the Annex |
| **Model(s):** | D13003, D13003AC |
| **Standard(s):** | EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking |
| **Issue date:** | 2020-05-20 |
| **Revision date:** | 2021-03-30 |
| **Expiry date:** | 2025-05-19 |

The product(s) on this certificate and the Technical File have been assessed and found to be in conformance with the applicable Essential Health and Safety Requirements in Annex II of the PPE regulation 2016/425.
Any changes to the design, manufacturing location or manufacture of the PPE product certified here must be advised to CCQS Certification Services Limited for review.
CE marking shall not be applied until the requirements of all the PPE Regulation 2016/425 and relevant EN Harmonised standards and/or Technical specifications have been met.
If the certified product is Category III then this certificate is only valid if used in conjunction with Conformity Assessment against Module C2 or Module D.
This certificate remains the property of CCQS and maybe withdrawn at any time if it is considered that the equipment is no longer in conformity with the requirements of the PPE Regulation 2016/425.

CE

Approved by Ireland Government
as a Notified Body
for CE Marking No.2834

ISO 17065 INAB ACCREDITED PRODUCT CERTIFICATION DETAILED IN SCOPE REG NO.6028

**Approved by:**

CCQS Ireland Certification

**Owen Bian - Director**

**CCQS Certification Services Limited**
Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin15, D15 AKK1, Ireland
Tel: +00 353 1 588 6920 Website: www.ccqs.co.uk E-mail: info@ccqs.ie
If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.

# Module B EU Type-Examination Certificate

# Annex

For the requirements of PPE Regulation 2016/425

Certificate No.: CE-PC-200428-308-01-9D

**Applicable standards and specification:**
EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking

| Model reference | Product description |
|---|---|
| **D13003** | Folding filtering half mask fitted with ear loops and head harness retaining clip, no valves, internal metal nose clip<br>Mask body colour: White or Black variant<br>Classification: FFP2 NR<br>Test report No.: 2020(D) - 0628, 2020(F) - 0591 |
| **D13003AC** | Folding filtering half mask fitted with ear loops and head harness retaining clip, no valves, external metal nose clip<br>Mask body colour: White<br>Classification: FFP2 NR<br>Test report No.: 2020(D) - 0628, 2020(D) - 0629T |

| Certificate Revision | Revision date | Revision details |
|---|---|---|
| A | 2020-05-20 | Initial issue |
| B | 2020-07-02 | Extension of expiry date to 5 years |
| C | 2020-12-22 | Addition of new raw material supplier of D13003 and certificate product listings updated to reflect test reports |
| D | 2021-03-30 | D13003 Addition of mask body colour Black variant |

CCQS Ireland Certification

**CCQS Certification Services Limited**
Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin15, D15 AKK1, Ireland
Tel: +00 353 1 588 6920 Website: www.ccqs.co.uk E-mail: info@ccqs.ie

# Declaration of Conformity

**Manufacturer:** Lyncmed Medical Technology (Beijing) Co.,Ltd.

Room 1601, Building No.2, Zhubang 2000 Busniess Building, Balizhuang Xili 99, Chaoyang District, 100022 Beijing, PEOPLE'S REPUBLIC OF CHINA

**Trade name:** LyncMed

**Product :** Face Mask Type IIR

**Code：** 302089

**Class:** Class I,

**Classification rule:** Rule 1, Chapter III, annex VIII, EU 2017/745;

**Basic UDI-DI:** 697160547A0X7

**Standards:** EN 14683:2019, 13485:2016,

**Conformity assessment procedure:** Annex II + III

We, the manufacturer herewith declare on our own responsibility that the above product meets the provisions of the regulation (EU) 2017/745.

**Authorized representative:**

Lyncmed technology SRL
Italy Milano(MI) Via Procaccini Giulio Cesare 32 Cap 20154

Beijing, 2021.1.1 ,General manager

Place,date Name, function

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 750475 (Issue Date: 09/06/2021)**

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 750476 (Issue Date: 09/06/2021).

Changsha, China, 10/06/2021

Ou Yang Zhou Ya

(Surname, Name)

Quality Manager

Hunan Dreaming Cloud E-Commerce CO., Ltd.

# DICHIARAZIONE EUROPEA DI CONFORMITÁ

La Dichiarazione di Conformitá, rilasciata sotto la responsabilitá esclusiva del produttore

**Hunan Dreamin Cloud E-Commerce CO., Ltd**

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

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

dichiara i seguenti Dispositivi di Protezione Individuale (PPE)
**Descrizione del prodotto: HYGISUN Semimaschera Filtrante Antiparticolato**
**Modello del prodotto: HS0501A FFP2 NR senza valvola**

é/sono in conformità con le disposizioni della seguente Regolamentazione Europea

**Regolamentazione PPE (Dispositivi di Protezione Individuale)**

Il modello é/sono in conformità con le disposizioni di Regolamentazione (EU) 2016/425, PPE ad uso degli operatori sanitari come da raccomandazione della Commissione 2020/403, e con la Norma Nazionale trasposta all'adattata Norma Europea numero:

**EN 149:2001+A1:2009**

ed é/sono identico al PPE che è il soggetto di esami di tipo europeo (Modulo B della Regolamentazione (EU) 2016/425)) referenziato nel certificato numero:

**Numero di Certificato: CE 750475 (data di rilascio: 09/06/2021)**

rilasciato da:

BSI Group The Netherlands B.V.
John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands (Ente Notificato Numero 2797)

ed é/sono in conformità con le procedure stabilite nel Modulo C2 di Regolamentazione (EU) 2016/425 sotto la supervisione del BSI Group The Netherlands B.V. (Ente Notificato Numero 2797), referenziato nel certificato CE 750476 (data di rilascio: 09/06/2021) rilasciato da BSI.

Changsha, China, 11/01/2022

Ou Kang Zhou Ya

(Surname, Name)

Quality Manager

Hunan Dreaming Cloud E-Commerce CO., Ltd.

# 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 750475 (Ausstellungsdatum: 09/06/2021)**

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 750476 (Ausstellungsdatum: 09/06/2021) verwiesen wird.

Changsha, China, 10.06.2021

OuYang Zhouya

OuYang Zhouya

(Nachname Name)

Qualitätsmanager

Hunan Dreaming Cloud E-Commerce CO., Ltd.

# 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 Hagenaars, Managing Director

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

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



PRODUCTS
RvA C 646

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# EU Type Examination Certificate

No. CE 750475

**Product Specification**

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

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

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

# 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

# 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 Hagenaars, Managing Director

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

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



PRODUCTS
RvA C 646

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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:

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

**Certificate Administration Details:**

**Certificate Amendment Record:**

| Issue date | Comments | BSI Review No. |
|---|---|---|
| June 2021 | First issue.<br>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
Latest Issue: 2021-06-09

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

LYNCMED MEDICAL TECHNOLOGY (BEILING) CO., LTD.
ROOM 1601, BUILDING NO.2, ZHUBANG 2000 BUSINESS BUILDING, BALIZHUANG XILI 99, CHAOYANG DISTRICT, 100022 BEIJING, CHINA

The following sample(s) was/were submitted and identified on behalf of the client as:

| | | |
|---|---|---|
| Sample Description | : | (A)Disposable surgical face mask |
| SGS Internal Ref No. | : | SHHL2006523830MD |
| Sample Color | : | (A)Blue |
| Manufacturer | : | LYNCMED MEDICAL TECHNOLOGY (BEILING) CO., LTD. |
| Roll/ Lot No. | : | 20200603 |
| Test Performed | : | Selected test(s) as requested by applicant |
| Sample Receiving Date | : | Jun 30, 2020 |
| Testing Period | : | Jun 30, 2020 - Jul 22, 2020 |
| Test Result(s) | : | Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s). |

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

Dongjing Liu / Hailian Xuan (Authorized Signatory)



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Test Result

**EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods**

**Clause 5.2 Performance Requirement**

**Clause 5.2.2 Bacterial Filtration Efficiency (BFE)**
(EN 14683:2019+AC:2019 Annex B)

Sample: A

| | | |
|---|---|---|
| Test Side | : | Inside |
| Test Area | : | Approximately 60 $cm^2$ |
| Flow Rate | : | 28.3 L/min |
| Pre-Conditioning | : | Minimum of 4 hours at 21±5°C and 85±5% R.H. |
| Dimensions of test specimen | : | ~170mm x 160mm |
| Positive Control Average | : | 2013.5 CFU |
| Negative Monitor Count | : | < 1 CFU |
| Mean Particle Size | : | 3.0 ±0.3μm |
| Test bacteria | : | Staphylococcus aureus ATCC 6538 |

| Test Item | Specimen No. | Result |
|---|---|---|
| Bacterial Filtration Efficiency (BFE) | 1 | 99.9% |
| | 2 | 99.9% |
| | 3 | 99.9% |
| | 4 | 99.8% |
| | 5 | 99.9% |

Remark:

1) Performance Requirement: Type I≥95%, Type II≥98%, Type IIR ≥98%
2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.


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**Clause 5.2.3 Breathability**
(EN 14683 :2019+AC:2019 Annex C)

Sample: A
Test Side : Randomly test in different location (1 around and 4 away from the centric point) on each of the 5 masks
Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
Test Area : 4.9 $cm^2$
Flow Rate : 8 l/min

| Specimen No. | Test Area No. | Different Pressure for each tested area (Pa/$cm^2$) | The average value for each test specimen (Pa/$cm^2$) |
|---|---|---|---|
| 1 | 1-1 | 45.8 | 48 |
| | 1-2 | 48.5 | |
| | 1-3 | 49.6 | |
| | 1-4 | 45.2 | |
| | 1-5 | 49.5 | |
| 2 | 2-1 | 48.8 | 47 |
| | 2-2 | 49.3 | |
| | 2-3 | 44.9 | |
| | 2-4 | 45.1 | |
| | 2-5 | 47.9 | |
| 3 | 3-1 | 49.2 | 48 |
| | 3-2 | 44.3 | |
| | 3-3 | 48.5 | |
| | 3-4 | 49.7 | |
| | 3-5 | 46.3 | |
| 4 | 4-1 | 54.5 | 48 |
| | 4-2 | 51.2 | |
| | 4-3 | 42.6 | |
| | 4-4 | 45.4 | |
| | 4-5 | 45.8 | |
| 5 | 5-1 | 48.9 | 49 |
| | 5-2 | 49.6 | |
| | 5-3 | 47.3 | |
| | 5-4 | 48.5 | |
| | 5-5 | 51.0 | |

Remark:
1) Performance Requirement: Type I<40 Pa/$cm^2$, Type II<40 Pa/$cm^2$, Type IIR<60 Pa/$cm^2$
2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.


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**Clause 5.2.4 Splash Resistance**
(ISO 22609 :2004)

Sample: A
Test Blood Pressure : 16.0kPa
Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
Distance of the mask to the tip of cannula : 300±10mm

| Test Specimen# | Penetration on inside surface | Conclusion | Test Specimen# | Penetration on inside surface | Conclusion |
|---|---|---|---|---|---|
| 1 | None Seen | Pass | 17 | None Seen | Pass |
| 2 | None Seen | Pass | 18 | None Seen | Pass |
| 3 | None Seen | Pass | 19 | None Seen | Pass |
| 4 | None Seen | Pass | 20 | None Seen | Pass |
| 5 | None Seen | Pass | 21 | Seen | Fail |
| 6 | None Seen | Pass | 22 | None Seen | Pass |
| 7 | None Seen | Pass | 23 | None Seen | Pass |
| 8 | None Seen | Pass | 24 | None Seen | Pass |
| 9 | None Seen | Pass | 25 | None Seen | Pass |
| 10 | None Seen | Pass | 26 | None Seen | Pass |
| 11 | None Seen | Pass | 27 | None Seen | Pass |
| 12 | None Seen | Pass | 28 | None Seen | Pass |
| 13 | None Seen | Pass | 29 | None Seen | Pass |
| 14 | None Seen | Pass | 30 | None Seen | Pass |
| 15 | None Seen | Pass | 31 | None Seen | Pass |
| 16 | None Seen | Pass | 32 | None Seen | Pass |
| Number of Pass: | | 31 | | | |
| Overall result: | | Acceptable | | | |

Remark:
1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR: ≥16.0kPa
2) Test was conducted within 60s after removal from conditioning chamber.
3) An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show pass results.


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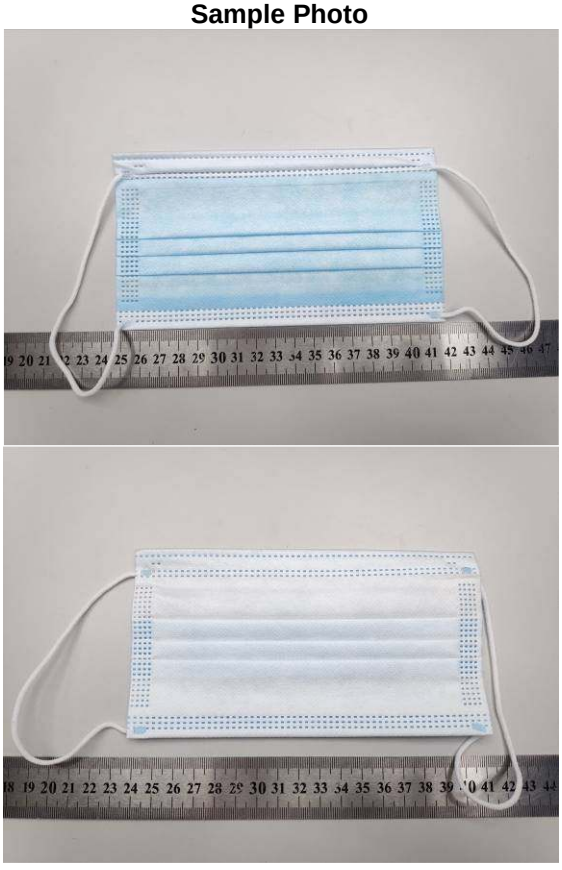
**Clause 5.2.5 Microbial Cleanliness**
(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

Sample: A

| Test Specimen# | Mask Weight(g) | Total Bioburden, (CFU/mask) | Total Bioburden, (CFU/g) |
|---|---|---|---|
| 1# | 3.03 | 21 | 6.93 |
| 2# | 3.01 | 18 | 5.98 |
| 3# | 3.06 | 60 | 19.61 |
| 4# | 3.04 | 6 | 1.97 |
| 5# | 3.06 | 33 | 10.78 |

Remark: Performance Requirement: Type I≤30 CFU/g, Type II≤30 CFU/g, Type IIR≤30 CFU/g

**Sample Photo**



The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

***End of Report***



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