

EU Type Examination Certificate

This is to certify that:

Luoyang Sunmed Devices Co., Ltd.
No.8 Huaxia Road, Hi-tech Zone
Luoyang Area of China(Henan)
Pilot Free Trade Zone
Henan
471003
China

Holds Certificate Number:

CE 749655

In respect of:

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

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

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

Drs. Dave Hagenaaars, Managing Director

First Issued: 2021-12-15

Latest Issue: 2021-12-15

Effective Date: 2021-12-15

Expiry Date: 2026-12-15

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EU Type Examination Certificate

No. CE 749655

Product Specification

Vertical Flat Fold Particulate Half Masks

Technical specification: EN 149:2001+A1:2009 Respiratory protective devices – Filtering half masks to protect against particles.

Classification – Single shift NR (without Clogging Option D)

FFP Class: FFP2

Model: **S910** (Ear loops, without exhalation valve)

FFP Class: FFP2

Model: **S910V** (Ear loops, with exhalation valve)

FFP Class: FFP2

Model: **S912** (Head straps, without exhalation valve)

FFP Class: FFP2

Model: **S912V** (Head straps, with exhalation valve)

FFP Class: FFP2

Model: **S9501+** (Ear loops, without exhalation valve)

FFP Class: FFP2

Model: **S9501V+** (Ear loops, with exhalation valve)

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

EU Type Examination Certificate

No. CE 749655

Certificate Administration Details

Technical File Reference: Luoyang Sunmed - Technical Files

Certificate Amendment Record

Issue date	Comments
December 2021	First issue under PPE Regulation (EU) 2016/425.

BSI Project Number

2797:21:3429816

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 Quality Assurance of the Production Process, Annex VIII (Module D), as referenced on BSI issued Certificate CE 749657.

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Conformity to Type based on Quality Assurance of the Production Process

This is to certify that:

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No.8 Huaxia Road, Hi-tech Zone
Luoyang Area of China(Henan)
Pilot Free Trade Zone
Henan
471003
China

Holds Certificate Number:

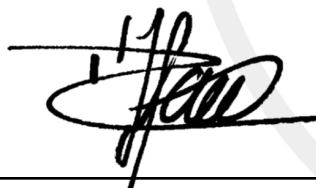
CE 749657

In respect of:

The Manufacture of Respiratory Protective Equipment

on the basis that BSI carried out the quality assurance assessment under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex VIII (Module D)

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



Drs. Dave Hagenaaers, Managing Director

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Conformity to Type based on Quality Assurance of the Production Process

No. CE 749657

Manufacturing sites:

Luoyang Sunmed Devices Co., Ltd.
No. 8 Huaxia Road, Hi-Tech Zone, Luoyang Area of China (Henan) Pilot Free Trade Zone
471003
China

Product Specification:

The products covered by the scope of this certificate conform to the following standard:

Standard	Product Type
EN 149:2001 + A1:2009	Respiratory protective devices. Filtering half masks to protect against particles

Certificate Amendment Record:

Issue date	Comments
December 2021	First issue

BSI Review No.

2797:21:3429817

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 products, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes.

The validity of the Certificate is also dependent on the maintenance of a documented quality system.

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