



Certificate CN21/42438

The management system of

# Hangzhou Shanyou Medical Equipment Co., Ltd.

No. 138 Louta Development Zone, Guancun Village, Louta Town, Xiaoshan District, Hangzhou City, Zhejiang Province, P.R. China

has been assessed and certified as meeting the requirements of

## Regulation (EU) 2016/425 Module D

For the following activities

**Manufacture of FFP2 particle filtering half masks**  
(Note: all products marked CE0598 must have a valid EU Type Examination Certificates issued under Module B or a valid EC type-examination certificate issued under Article 10 of the PPE Directive 89/686/EEC.)

This certificate is valid from 12 June 2021 until 11 June 2024 and remains valid subject to satisfactory surveillance audits.  
Re certification audit due before 23 April 2024  
Issue 1. Certified since 12 June 2021

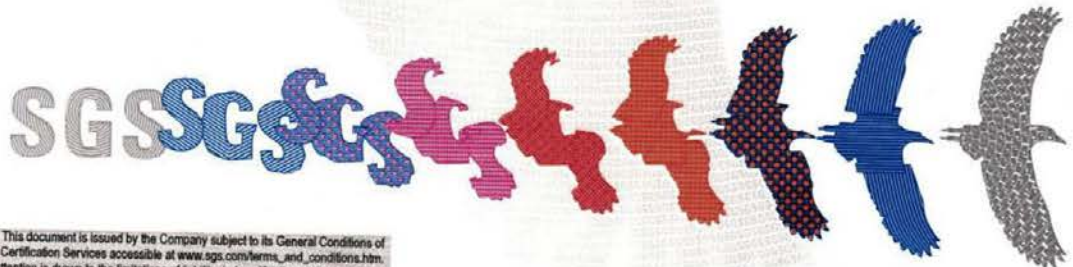
Authorised by

**SGS FIMKO OY, Notified Body 0598**

Takomitie 8, FI-00380 Helsinki, Finland  
t +358 9 696 361 f +358 9 692 5474 www.sgs.com



Page 1 of 1



This document is issued by the Company subject to its General Conditions of Certification Services accessible at [www.sgs.com/terms\\_and\\_conditions.htm](http://www.sgs.com/terms_and_conditions.htm). Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at <http://www.sgs.com/en/certified-clients-and-products/certified-client-directory>. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

Certificate FI20/966870

# Hangzhou Shanyou Medical Equipment Co., Ltd.

NO. 138 Louta Development Zone, Guancun Village,  
Louta Town, Xiaoshan District,  
Hangzhou, Zhejiang 311266,  
China

It is certified that the manufacturer's technical file and the PPE product detailed on  
page 2 have been assessed and found to be in accordance with

## Regulation (EU) 2016/425 Module B, EU type-examination

This certificate is valid from 12 October 2020 until 12 October 2025  
1. Certified since 12 October 2020

Authorised by

SGS FIMKO OY, Notified Body 0598  
Takomotie 8, FI-00380, Helsinki, Finland  
t +358 9 696 361 f +358 9 692 5474 www.sgs.com

**FINAS**  
Finnish Accreditation Service  
S003 (EN ISO/IEC 17065)

Page 1 of 2



This document is issued by the Company subject to its General Conditions of  
Certification Services accessible at [www.sgs.com/terms\\_and\\_conditions.htm](http://www.sgs.com/terms_and_conditions.htm).  
Attention is drawn to the limitations of liability, indemnification and jurisdictional  
issues established therein. The authenticity of this document may be verified at  
<http://www.sgs.com/en/certified-clients-and-products/notified-client-directory>.  
Any unauthorized alteration, forgery or falsification of the content or appearance  
of this document is unlawful and offenders may be prosecuted to the fullest  
extent of the law.

## Hangzhou Shanyou Medical Equipment Co., Ltd.

### Regulation (EU) 2016/425 Module B, EU type-examination

Issue 1

PPE Product

WORK (logo) SYMS-1 particle filtering half mask, consisting of a four layer (Polypropylene/Hot air cotton) disposable face mask, with Polyethylene covered Iron wire nose clip and Polyamide/Spandex mask straps.

It is certified that the manufacturer's technical file and the above mentioned PPE have been assessed and found to meet the applicable Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 Personal Protective Equipment

The following have been applied:

EN 149: 2001 +A1:2009 (Respiratory protective devices- filtering half masks to protect against particles) device classification: FFP2 NR.



This certificate is issued on strict condition that appropriate checks on manufactured PPE, as detailed in Article 19(c) of the regulation are implemented and maintained while the model is in production.

Certification is based on technical file reference:

WK01, Dated 22.07.2020

SGS Reference Number UK/CRS 242026

This certificate remains the property of SGS Fimko Oy to whom it must be returned on request

**EU DECLARATION OF CONFORMITY**

Name and address of the Manufacturer: **Hangzhou Shanyou Medical Equipment Co., Ltd.**  
No. 138, Louta Development Zone, Guancun Village, Louta Town, Xiaoshan District, Hangzhou, 311266, Zhejiang, China

Name and address of the European Authorized Representative: **CMC Medical Devices & Drugs S.L**  
C/Horacio Lengo Nº 18, CP 29006, Málaga-Spain

This declaration of conformity is issued under the sole responsibility of the manufacturer.

The manufacturer declares that the PPE products described hereafter:

Product Name: **Filtering Half Mask**

Product Photograph:



Type/Class: **FFP2 NR**  
Model/REF.: **SYMS-1**  
Certificate Serial Nr.: **FI20/966870**

is in conformity with the provisions of regulation (EU) 2016/425 of the European parliament and of the council of 9 March 2016 on Personal protective equipment, and conformity with the requirements of above regulation is testified by complete adherence to the following technical specifications:

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

Is identical to the PPE which is the subject of EU type-examination for Regulation (EU) 2016/425 issued by SGS Fimko Oy, Takomotie 8, FI-00380 Helsinki, Finland, Notified Body number: 0598

Is identical to the PPE which is subject to the procedure set out in Module D (with certificate CN21/42438) of Regulation(EU)2016/425 Personal Protective Equipment under the supervision of the notified body SGS Fimko Oy, Takomotie 8,FI-00380 Helsinki, Finland, Notified Body number: 0598

The product(s) of the declaration described above is in conformity with the requirement of following test report: SL52035261241701TX.

Declaration of Conformity is valid until: 12/10/2025

Hangzhou, 12/06/2021

June 12<sup>th</sup>, 2021  
Place and date

余百明 (Baiming Yu) / General Manager

Baiming Yu  
Name and function





**EC Certificate**  
**Directive 93/42/EEC Annex V**  
**Production Quality Assurance**  
**Medical Devices**

**Registration No.:** DD 60151185 0001

**Report No.:** 15049271 019

**Manufacturer:** Hangzhou Shanyou Medical Equipment  
Co., Ltd.  
No. 138,Louta Development Zone  
Guancun Village,Louta Town  
Xiaoshan District  
Hangzhou  
311266 Zhejiang  
P.R. China

**Products:** Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60147797 0001

**Expiry Date:** 2024-05-26

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

**Effective Date:** 2020-08-07

**Date:** 2020-08-07

Notified Body



Fuxiu Sheng

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** DD 60151185 0001  
**Report No.:** 15049271 019

**Manufacturer:** Hangzhou Shanyou Medical Equipment  
Co., Ltd.  
No. 138, Louta Development Zone  
Guancun Village, Louta Town  
Xiaoshan District  
Hangzhou  
311266 Zhejiang  
P.R. China

**Products:**

- Endotracheal Tubes
- Laryngeal Mask Airways
- Laryngoscope Blades
- Face Masks  
(Oxygen Mask, Non-rebreathing Mask, Nebulizer Mask)
- Suction Catheters
- Nasal Oxygen Cannulas
- Disposable Breathing Circuits
- Yankauer Suction Sets
- Anesthesia Masks
- Filters/HMEF
- Catheter Mounts
- Nasogastric Tubes

Aspects of manufacture concerned with securing and  
maintaining sterile conditions only:

- Endotracheal Tube Holders
- Artery Compression Tourniquets
- Intubating Stylets
- Guedel Airways
- Medical Face Masks

**Date:** 2020-08-07

**Notified Body**



**Fuxiu Sheng**





# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Hangzhou Shanyou Medical Equipment  
Co., Ltd.**  
No. 138, Louta Development Zone  
Guancun Village, Louta Town  
Xiaoshan District  
Hangzhou  
311266 Zhejiang  
P.R. China

has established and applies a quality management system for medical devices  
for the following scope:

**(see attachment for scope included)**

Proof has been furnished that the requirements specified in

## EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-07-31  
Certificate Registration No.: SX 60151059 0001  
An audit was performed. Report No.: 15049271 017  
This Certificate is valid until: 2023-04-17

Certification Body



Date 2020-07-31



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60151059 0001  
**Report No.:** 15049271 017

**Organization:** Hangzhou Shanyou Medical Equipment  
Co., Ltd.  
No. 138,Louta Development Zone  
Guancun Village,Louta Town  
Xiaoshan District  
Hangzhou  
311266 Zhejiang  
P.R. China

**Scope:** Design and Development, Manufacture and Distribution of  
Disposable Breathing Circuits;  
Manufacture and Distribution of Endotracheal Tubes,  
Laryngeal Mask Airways, Laryngoscope Blades, Face Masks  
(Oxygen Mask, Non-rebreathing Mask, Nebulizer Mask),  
Suction Catheters, Nasal Oxygen Cannulas, Endotracheal Tube  
Holders, Artery Compression Tourniquets, Intubating Stylets,  
Guedel Airways, Yankauer Suction Sets, Anesthesia Masks,  
Filters/HMEF, Catheter Mounts, Nasogastric Tubes,  
Medical Face Masks

**Certification Body**



**Date:** 2020-07-31

  
**Fuxiu Sheng**

