

6pcs box



**SICANIA LABS LTD**

Registered in England No: 12216996, Registered Office: 160 Kemp House, City Road, London EC1V 2NX, United Kingdom  
VAT No. GB348686154 EORI No. GB072588878000

10pcs box



20pcs box



## Masks photo



## 6 pcs packing



<p><b>SL+CARE</b> SICANIA LABS</p> <p>FFP2 NR <b>SELF-PRIMING FILTER RESPIRATOR</b> <b>FILTRIERENDE ATEMSCHUTZMASKE</b> (Non-Medical)</p> <p>ON HONGYU 红雨</p> <p>BOX SIZE: 15*3*12.5 cm MADE IN CHINA</p> <p><b>6</b> PCS BOXES 200BOXES 1200PCS</p> <p>hongyu 红雨</p>	<p><b>SL+CARE</b> SICANIA LABS</p> <p>G.W: 15 KGS N.W: 14 KGS Meas: 62.5*31.5*64.5 CM MFG: 2021/03/10 EXP: 2023/03/09 LOT: 210310</p> <p>Brand Owner &amp; Authorized Representative U.S. &amp; UK SICANIA LABS LTD 148 Gungah Road, 120 Road London EC1A 2NA, United Kingdom Registered in Singapore, No. 12174299 Tel: +65 655 339 5444 E-mail: sales@sicaniaindonesia.com Website: www.sicaniaindonesia.com</p>	<p><b>SL+CARE</b> SICANIA LABS</p> <p>FFP2 NR <b>SELF-PRIMING FILTER RESPIRATOR</b> <b>FILTRIERENDE ATEMSCHUTZMASKE</b> (Non-Medical)</p> <p>ON HONGYU 红雨</p> <p>BOX SIZE: 15*3*12.5 cm MADE IN CHINA</p> <p><b>6</b> PCS BOXES 200BOXES 1200PCS</p> <p>hongyu 红雨</p>	<p><b>SL+CARE</b> SICANIA LABS</p> <p>G.W: 15 KGS N.W: 14 KGS Meas: 62.5*31.5*64.5 CM MFG: 2021/03/10 EXP: 2023/03/09 LOT: 210310</p> <p>Importeur / Importer: ThinkClean Dada &amp; Hepping GbR Cottbusser Weg 16 72189 Rottenburg a.N. Germany</p>
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## 10 pcs packing



15x4.5x12.5cm

<p><b>SL+CARE</b> SICANIA LABS</p> <p>FFP2 NR <b>SELF-PRIMING FILTER RESPIRATOR</b> <b>FILTRIERENDE ATEMSCHUTZMASKE</b> (Non-Medical)</p> <p>EN 149:2001+AT2009</p> <p>BOX SIZE: 15*4.5*12.5 cm MADE IN CHINA</p> <p><b>10</b> PER BOXES 100BOXES 1000PCS</p> <p>honyu 红雨</p>	<p><b>SL+CARE</b> SICANIA LABS</p> <p>G.W: 11 KGS N.W: 10 KGS Meas: 47.5*31.5*64.5 CM MFG: 2021/03/10 EXP: 2023/03/09 LOT: 210310</p> <p>Importeur / Importeur: ThinkClean Doid &amp; Hopring GbR Cottbauer Weg 16 72108 Rottenburg a.N. Germany</p>	<p><b>SL+CARE</b> SICANIA LABS</p> <p>FFP2 NR <b>SELF-PRIMING FILTER RESPIRATOR</b> <b>FILTRIERENDE ATEMSCHUTZMASKE</b> (Non-Medical)</p> <p>EN 149:2001+AT2009</p> <p>BOX SIZE: 15*4.5*12.5 cm MADE IN CHINA</p> <p><b>10</b> PER BOXES 100BOXES 1000PCS</p> <p>honyu 红雨</p>	<p><b>SL+CARE</b> SICANIA LABS</p> <p>G.W: 11 KGS N.W: 10 KGS Meas: 47.5*31.5*64.5 CM MFG: 2021/03/10 EXP: 2023/03/09 LOT: 210310</p> <p>Importeur / Importeur: ThinkClean Doid &amp; Hopring GbR Cottbauer Weg 16 72108 Rottenburg a.N. Germany</p>
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## 20 pcs packing

150x90x125mm



<p><b>SL+CARE</b> SICANIA LABS</p> <p>FFP2 NR <b>SELF-PRIMING FILTER RESPIRATOR</b> <b>FILTRIERENDE ATEMSCHUTZMASKE</b> (Non-Medical)</p> <p>EN 149:2001+A1:2010</p> <p>REGULATED CERTIFIED RESPIRATOR AFTER USE IMMEDIATE DISPOSAL REUSABLE RESPIRATOR (NON-MEDICAL) REUSABLE RESPIRATOR (NON-MEDICAL) REUSABLE RESPIRATOR (NON-MEDICAL) REUSABLE RESPIRATOR (NON-MEDICAL) REUSABLE RESPIRATOR (NON-MEDICAL)</p> <p>BOX SIZE: 15*9*12.5 cm MADE IN CHINA</p> <p>hongyu 红雨</p> <p><b>20</b> PCS BOXES 50 BOXES 1000PCS</p>	<p><b>SL+CARE</b> SICANIA LABS</p> <p>G.W: 11 KGS N.W: 10 KGS Meas: 47.5*31.5*64.5 CM MFG: 2021/03/10 EXP: 2023/03/09 LOT: 210310</p> <p>Importeur / Authorized Representative: S.S. &amp; H. SICANIA LABS LTD 160 Kemp House, City Road London EC1V 2NX, United Kingdom Registered in England No. 13116299 Tel: +44 (0) 202 219 8262 E-mail: sales@sicaniaind.com Web: www.sicaniaind.com</p>	<p><b>SL+CARE</b> SICANIA LABS</p> <p>FFP2 NR <b>SELF-PRIMING FILTER RESPIRATOR</b> <b>FILTRIERENDE ATEMSCHUTZMASKE</b> (Non-Medical)</p> <p>EN 149:2001+A1:2010</p> <p>REGULATED CERTIFIED RESPIRATOR AFTER USE IMMEDIATE DISPOSAL REUSABLE RESPIRATOR (NON-MEDICAL) REUSABLE RESPIRATOR (NON-MEDICAL) REUSABLE RESPIRATOR (NON-MEDICAL) REUSABLE RESPIRATOR (NON-MEDICAL)</p> <p>BOX SIZE: 15*9*12.5 cm MADE IN CHINA</p> <p>hongyu 红雨</p> <p><b>20</b> PCS BOXES 50 BOXES 1000PCS</p>	<p><b>SL+CARE</b> SICANIA LABS</p> <p>G.W: 11 KGS N.W: 10 KGS Meas: 47.5*31.5*64.5 CM MFG: 2021/03/10 EXP: 2023/03/09 LOT: 210310</p> <p>Importeur / Importer: ThinkClean David &amp; Hepping GbR Cottbusser Weg 16 72108 Rottenburg a.N. Germany</p>
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1 pc pouch

16x12.5cm



Instructions leaflet





## EU DECLARATION OF CONFORMITY

**Manufacturer:** ZHEJIANG HONGYU MEDICAL COMMODITY CO.,LTD.  
No.668 Chanhua Road, Fotang Town Industrial Functional Area,322002 Yiwu City,  
Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

**Product:** Disposable protective mask FFP2, model HY1117

The manufacturer hereby declares under its sole responsibility that the above FFP2 mask complies with the following harmonised EU standards (Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC):

EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking

EN 13274-7:2019	Determination of the passage of particle filters
EN 13274-3:2001	Determination of the breathing
EN 13274-4:2001	Flame tests
EN 13274-2:2019	Practical performance tests
EN 13274-1:2001	Determination of the inward leakage
EN 13274-6:2001	Determination of the carbon dioxide content of the inhaled

The notified body SGS FIMKO OY FINLAND (identification number: 0598) has carried out the EU type examination (module B) and issued the EU type examination certificate with the certificate number FI20/966730.

The PPE is subject to the following conformity assessment procedure: Conformity to type based on internal production control with supervised product checks at irregular intervals (module C2 - certificate number CN20/42413) under surveillance of the notified body SGS FIMKO OY FINLAND (identification number: 0598).

Signed for and on behalf of:

**Manufacturer:** ZHEJIANG HONGYU MEDICAL COMMODITY CO.,LTD.

**General Manager:** Jin HangYu

**Signature:** \_\_\_\_\_

**Place:**

Yiwu, Zhejiang, China

**Date:**

24/10/2020



SGS FIMKO OY, Notified Body 0598  
Tukimiehenkatu 4, FI-00030 Helsinki, Finland  
+358 9 806361 | +358 9 6925474  
[www.sgs.com](http://www.sgs.com)



Certificate FI20/966730

# ZHEJIANG HONGYU MEDICAL COMMODITY CO.,LTD

No. 668 ChanHua Road Fotang Town Industrial Functional Area  
322002 Yiwu 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 29 September 2020 until 29 September 2025  
1. Certified since 29 September 2020

Authorised by

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

SGS FIMKO OY, Notified Body 0598

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

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# ZHEJIANG HONGYU MEDICAL COMMODITY CO.,LTD

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

Issue 1

PPE Product

HONGYU (logo) HY1117, 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: PPE-TF-04, Revision A/0,  
dated 2020/08/07

SGS Reference Number UK/CRS 241831

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

Certificate CN20/42413

The management system of

# ZHEJIANG HONGYU MEDICAL COMMODITY CO.,LTD.

No.668 Chanhua Road, Fotang Town Industrial Functional Area,  
322002 Yiwu City, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

has been assessed and certified as meeting the requirements of

## Regulation (EU) 2016/425 Module C2

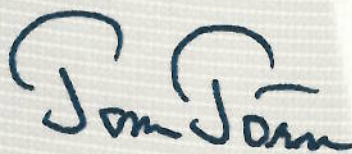
For the following activities

**Manufacture of HONGYU (logo) HY-1117 and HY-1118 single use  
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 24 October 2020  
and remains valid subject to satisfactory surveillance audits.  
Issue 1. Certified since 24 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)

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# EC Certificate



## Production Quality Assurance MDD Annex V

Registration No.: DD 2253563-1

Manufacturer: Zhejiang Hongyu Medical Commodity Co.,Ltd  
No.668 ChanHua Road,  
Fotang Town Industrial Functional Area  
Yiwu City,  
322002 Zhejiang  
P.R. China

Products: Aspects of manufacture concerned with securing and maintaining sterile conditions of Medical Face Masks, PVA Swabs

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.

Report No.: 17054622 002

Effective date: 2020-09-22

Expiry date: 2024-05-26

Issue date: 2020-09-22



Wenxiang Zhang  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

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