



## EU Type Examination Certificate

This is to certify that:

Germany

Holds Certificate Number: CE 730303

In respect of:

**Model HYGISUN HS0501A Face mask**  
**To technical specification Annex II (EHSR) of the PPE Regulation (EU) 2016/425**  
**PPE for use by healthcare professionals as per Commission recommendation 2020/403**

on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Previous Notified Body: BSI 0086

First Issued: 2020-07-03

Latest Issue: 2020-07-03

Drs. Dave Hagenlaars, Managing Director

Effective Date: 2020-07-03

Expiry Date: 2021-07-03

Page: 1 of 3



...making excellence a habit.™

This certificate has been issued by and remains the property of BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands, and should be returned immediately upon request. To check its validity telephone: +31 (0) 34607900. An electronic certificate can be authenticated [onlin@](https://www.bsi.nl).

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

## EU Type Examination Certificate

No. CE 730303

### Product Specification

**Product Name:** Particulate Respirator.  
**Product Type:** Particulate filtering half masks for use by Healthcare professionals.  
**Model:** **HYGISUN HS0501A.**  
**Classification:** FFP2 NR un-valved.

**Technical Specification:** Technical specification to satisfy Annex II of the PPE Regulation (EU) 2016/425.

**Product Description:** The respirator is non-reusable, secured to the face of the user by a pair of elasticated ear straps, and has no exhalation valve. The respirator is FFP2 class, vertical fold flat type.

The respirator listed on this certificate is for use by healthcare workers, first responders and other personnel involved in the efforts to contain the COVID-19 virus and avoid its further spread.

The product covered by this certificate is not approved for industrial applications and the certificate is only valid as long as EU Commission recommendation sheet 2020/403 remains applicable.

**Product Assessments:** BSI's PPE for Healthcare Professionals 2020/403 – RPE Technical Specification.

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

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

Page: 2 of 3

This certificate has been issued by and remains the property of BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands and should be returned immediately upon request. To check its validity telephone +31 (0) 2440700. An electronic certificate can be authenticated [going](https://www.bsi.nl).

BSI Group The Netherlands B.V., registered in the Netherlands under number 33294264, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands. A member of the group of Companies.

## EU Type Examination Certificate

No. CE 730303

### Certificate Administration Details

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

### Certificate Amendment Record:

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

### Certificate validity

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspect of the overall process utilised in the manufacture of the product, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes.

The validity of the Certificate for the products is also dependent on the maintenance of the EU Conformity to Type based on Internal Production Control plus supervised product checks at random intervals, Annex VII (Module C2) as referenced on BSI issued Certificate CE 730304.

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

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

Page: 3 of 3

This certificate has been issued by and remains the property of BSI Group The Netherlands B.V., Joden Pl. Koningplein 9, 1066 CP Amsterdam, The Netherlands and should be returned immediately upon request.  
To check its validity telephone: +31 20 3450780. An electronic certificate can be authenticated [online](#).

BSI Group The Netherlands B.V., registered in the Netherlands under number 32264284, at Joden Pl. Koningplein 9, 1066 CP Amsterdam, The Netherlands  
A member of the Bureau of Companies.



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

This is to certify that:

Germany

Holds Certificate Number: CE 730304

In respect of:

**For the manufacture of particulate respirators to technical specification to satisfy Annex II of the PPE Regulation (EU) 2016/425.**

on the basis that BSI carried out the supervised production checks at random intervals under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex VII (Module C2)

For and on behalf of BSI, a Notified  
Body for the above Regulation  
(Notified Body Number 2797):

Previous Notified Body: BSI 0086

First Issued: 2020-07-03

Latest Issue: 2020-07-03

Drs. Dave Hagenlaars, Managing Director

Effective Date: 2020-07-03

Expiry Date: 2021-07-03

Page: 1 of 3



...making excellence a habit.™

This certificate has been issued by and remains the property of BSI Group The Netherlands B.V., John M. Kuyperplein 9, 1056 EP Amsterdam, The Netherlands and should be returned immediately upon request.  
To check its validity telephone: +31 (0) 40 400760. An electronic certificate can be authenticated [online](https://www.bsi.nl/certificates).

BSI Group The Netherlands B.V., registered in the Netherlands under number 53264284, at John M. Kuyperplein 9, 1056 EP Amsterdam, The Netherlands is a member of the Group of Companies.

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

No. CE 730304

**Product manufactured by:**

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

**Product details**

The respiratory protective device covered by the scope of this Module C2 Certificate and the Technical Specification to which the product is manufactured are as follows:

<b>Product type:</b>	Particulate filtering half masks for use by Healthcare professionals.
<b>Model and classifications:</b>	HYGISUN HS0501A FFP2 NR
<b>Technical Specification:</b>	Technical specification to satisfy Annex II of the PPE Regulation (EU) 2016/425. BSI's PPE for Healthcare Professionals 2020/403 – RPE Technical Specification.

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

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

Page: 2 of 3

This certificate has been issued by and remains the property of BSI Group The Netherlands B.V., John M. Keynesplein 9, 1055 EP Amsterdam, The Netherlands and should be returned immediately upon request.  
To check its validity telephone +31 20 4607700. An electronic certificate can be authenticated [online](https://www.bsi.nl).

BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1055 EP Amsterdam, The Netherlands  
A member of the BSI Group of Companies.

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

No. CE 730304

Certificate Administration Details:

Certificate Amendment Record and BSI Internal Review relating to this Certificate

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

Certificate validity

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspects of the overall quality system utilized in the manufacture of the products, failure to do so could invalidate the Certificate in respect of product manufactured after the introduction of such changes.

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

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

Page: 3 of 3

This certificate has been issued by and remains the property of BSI Group The Netherlands B.V., John M. Keynesplein 9, 1026 EP Amsterdam, The Netherlands and should be returned immediately upon request.  
To check its validity telephone +31 20 3440780. An electronic certificate can be authenticated [online](http://www.bsi.nl).

BSI Group The Netherlands B.V., registered in the Netherlands under number 33204284, at John M. Keynesplein 9, 1026 EP Amsterdam, The Netherlands  
A member of the Bureau of Lloyd's.

**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:

hereby declaring the following Personal Protective Equipment (PPE)

**Product Description: HYGISUN Particulate Filtering Half Mask**

**Product Model/s: HS0501A FFP2 NR without valve**

is/are in conformity with the provisions of the following European Regulation

**PPE (Personal Protective Equipment) Regulation**

The model is/are in conformity with the provisions of Regulation (EU) 2016/425, PPE for use by  
healthcare professionals as per Commission recommendation 2020/403, and with the National  
Standard transposing the harmonised European Standard Number(s):

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

and is/are identical to the PPE which is/are the subject of EU type-examination (Module B of  
Regulation (EU) 2016/425) referenced on the certificate number:

**Certificate No.: CE 730303 (Issue Date: 03/07/2020)**

issued by

BSI Group The Netherlands B.V.

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

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

Changsha, China, 04/07/2020

Ouyang, Zhouya

Quality Manager

Hunan Dreaming Cloud E-Commerce CO., Ltd.

