

Certificate F120/965917

# Zhejiang Lanhine Medical Products LTD.

1989 Cidong Road, Cidongbinhai District,  
315300 Cixi City Zhejiang Province,  
PEOPLE'S REPUBLIC OF 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 03 June 2020 until 03 June 2025  
1. Certified since 03 June 2020

Authorised by

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

SGS FIMKO OY, Notified Body 0598

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Certificate FI20/965917, continued

# Zhejiang Lanhine Medical Products LTD.

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

Issue 1

PPE Product

Lanhine (logo) Model 1:15801, fold flat, single use Particle filtering half mask.

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) for a performance classification FFP2 NR.

This certificate is issued on the 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: Model 1:15801 Revision A1 dated May 24th 2020

SGS Reference Number UK/CRS 241151.

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

Certificate CN20/42519

The management system of

# Zhejiang Lanhine Medical Products Ltd.

No. 1989 Cidong Road, Cidongbinhai District,  
Cixi 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 particle Filtering Half Protective Mask**

(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 3 November 2020 until 2 November 2023

and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 20 October 2023

Issue 1. Certified since 3 November 2020

Authorised by

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