ASPIRATION LIFE

FACE MASKS

EN 149 : 2009 +A1 : 2009 FFP2 NR

Zhiyi

e: sales@aspirationlife.com | t: 0113 4810000

ISO 13485（平面口罩认证）

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q6 17 09 68194 007

Holder of Certificate: **Zhangjiagang Zhiyi Medical Health Products Co., Ltd.**
Renmin Road, Leyu Town
215622 Zhangjiagang City, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Zhangjiagang Zhiyi Medical Health Products Co., Ltd.
Renmin Road, Leyu Town, 215622 Zhangjiagang City, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Production and Distribution of Surgical Drape, Dental Apron for Hospital Usage, Surgical Gown, Sterile Surgical Kit, Face Mask**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1752410

Valid from: 2018-01-01
Valid until: 2020-12-31

Date, 2017-12-05

Stefan Preiß

Page 1 of 1

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

ZHIYI MEDICAL

EU DECLARATION OF CONFORMITY

CE

We,

Manufacturer: Zhangjiagang Zhiyig Medical Health Products CO.,LTD.

Address: Renmin Road, Changfeng, Leyu Town, Zhangjiagang City . Jiangsu Province, China.

Declare on our own responsibility, that the :

Product Name: FFP2 NR

Model Name: ZY-MASK-01

Are in compliance with following Regulation/directive:

R 2016/425 Personal Protective Equipment

and are in compliance with following harmonized standard:

BSI's PPE for Healthcare Professionals 2020/403 – RPE Technical Specification

Identical products were certified by Notified Body for PPE PModule B+C2

Notified Body No: 2797

BSI GROUP THE NETHERLAND B.V

John M. Keynesplein 9，1066 EP Amsterdam

Zhangjiagang 2020.5.6

Place,date

张家港市志益医材有限公司
ZHANGJIAGANG ZHIYI
MEDICAL HEALTH PRODUCTS CO., LTD

Signature,Function

* This filtering half mask is manufactured for COVID-protection only.
* This filtering half mask is not a PPE device for general use and shall not be used for purposes other than protection against COVID-19.

Zhangjiagang Zhiyi Medical Health Products CO.,LTD.
Renmin Road, Changfeng, Leyu Town, Zhangjiagang City,
Jiangsu Province, China

BSI CE 证书（个人防护口罩认证=GB2626-2006）

EU Type Examination Certificate

This is to certify that:

Zhangjiagang Zhiyi Medical Health Products Co Ltd
Renmin Road, Leyu Town
Zhangjiagang City
Jiangsu
215622
China

Holds Certificate Number: CE 728383

In respect of:

Model ZY Mask and Covaflu (By Clinova) Face mask
To technical speciation Annex II (EHSR) of the PPE Regulation (EU) 2016/425
PPE for use by healthcare professionals as per Commission recommendation 2020/403

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 2797):

Drs. Dave Hagenaars, Managing Director

Previous Notified Body: BSI 0086
First Issued: 2020-04-28
Latest Issue: 2020-04-28

Effective Date: 2020-04-28
Expiry Date: 2021-04-28

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EU Type Examination Certificate

No. CE 728383

Product Specification

Product Name:	ZY Mask and Covaflu Mask
Product Type:	Filtering half masks for use by Healthcare professionals
Models:	ZY-MASK-01 ZY-MASK-02 Covaflu ZY-MASK-01 (by Clinova) Covaflu ZY-MASK-02 (by Clinova)
Technical Specification:	Technical specification to satisfy Annex II of the PPE Regulation (EU) 2016/425
Product Description:	The mask(s) listed on this certificate are for use by healthcare workers, first responders and other personnel involved in the efforts to contain the COVID-19 virus and avoid its further spread. The product(s) covered by this certificate is/are not approved for industrial applications and the certificate is only valid as long as EU Commission recommendation sheet 2020/403 remains applicable.
Product Assessments:	GB2626:2006 Respiratory Protection – Non-powered air purifying particle respirator Classification KN95

First Issued: 2020-04-28
Latest Issue: 2020-04-28

Effective Date: 2020-04-28
Expiry Date: 2021-04-28

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EU Type Examination Certificate

No. CE 728383

Certificate Administration Details

Technical File Reference: ZY-MASK-01, Revision 0 and ZY-MASK-02, Revision 0

Certificate Amendment Record:

Issue date	Comments	BSI Review No.
April 2020	First issue.	2797:20:3204120

Certificate validity

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspect of the overall process utilised in the manufacture of the product, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes.

The validity of the Certificate for the products is also dependent on the maintenance of the Conformity to Type Based on Internal Production Control Plus Supervised Product Checks at Random Intervals, Annex VII (Module C2), as referenced on BSI issued Certificate CE 728384.

First Issued: 2020-04-28
Latest Issue: 2020-04-28

Effective Date: 2020-04-28
Expiry Date: 2021-04-28

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Conformity to Type based on Internal Production Control plus supervised product checks at random intervals

This is to certify that:

Zhangjiagang Zhiyi Medical Health
Product Co Ltd
Renmin Road, Leyu Town
Zhangjiagang City
Jiangsu
215622
China

Holds Certificate Number: CE 728384

In respect of:

The manufacture of face masks to Technical Specification to Annex II of Regulation (EU) 2016/425

on the basis that BSI carried out the supervised production checks at random intervals under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex VII (Module C2)

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):
Previous Notified Body: BSI 0086
First Issued: 2020-04-28
Latest Issue: 2020-04-28

Drs. Dave Hagenaars, Managing Director

Effective Date: 2020-04-28
Expiry Date: 2021-04-28

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Conformity to Type based on Internal Production Control plus supervised product checks at random intervals

No. CE 728384

Product manufactured by:

Zhangjiagang Zhiyi Medical Health
Product Co Ltd
Renmin Road, Leyu Town
Zhangjiagang City
Jiangsu
215622
China

Product details

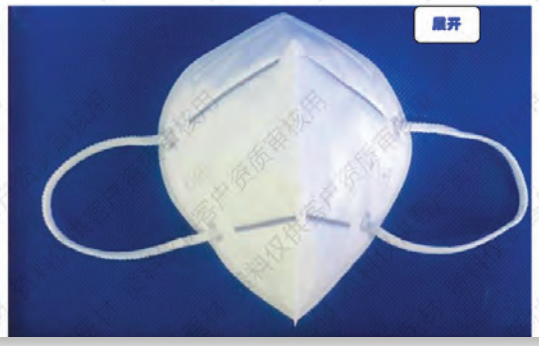
The respiratory protective device covered by the scope of this Module C2 Certificate and the Technical Specification to which the product is manufactured are as follows:

Product type:	Filtering Face Piece for use by Healthcare professionals.
Model and classifications:	Models covered in this recommendation: ZY-MASK-01 ZY-MASK-02 Identical masks with additional branding Covaflu ZY-MASK-01 (by Clinova) identical to ZY-MASK-01 Covaflu ZY-MASK-02 (by Clinova) identical to ZY-MASK-02
Technical Specification:	Technical specification to satisfy Annex II of the PPE Regulation (EU) 2016/425. BSI's PPE for Healthcare Professionals 2020/403 – RPE Technical Specification.

First Issued: 2020-04-28
Latest Issue: 2020-04-28

Effective Date: 2020-04-28
Expiry Date: 2021-04-28

1、产品：C 型 KN95



EN 149：2001+A1：2009（C 型）

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3175188/2 of 2 Issue 2 - Test Report.

Test Report 3175188/2 of 2 Issue 2.

Zhangjiagang Zhiyi Medical Health Products Co., Ltd

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Introduction.

This report has been prepared by Paul Waller and relates to the activity detailed below:

Job/Registration Details		Client Details
Job number:	**3175188/2 of 2 Issue 2**	Zhangjiagang Zhiyi Medical Health Products Co., Ltd
Job type:	Testing Samples Submitted	Renmin Road
Start Date:	20/04/2020	Leyu Town
Test type:	Type	Zhangjiagang city
Sample ID:	10189445	Jiangsu
Registration:	**CE 727911**	215622
Scheme:	Negative pressure RPE	China
Protocol:	PP123	
Scheme Manager:	Nathan Shipley	

The report has been approved for issue by M Mayo – Testing Team Manager

Approved For Issue	
	Issue Date: 7 May 2020

Objectives.

This is an independent test evaluation to only certain clauses or sub-clauses of the agreed specification in accordance with the following test programme:

BSI COVID-19 filtering face piece technical specification, for COVID-19 masks for use by healthcare workers

Product Scope.

COVID-19 masks for use by healthcare workers

Report Summary.

The samples were received on 20 April 2020 and the testing was started on 20 April 2020.
This issue supersedes all previous issues. The amendment giving rise to this issue can be ascertained by contacting the authorizing signatory at the address shown.

The samples submitted complied with the requirements of the test work conducted.

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Test Samples.

Sample ID	ER Number	Description
1 to 19	10189445	Model: ZY-MASK-01 Vertical fold flat mask

Description of Test Samples.

Sample Description
COVID-19 masks for use by healthcare workers: Model: ZY-MASK-01 Vertical fold flat mask

Test Requirements.

Testing in accordance with BSI COVID-19 filtering face piece technical specification
Technical testing specification for COVID-19 masks for use by healthcare workers

EN 149:2001+A1:2009 Performance requirement	EN 149:2001+A1:2009 Test method clause	Requirement	Assessment
7.7 Practical performance The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard. Where practical performance tests show the apparatus has imperfections related to wearer's acceptance, the test house shall provide full details of those parts of the practical performance tests which revealed these imperfections. *2 test subjects, masks tested 'As received'*	Testing shall be done in accordance with 8.4.	During the tests the particle filtering half mask shall be subjectively assessed by the wearer and after the test, comments on the following shall be recorded: a) head harness comfort; b) security of fastenings; c) field of vision; d) any other comments reported by the wearer on request.	Pass
7.9 Leakage 7.9.1 Total inward leakage *5 test subjects, masks tested 'As received'*	Testing shall be done in accordance with 8.5.	All samples must achieve All individual exercise results tests shall be not greater than 11 % (for FFP2) and, in addition, all arithmetic means for the total inward leakage shall be not greater than 8 % (for FFP2)	Pass
7.9 Leakage 7.9.2 Penetration of filter material *3 test samples masks tested 'As received', for NaCl (Sodium Chloride) and PO (Paraffin oil), 3min test*	Testing shall be done in accordance with 8.11	6% for both PO and NaCl	Pass
7.12 Carbon dioxide content of the inhalation air *3 test samples, masks tested 'As received'*	Testing shall be done in accordance with 8.7.	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume).	Pass
7.16 Breathing resistance *3 test samples, masks tested 'As received'*	Testing shall be done in accordance with 8.9	The breathing resistances shall meet the requirements of; 30l/min – 0.7mbar (inhale) 95l/min – 2.4mbar (inhale) 160l/min – 3.0mbar (exhale) If achieves cl 7.9.2 FFP3 class 30l/min – 1.0mbar (inhale) 95l/min – 3.0mbar (inhale) 160l/min – 3.0mbar (exhale)	Pass
Appendix A - Test Panel Data			
Product Photographs			

Glossary of Terms.

Pass: Complies. Tested by BSI engineers at BSI laboratories
Pass 1: Complies. Witnessed by BSI engineers in manufacturers laboratory.
Pass 2: Complies. Tests carried out by third party lab; results accepted by BSI.
Pass*: Report resulted in uncertainty and states that Compliance is more probable than non-compliance.
Fail: Non-compliance. Product does not meet the requirements of this clause.
Fail*: Report resulted in uncertainty and states that Non-compliance is more probable than compliance.
N/T: Not Tested
N/A: Not Applicable
AR: As Received
TC: Temperature Conditioned
SW: Simulated Wear
FT: Flow Tested
MS: Mechanical strength
MMDF: Manufactures Minimum Design Flow
MMDC: Manufactures Minimum Design Condition

Conditions of Issue.

This Test Report is issued subject to the conditions stated in current issue of 'BSI Terms of Service'. The results contained herein apply only to the particular sample(s) tested and to the specific tests carried out, as detailed in this Test Report. The issuing of this Test Report does not indicate any measure of Approval, Certification, Supervision, Control or Surveillance by BSI of any product. No extract, abridgement or abstraction from a Test Report may be published or used to advertise a product without the written consent of BSI, who reserve the absolute right to agree or reject all or any of the details of any items or publicity for which consent may be sought.

Should you wish to speak with BSI in relation to this report, please contact Customer Services on +44 (0)8450 80 9000.

BSI
Kitemark House
Maylands Avenue
Hemel Hempstead
Hertfordshire
HP2 4SQ

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Opinions and Interpretations expressed herein are outside the scope of our UKAS accreditation.
Unless otherwise stated, any results not obtained from testing in a BSI laboratory are outside the scope of our UKAS accreditation.

Test Results.

Testing in accordance with BSI COVID-19 filtering face piece technical specification
BS EN 149:2001 +A1:2009 Technical testing specification for COVID-19 masks for use by healthcare workers

CLAUSE	REQUIREMENTS	ASSESSMENT
7.7	**Practical performance** The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard. Where practical performance tests show the apparatus has imperfections related to wearer's acceptance, the test house shall provide full details of those parts of the practical performance tests which revealed these imperfections. Test in accordance with clause 8.4 of the standard.	Pass
	Testing in accordance with BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers *During the tests the particle filtering half mask shall be subjectively assessed by the wearer and after the test, comments on the following shall be recorded: a) head harness comfort; b) security of fastenings; c) field of vision; d) any other comments reported by the wearer on request.*	

Table A: Practical performance

Test candidate	Sample	Comments: Head harness comfort	Comments: Security of fastenings	Comments: Field of vision	Comments: Any other comments	Assessment
RF1	1 AR	Fine	Good	Fine	None	Pass
GR1	2 AR	OK	Good	OK	Ear loop adjuster was a little uncomfortable	Pass

7.9	**Leakage**	
7.9.1	Total inward leakage The laboratory tests shall indicate that the particle filtering half mask can be used by the wearer to protect with high probability against the potential hazard to be expected. The total inward leakage consists of three components: face seal leakage, exhalation valve leakage (if exhalation valve fitted) and filter penetration. Test in accordance with clause 8.5 of the standard.	Pass
	Testing in accordance with BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers *5 test subjects, masks tested 'As received'. All individual exercise results tests shall be not greater than 11 % (for FFP2) and, in addition, all arithmetic means for the total inward leakage shall be not greater than 8 % (for FFP2).*	

Table B: Clause 7.9.1 - Total inward leakage

Test candidate	Sample	Pre test condition	Inward Leakage (%) A Walking	B Walking with head side to side	C Walking with head up & down	D Walking and talking	E Walking	Average	Assessment
LM2	3	AR	1.30	1.18	2.21	1.43	1.74	1.57	Pass
AA1	4	AR	4.69	7.75	5.19	2.28	4.21	4.21	Pass
SR1	5	AR	2.61	2.71	2.27	1.61	2.06	2.06	Pass
SI1	6	AR	1.20	1.33	2.11	1.58	1.41	1.52	Pass
MM2	7	AR	1.72	0.80	1.17	0.61	1.24	1.11	Pass

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
7.9.2	Penetration of filter material ***Testing in accordance with BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers*** *3 test samples masks tested 'As received', for NaCl (Sodium Chloride) and PO (Paraffin oil), 3 min test. Testing shall be done in accordance with 8.11. 6% limit for both PO and NaCl*	Pass

Table C: Clause 8.11 - Sodium Chloride penetration test

Sample number	Pre-test condition	Flow through filter (l/min)	Penetration (%) Limit	Penetration (%) Actual
8	AR	95	< 6	0.1240
9	AR			0.0195
10	AR			0.0766

Table D: Clause 8.11 - Paraffin oil penetration test

Sample number	Pre-test condition	Flow through filter (l/min)	Penetration (%) Limit	Penetration (%) Actual
11	AR	95	< 6	0.9175
12	AR			0.4045
13	AR			1.8150

7.12	**Carbon dioxide content of inhalation air** The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0% (by volume). Test in accordance with clause 8.7 of the standard.	Pass

Table E: Clause 8.7 - Carbon Dioxide content of the inhalation air

Sample	Pre-test condition	Dead space CO_2 (%) Limit	Dead space CO_2 (%) Measured
14	AR	< 1.0	0.45
15	AR		0.45
16	AR		0.50

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3175188/2 of 2 Issue 2 - Test Report.

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
7.16	**Breathing resistance** ***Testing in accordance with BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers*** *3 test samples masks tested 'As received'. Test in accordance with clause 8.9 of the standard.* *The breathing resistances shall meet the requirements of FFP2:* *30l/min – 0.7mbar (inhale); 95l/min – 2.4mbar (inhale), 160l/min – 3.0mbar (exhale)* *If achieves clause 7.9.2 FFP3 class (<1% penetration):* *30l/min – 1.0mbar (inhale); 95l/min – 3.0mbar (inhale), 160l/min – 3.0mbar (exhale)*	Pass

Table F: Clause 8.9 – Breathing resistance. Inhalation resistance at a continuous flow

Sample	Pre-test condition	Continuous flow (l/min)	Inhalation resistance (mbar)	
			Limit	Measured
17	AR	30	< 0.7	0.42
18	AR			0.43
19	AR			0.47
17	AR	95	< 2.4	1.37
18	AR			1.36
19	AR			1.48

Table G: Clause 8.9 – Breathing resistance. Exhalation resistance at a continuous flow, measured in five orientations with the worst case reported

Sample	Pre-test condition	Continuous flow (l/min)	Exhalation resistance (mbar)	
			Limit	Measured
17	AR	160	< 3.0	2.25
18	AR			2.27
19	AR			2.18

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3175188/2 of 2 Issue 2 - Test Report.

Appendix A. – Test Panel Data

Test Candidate	Facial Dimensions (mm)					Sex
	Length of face	Width of face	Face depth	Width of mouth	Head Circumference	
RF1	104	122	121	55	549	Male
AA1	125	144	130	47	581	Male
MM2	119	150	115	53	595	Male
GR1	124	145	126	49	590	Male
SR1	118	133	130	52	585	Male
SI1	121	135	142	48	575	Male
LM2	110	148	125	44	589	Male

Note: All candidates were clean shaven

Product photographs.

Front view

Side View

Inside View

End of Report

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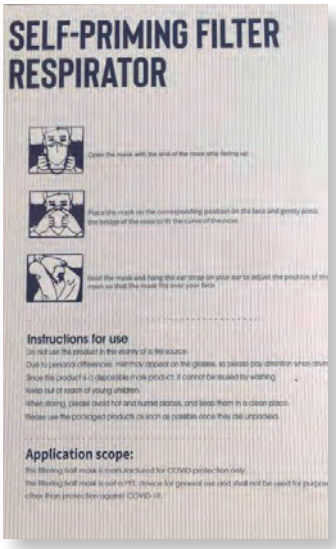

ASPIRATION LIFE

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