

Certificate FI20/967136

## Nantong Huaxu Medical Equipment Co, Ltd.

NO.889 Zhaoxia Road, High Tech Industry Zoon,  
Nantong City,  
Jiangsu Province,  
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 04 November 2020 until 04 November 2025

1. Certified since 04 November 2020

Authorised by

SGS FIMKO OY, Notified Body 0598

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

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Certificate FI20/967136, continued

## **NANTONG HUAXU MEDICAL EQUIPMENT CO.,LTD**

### **Regulation (EU) 2016/425**

**Module B, EU type-examination**

Issue 1

PPE Product

5C (logo) K-2020 particle filtering half mask, consisting of a five layer (Polypropylene/Ethylene) disposable face mask, with Polypropylene/Polyethylene nose bridge, and Polyamides/Polyurethanes Ear band.

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:

HUAXU CE001, Dated 01.09.2020

SGS Reference Number UK/CRS 242353

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

Certificate CN20/42726

The management system of

## Nantong Huaxu Medical Equipment Co., Ltd.

NO.889 Zhaoxia Road, High Tech Industry Zoon,  
Nantong City, Jiangsu Province, China

has been assessed and certified as meeting the requirements of

### Regulation (EU) 2016/425

Module C2

For the following activities

Manufacture of 5C (logo) K-2020 particle filtering half mask.  
(Note: All products marked CE0598 must have a valid EU type-  
examination certificate issued under Module B or a valid EC type-  
examination certificate issued under Article 10 of Directive  
89/686/EEC.)

This certificate is valid from 23 December 2020  
and remains valid subject to satisfactory surveillance audits.  
Issue 1. Certified since 23 December 2020

Authorised by

SGS FIMKO OY, Notified Body 0598

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