SICANIA LABS
GLOBAL HEALTHCARE SUPPLIERS

6pcs box

SICANIA LABS
GLOBAL HEALTHCARE SUPPLIERS

10pcs 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

SICANIA LABS
GLOBAL HEALTHCARE SUPPLIERS

20pcs box

Masks photo

SICANIA LABS
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6 pcs packing

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SICANIA LABS
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10 pcs packing

15x4.5x12.5cm

SICANIA LABS
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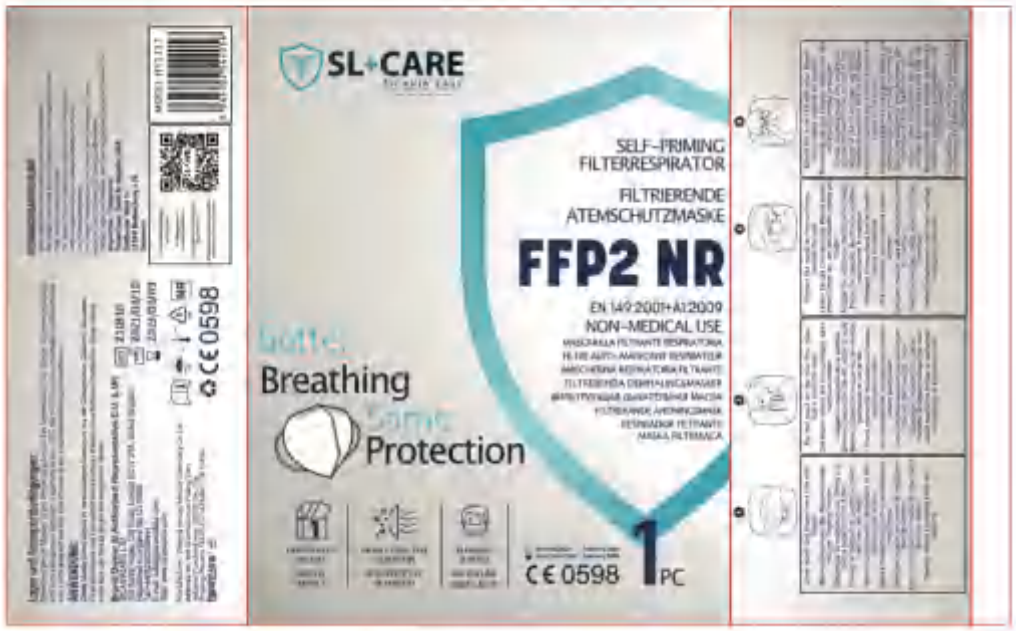
20 pcs packing

150x90x125mm

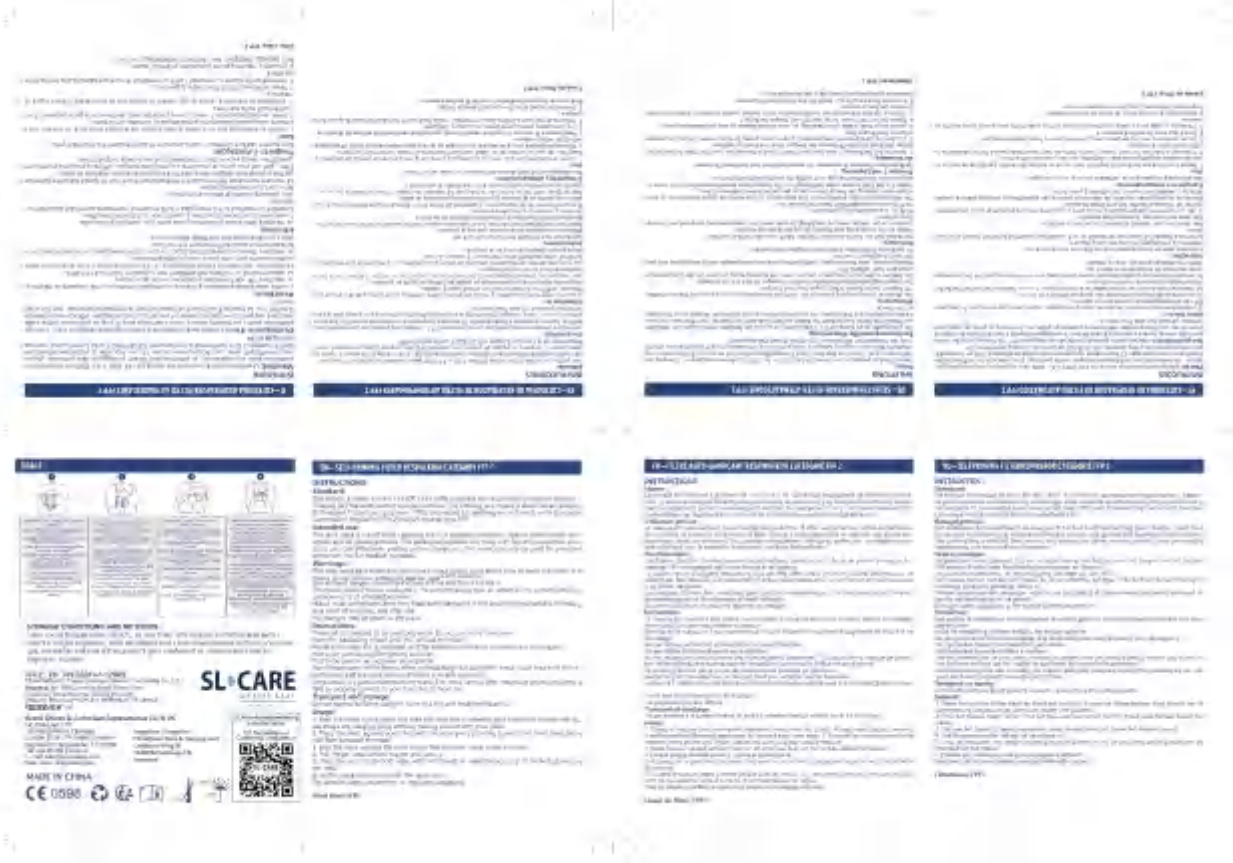
SICANIA LABS
GLOBAL HEALTHCARE SUPPLIERS

1 pc pouch

16x12.5cm



Instructions leaflet



SICANIA LABS
GLOBAL HEALTHCARE SUPPLIERS

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 13274-8:2001	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 HangYo

Signature:

Place: Yiwu, Zhejiang, China
Date: 24/10/2020

SGS CE 0598

SGS FIMKO OY, Notified Body 0598
Takomotie 8, FI-00380 Helsinki, Finland
T +358 9 696 361 F +358 9 696 5474
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 OFCHINA

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

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.

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

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

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

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

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

EC Certificate

TÜVRheinland®

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

TÜV Rheinland LGA Products GmbH TÜVRheinland III sterile

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.