

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

Registration No.: DD 60131859 0001

Report No.: 15085898 004

Manufacturer: Hubei Kangning Protective
Products Co., Ltd.
Special No.1 Xuefu Road
433000 Xiantao City, Hubei
China

Products: Medical Devices
(see attachment for products and additional site included)
Replaces Approval, Registration No: DD 60104371 0001

Expiry Date: 2023-10-22

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: 2018-12-04

Date: 2018-12-04



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.



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EU Type Examination Certificate

This is to certify that:

Handan Hengyong Protective & Clean
Products Co Ltd
C-1-901, 9 Yuhua West Road
Shijiazhuang
Hebei
050000
China

Holds Certificate Number:

CE 690991

In respect of:

**Filtering Masks To EN 149:2001 + A1:2009
Various Models**

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 0086):


Chris Lewis - Certification Director, Product Certification

First Issued: 2019-04-15

Latest Issue: 2019-04-15

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EU Type Examination Certificate

No. CE 690991

Product Specification

Half masks HY8200 Range without clogging

Description:	Vertical fold flat disposable face mask
Technical specification:	EN 149:2001+A1:2009 Respiratory protective devices – Filtering half masks to protect against particles. Classification – Single shift NR
FFP Class:	FFP1
Models:	HY 8210 HY 8212 (mask with exhalation valve fitted) HY 8214 (masks with activated charcoal) HY 8216 (mask with activated charcoal and exhalation valve fitted)
FFP Class:	FFP2
Models:	HY 8220 HY 8222 (mask with exhalation valve fitted) HY 8224 (masks with activated charcoal) HY 8226 (mask with activated charcoal and exhalation valve fitted)
FFP Class:	FFP3
Model:	HY 8232 (mask with exhalation valve fitted)

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EU Type Examination Certificate

No. CE 690991

Half masks HY8200 Range with clogging

Description: Vertical fold flat disposable face mask

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

Classification – Single shift NR D

FFP Class: FFP1D

Models:
HY 8210
HY 8212 (mask with exhalation valve fitted)
HY 8214 (masks with activated charcoal)
HY 8216 (mask with activated charcoal and exhalation valve fitted)

FFP Class: FFP2D

Models:
HY 8220
HY 8222 (mask with exhalation valve fitted)
HY 8224 (masks with activated charcoal)
HY 8226 (mask with activated charcoal and exhalation valve fitted)

FFP Class: FFP3D

Model: HY 8232 (mask with exhalation valve fitted)

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EU Type Examination Certificate

No. CE 690991

Product Specification (continued)

Half masks HY8600 Range without clogging

Description:	Conical disposable face mask
Technical specification:	EN 149:2001+A1:2009 Respiratory protective devices – Filtering half masks to protect against particles. Classification – Single shift NR
FFP Class:	FFP1
Models:	HY 8610 HY 8612 (mask with exhalation valve fitted) HY 8614 (mask with activated charcoal) HY 8616 (mask with activated charcoal and exhalation valve fitted)
FFP Class:	FFP2
Models:	HY 8620 HY 8622 (mask with exhalation valve fitted) HY 8626 (mask with activated charcoal and exhalation valve fitted)
FFP Class:	FFP3
Model:	HY 8632 (mask with exhalation valve fitted)

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Product Specification (continued)

Half masks HY8600 Range with clogging

Description: Conical disposable face mask

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

Classification – Single shift NR D

FFP Class: **FFP1D**

Models:
HY 8610
HY 8612 (mask with exhalation valve fitted)
HY 8614 (mask with activated charcoal)
HY 8616 (mask with activated charcoal and exhalation valve fitted)

FFP Class: **FFP2D**

Models:
HY 8620
HY 8622 (mask with exhalation valve fitted)
HY 8626 (mask with activated charcoal and exhalation valve fitted)

FFP Class: **FFP3D**

Model: **HY 8632** (mask with exhalation valve fitted)

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Product Specification (continued)

Half masks HY8900 Range without clogging

Description: **Horizontal fold flat disposable face mask**

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

Classification – Single shift NR

FFP Class: **FFP1**

Models: **HY 8910**
HY 8912 (mask with exhalation valve fitted)
HY 8914 (mask with activated charcoal)
HY 8916 (mask with activated charcoal and exhalation valve fitted)

FFP Class: **FFP2**

Models: **HY 8920**
HY 8922 (mask with exhalation valve fitted)
HY 8924 (mask with activated charcoal)
HY 8926 (mask with activated charcoal and exhalation valve fitted)

FFP Class: **FFP3**

Model: **HY 8932** (mask with exhalation valve fitted)

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Half masks HY8900 Range with clogging

Description: **Horizontal fold flat disposable face mask**

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

Classification – Single shift NR D

FFP Class: **FFP1D**

Models:
HY 8910
HY 8912 (mask with exhalation valve fitted)
HY 8914 (mask with activated charcoal)
HY 8916 (mask with activated charcoal and exhalation valve fitted)

FFP Class: **FFP2D**

Models:
HY 8920
HY 8922 (mask with exhalation valve fitted)
HY 8924 (mask with activated charcoal)
HY 8926 (mask with activated charcoal and exhalation valve fitted)

FFP Class: **FFP3D**

Model: **HY 8932** (mask with exhalation valve fitted)

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Product Specification (continued)

Larger Conical HY9600 Range with clogging

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

Classification – Single shift NR D

FFP Class: **FFP1D**

Models: **HY 9610**
HY 9612 (mask with exhalation valve fitted)
HY 9614 (mask with activated charcoal)
HY 9616 (mask with activated charcoal and exhalation valve fitted)

FFP Class: **FFP2D**

Models: **HY 9620**
HY 9622 (mask with exhalation valve fitted)
HY 9626 (mask with activated charcoal and exhalation valve fitted)

FFP Class: **FFP3D**

Models: **HY 9630**
HY 9632 (mask with exhalation valve fitted)

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No. CE 690991

Product Specification (continued)

Cymbiform Foldable HY9300 Range with clogging

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

Classification – Single shift NR D

FFP Class **FFP1D**

Models: **HY 9310**
HY 9312 (mask with exhalation valve fitted)
HY 9316 (mask with activated charcoal and exhalation valve fitted)

FFP Class **FFP2D**

Models: **HY 9320**
HY 9322 (mask with exhalation valve fitted)
HY 9326 (mask with activated charcoal and exhalation valve fitted)

FFP Class **FFP3D**

Models: **HY 9330**
HY 9332 (mask with exhalation valve fitted)
HY 9336 (mask with activated charcoal and exhalation valve fitted)

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Product Specification (continued)

Larger Conical HY9900 Range with PE mesh cover with clogging

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

Classification – Single shift NR D

FFP Class: **FFP1D**

Models:
HY 9910
HY 9912 (mask with exhalation valve fitted)
HY 9914 (mask with activated charcoal)
HY 9916 (mask with activated charcoal and exhalation valve fitted)

FFP Class: **FFP2D**

Models:
HY 9920
HY 9922 (mask with exhalation valve fitted)
HY 9926 (mask with activated charcoal and exhalation valve fitted)

FFP Class: **FFP3D**

Models:
HY 9930
HY 9932 (mask with exhalation valve fitted)

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Product Specification (continued)

Multi-Chamber Re-Usable HY6600 Range with clogging

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

Classification – Multiple shifts R D

FFP Class: **FFP2 R D**

Models: **HY 6620**
HY 6622 (mask with exhalation valve fitted)
HY 6626 (mask with activated charcoal and exhalation valve fitted)

FFP Class: **FFP3 R D**

Models: **HY 6630**
HY 6632 (mask with exhalation valve fitted)
HY 6636 (mask with activated charcoal and exhalation valve fitted)

Conical Re-Usable HY6600 Range with clogging

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

Classification – Multiple shifts R D

FFP Class: **FFP3 R D**

Models: **HY 8632** (mask with exhalation valve fitted)

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EU Type Examination Certificate

No. CE 690991

Certificate Administration Details

Technical File Reference: Handan Hengyong Protective & Clean Products Technical File.

Certificate Amendment Record

Issue date	Comments	BSI Internal Project No.
April 2019	First issue to PPE Regulation 2016/425. Products previously certified to PPE Directive 89/686 by BSI on certificate CE 70730	0086:19:8910072

Note: The Certificate holder is responsible for keeping the Notified Body advised of changes to any aspect of the overall process used in the manufacture of the product.

Monitoring of manufactured PPE.

The EC Quality of Production by Monitoring requirements, Article 11B for the product are referenced in BSI Certificate number CE 79995.

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Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) Final Report

Test Article: KN-FM-N01
LOT: FM20170410
Product Name: Disposable medical face mask
Study Number: 960454-S01
Study Received Date: 24 Apr 2017
Testing Facility: Nelson Laboratories, LLC, a Business Unit of Sterigenics International
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: 801-STP0004 Rev 14

Summary: The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at $1.7 - 2.7 \times 10^3$ colony forming units (CFU) with a mean particle size (MPS) of $3.0 \pm 0.3 \mu\text{m}$. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-14 and EN 14683:2014, Annex B.

The Delta P test is performed to determine the breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test was designed to comply with MIL-M-36954C, Section 4.4.1.2 and complies with EN 14683:2014, Annex C.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side: Inside
BFE Test Area: $\sim 40 \text{ cm}^2$
BFE Flow Rate: 28.3 Liters per minute (L/min)
Delta P Flow Rate: 8 L/min
Conditioning Parameters: $85 \pm 5\%$ relative humidity (RH) and $21 \pm 5^\circ\text{C}$ for a minimum of 4 hours
Test Article Dimensions: $\sim 175 \text{ mm} \times \sim 155 \text{ mm}$
Positive Control Average: 2.4×10^3 CFU
Negative Monitor Count: < 1 CFU
MPS: $3.1 \mu\text{m}$



Study Director



Trang T. Truong, B.S.

Study Completion Date

08 May 2017



960454-S01

Results:

Test Article Number	Percent BFE (%)	Delta P (mm H ₂ O/cm ²)	Delta P (Pa/cm ²)
1	>99.9	5.3	52.5
2	>99.9	5.2	51.3
3	99.9	5.6	54.7

The filtration efficiency percentages were calculated using the following equation:

$$\% BFE = \frac{C - T}{C} \times 100$$

C = Positive control average

T = Plate count total recovered downstream of the test article

Note: The plate count total is available upon request