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

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

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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.

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 CN21/42178

The management system of

ZHEJIANG HONGYU MEDICAL COMMODITY CO., LTD.

No.668 Chanhua Road, Fotang Town Industrial Functional Area,
Yiwu City, Jinhua City, Zhejiang Province, P.R. China

has been assessed and certified as meeting the requirements of

Regulation (EU) 2016/425

Module D

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 12 February 2021 until 11 February 2024
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 3 February 2024
Issue 1. Certified since 12 February 2021

This is a multi-site certification
Additional site details are listed on the subsequent page

Authorised by

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Finnish Accreditation Service
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ZHEJIANG HONGYU MEDICAL COMMODITY CO., LTD.

Regulation (EU) 2016/425

Module D

Issue 1.

Detailed scope

Manufacture of FFP2 Protective Respirators (Note: all products marked CE0598 must have a valid EU Type Examination Certificates issued under Module B or a valid EC type examination certificate issued under Article 10 of the PPE Directive 89/686/EEC.)

Additional facilities

No.517 Shuangfeng Road, Fotang Town Industrial Functional Area, Yiwu City, Jinhua City, Zhejiang Province, P.R. China

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

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

THIS REPORT CANCELS AND SUPERSEDES THE TEST REPORT NO.SL52035272382701TX DATE: 2020-07-23 ISSUED BY SGS (Shanghai) UPDATED SAMPLE INFORMATION.

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description	:	(A)PROTECTIVE FACE MASK Request Age Grading: 2 years
SGS Internal Ref No.	:	SHHL2006525455MD
Style No.	:	HY1117
Sample Color	:	(A)WHITE
Manufacturer	:	ZHEJIANG HONGYU MEDICAL COMMODITY CO.,LTD
Country of Origin	:	China
Supplier	:	ZHEJIANG HONGYU MEDICAL COMMODITY CO.,LTD
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Jul 06, 2020
Testing Period	:	Jul 06, 2020 - Jul 23, 2020
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Conclusion:

Sample No.	Recommendation Level
(A)	FFP2 NR

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

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Test Result

Personal Protective Equipment - Respiratory Protective Devices- Filtering Half Masks to Protect against Particles- Requirements, Testing, Marking
EN 149:2001+A1:2009

Clause 7.4 Packaging
(EN 149:2001+A1:2009 Clause 8.2)

Test Requirement	Results	Comment
Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	Comply	Pass

Clause 7.5 Material
(EN 149:2001+A1:2009, Clause 8.2 & 8.3.1 & 8.3.2)

Test Requirement	Results	Comment
Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.	Comply	Pass
After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.	Comply	
When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	Comply	
Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Comply	

Clause 7.6 Cleaning and Disinfecting
(EN 149:2001+A1:2009, Clause 8.4 & 8.5 & 8.11)

Test Requirement	Results	Comment
If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer. With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.	Not applicable (Not designed to be re-usable)	N.A.

Clause 7.7 Practical Performance
(EN 149:2001+A1:2009, Clause 8.4)

Test Requirement	Results	Comment
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.	No imperfections	Pass

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Clause 7.8 Finish of Parts
(EN 149:2001+A1:2009, Clause 8.2)

Test Requirement	Results	Comment
Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	No sharp edges or burrs	Pass

Clause 7.9.1 Total Inward Leakage
(EN 149:2001+A1:2009, Clause 8.5)

Test Requirement	Results	Comment
The total inward leakage consists of three components: face seal leakage, exhalation value leakage(if exhalation value fitted) and filter penetration. For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than: 25% for FFP1, 11% for FFP2, 5% for FFP3 and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than: 22% for FFP1, 8% for FFP2, 2% for FFP3	Detail refer to Appendix 1	Meet FFP1, Meet FFP2

Appendix 1: Summarization of Test Data

Inward Leakage Test Data

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head up/down(%)	Talk(%)	Walk(%)	Mean(%)
Zhou	1	A.R.	7.11	7.23	5.02	5.04	6.86	6.25
Luo	2	A.R.	6.70	7.20	6.98	6.40	7.72	7.00
Lu	3	A.R.	6.95	7.32	5.36	5.97	5.55	6.23
Wang	4	A.R.	6.02	5.75	4.94	5.56	4.98	5.45
Bao	5	A.R.	8.02	6.39	7.11	5.98	7.71	7.04
Ding	6	T.C.	7.37	5.21	5.55	4.54	4.96	5.53
Li	7	T.C.	6.17	7.65	7.69	8.15	7.13	7.36
Chen	8	T.C.	5.36	5.12	4.80	6.44	5.79	5.50
Song	9	T.C.	4.82	7.13	6.91	5.56	7.09	6.30
Ye	10	T.C.	5.98	8.24	7.60	6.87	7.79	7.30

Facial Dimension(mm)

Subject	Face length	Face Width	Face Depth	Mouth Width
Chen	125	150	120	58
Lu	115	132	107	48
Zhou	115	135	106	52
Li	125	130	107	46
Luo	125	136	100	43
Zheng	128	140	112	55
Wang	120	147	103	48
Song	120	140	100	50
Bao	130	134	104	50

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Ding	134	150	110	52
Liu	120	135	117	50
Ye	126	137	105	52

Clause 7.9.2 Penetration of Filter Material

(EN 149:2001+A1:2009, Clause 8.11 & EN 13274-7:2019)

Test Requirement	Results	Comment
The penetration of the filter of the particle filtering half mask shall meet the requirements of the following table.	Detail refer to Appendix 2	Meet FFP1, Meet FFP2

Classification	Maximum penetration of test aerosol	
	Sodium chloride test 95 l/min % max.	Paraffin oil test 95 l/min % max.
FFP1	20	20
FFP2	6	6
FFP3	1	1

Appendix 2: Summarization of Test Data

Penetration of filter material

Aerosol	Condition	Sample No.	Penetration (%)
Sodium chloride test	As received	1	0.637
		2	0.456
		3	0.523
	Simulated wearing treatment	4	0.467
		5	0.564
		6	0.574
	Mechanical strength +Temperature conditioned	7	0.852
		8	0.681
		9	0.778
Paraffin oil test	As received	10	1.247
		11	1.426
		12	1.368
	Simulated wearing treatment	13	1.372
		14	1.270
		15	1.359
	Mechanical strength +Temperature conditioned	16	4.067
		17	4.327
		18	3.964
Flow conditioning : Single filter: 95.0 L/min			

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Clause 7.10 Compatibility with Skin

(EN 149:2001+A1:2009, Clause 8.4 & 8.5)

Test Requirement	Results	Comment
Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.	No irritation or any other adverse effect to health	Pass

Clause 7.11 Flammability

(EN 149:2001+A1:2009, Clause 8.6)

Test Requirement	Results	Comment
The material used shall not present a danger for the wearer and shall not be of highly flammable nature When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame.	Detail refer to Appendix 3	Pass

Appendix 3: Summarization of Test Data

Flammability

Condition	Sample No.	Result
As received	1	NIL
	2	NIL
Temperature conditioned	3	NIL
	4	NIL

Clause 7.12 Carbon Dioxide Content of The Inhalation Air

(EN 149:2001+A1:2009, Clause 8.7)

Test Requirement	Results	Comment
The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume)	Detail refer to Appendix 4	Pass

Appendix 4: Summarization of Test Data

Carbon Dioxide Content of The Inhalation Air

Condition	Sample No.	Result(%)	
As received	1	0.4774	Mean value:0.48
	2	0.4782	
	3	0.4768	

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Clause 7.13 Head Harness

(EN 149:2001+A1:2009, Clause 8.4 & 8.5)

Test Requirement	Results	Comment
The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.	Comply	Pass
The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position and be capable of maintaining total inward leakage requirements for the device.	Comply	

Clause 7.14 Field of Vision

(EN 149:2001+A1:2009, Clause 8.4)

Test Requirement	Results	Comment
The field of vision is acceptable if determined so in practical performance tests.	Comply	Pass

Clause 7.15 Exhalation Valve(s)

(EN 149:2001+A1:2009, Clause 8.2 & 8.9.1 & 8.3.4 & 8.8)

Test Requirement	Results	Comment
(a) A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.	Not applicable due to No exhalation valve	N.A.
(b) If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9.	Not applicable due to No exhalation valve	
(c) Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.	Not applicable due to No exhalation valve	
(d) When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10N applied for 10 s.	Not applicable due to No exhalation valve	

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Clause 7.16 Breathing Resistance
(EN 149:2001+A1:2009, Clause 8.9)

Test Requirement	Results	Comment
The penetration of the filter of the particle filtering half mask shall meet the requirements of the following table.	Detail refer to Appendix 5	Meet FFP1, Meet FFP2, Meet FFP3

Classification	Maximum permitted resistance (mbar)		
	Inhalation		Exhalation
	30 l/min	95 l/min	160 l/min
FFP1	0.6	2.1	3.0
FFP2	0.7	2.4	3.0
FFP3	1.0	3.0	3.0

Appendix 5: Summarization of Test Data

Breathing resistance (mbar)

	Flow rate(l/min)		1					2					3				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
As received	Inhalation	30	0.2	0.3	0.2	0.3	0.3	0.3	0.3	0.3	0.2	0.3	0.3	0.3	0.3	0.3	0.3
		95	0.7	0.8	0.7	0.8	0.7	0.8	0.7	0.8	0.7	0.8	0.7	0.7	0.8	0.7	0.8
	Exhalation	160	2.0	2.1	2.2	2.0	2.1	2.1	2.0	2.1	2.0	2.1	2.1	2.0	2.0	2.1	2.1
	Flow rate(l/min)		4					5					6				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
Simulated wearing treatment	Inhalation	30	0.3	0.3	0.3	0.2	0.3	0.3	0.2	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.2
		95	0.8	0.9	0.8	0.9	0.8	0.9	0.9	0.8	0.8	0.9	0.9	0.8	0.9	0.9	0.8
	Exhalation	160	2.1	2.0	2.0	2.0	2.1	2.0	2.1	2.1	2.0	2.0	2.1	2.0	2.0	2.1	2.0
	Flow rate(l/min)		7					8					9				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
Temperature conditioned	Inhalation	30	0.2	0.2	0.2	0.3	0.3	0.3	0.3	0.2	0.3	0.2	0.3	0.3	0.2	0.2	0.3
		95	0.8	0.7	0.8	0.7	0.7	0.8	0.7	0.7	0.8	0.8	0.7	0.7	0.8	0.8	0.7
	Exhalation	160	1.9	2.0	1.9	2.0	2.0	1.9	1.9	2.0	1.9	2.0	1.9	2.0	1.9	1.9	2.0

A: facing directly ahead; B: facing vertically upwards; C: facing vertically downwards; D: lying on the left side; E: lying on the right side

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Clause 7.17 Clogging
(EN 149:2001+A1:2009, Clause 8.9 & 8.10)

Test Requirement	Results	Comment
Clause 7.17.2 Breathing resistance Valved particle filtering half masks: After clogging the inhalation resistances shall not exceed: FFP1: 4 mbar, FFP2: 5 mbar, FFP3: 7 mbar at 95L/min continuous flow The exhalation resistance shall not exceed 3 mbar at 160 L/min continuous flow. Valveless particle filtering half masks: After clogging the inhalation and exhalation resistances shall not exceed: FFP1: 3 mbar, FFP2: 4 mbar, FFP3: 5 mbar at 95L/min continuous flow	Optional for single shift device only	N.A.
Clause 7.17.3 Penetration of filter material All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement shall also meet the requirements.	Optional for single shift device only	N.A.

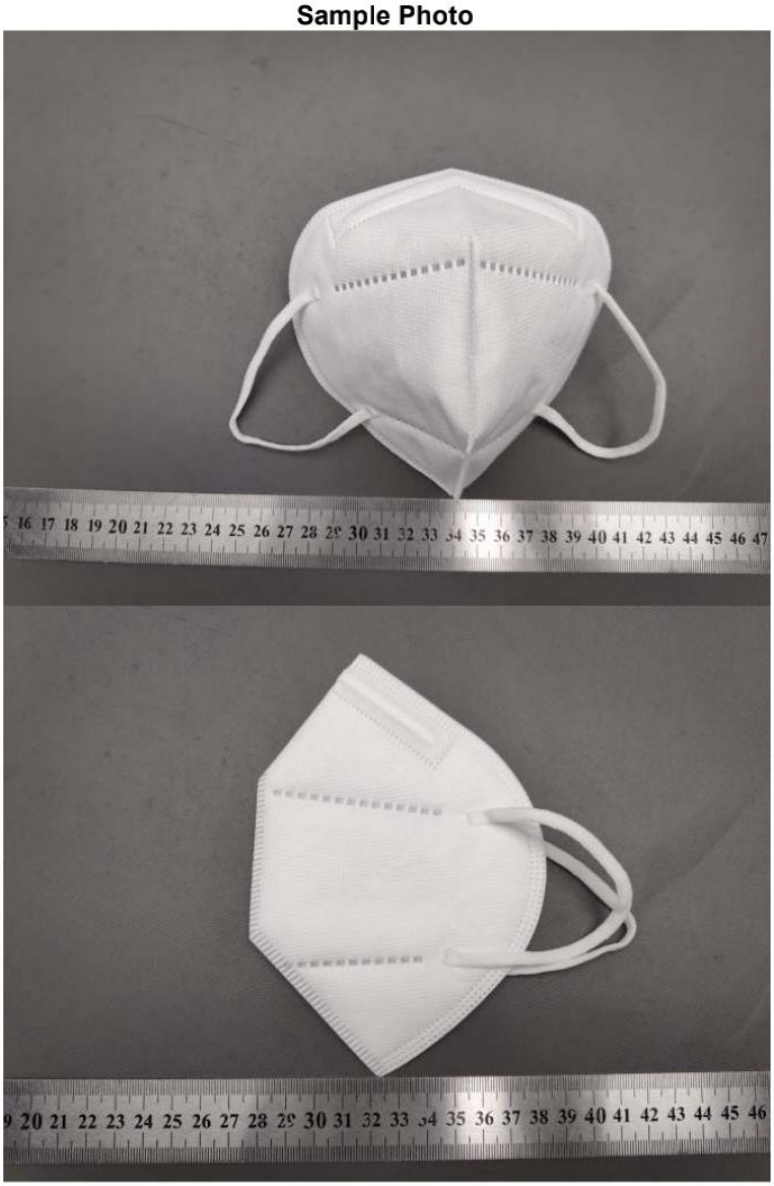
Classification	Maximum penetration of test aerosol	
	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
	%	%
	max.	max.
FFP1	20	20
FFP2	6	6
FFP3	1	1

Clause 7.18 Demountable Parts
(EN 149:2001+A1:2009, Clause 8.2)

Test Requirement	Results	Comment
All demountable parts (if fitted) shall be readily connected and secured, where possible by hand	No demountable parts	N.A.

Test	Uncertainty
Total inward leakage	3.4%
Penetration of filter material	4.8%
Carbon dioxide content of the inhalation air	3.9%
Breathing resistance (30L/min)	5.9%
Breathing resistance (95L/min)	4.9%
Breathing resistance (160L/min)	4.3%

Sample Photo



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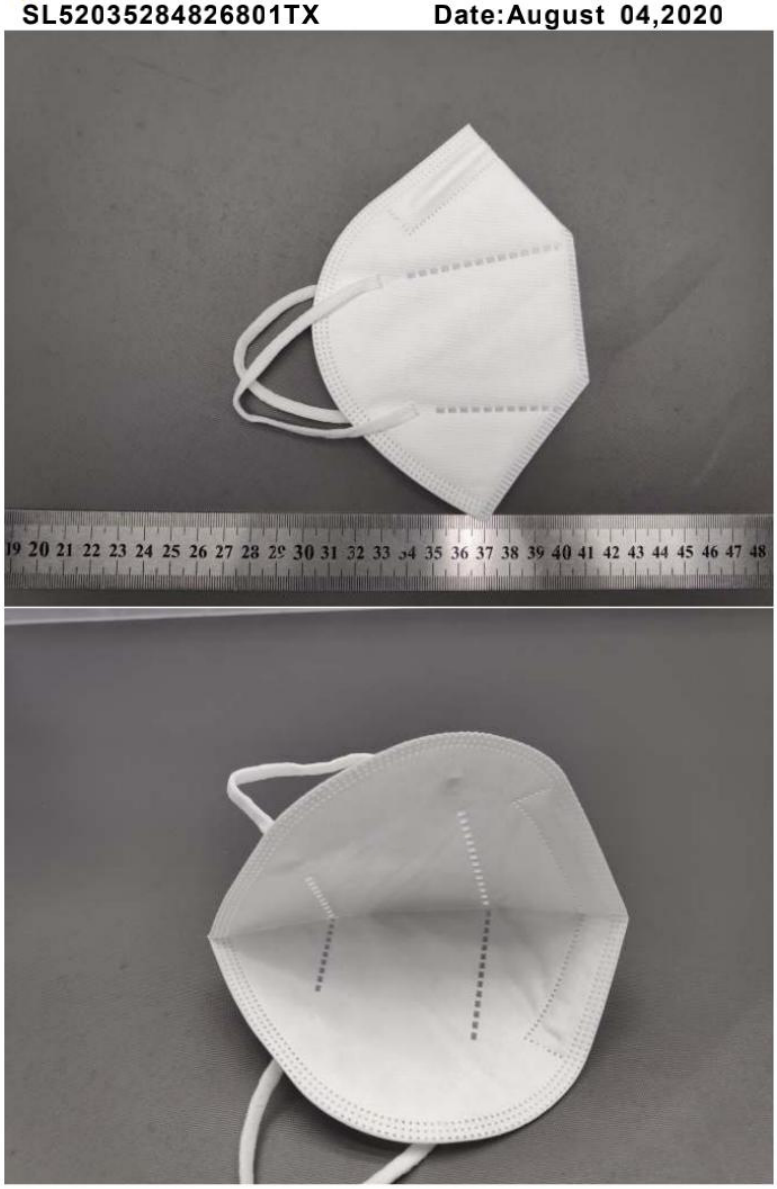

End of Report

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Back

Certified Management System

MDD Annex V

Certificate Holder: Zhejiang Hongyu Medical Commodity Co.,Ltd

Test Mark Number: 9000008261

The certificate holder's Management System corresponds to standard MDD Annex V.

The organization "Zhejiang Hongyu Medical Commodity Co.,Ltd" as named in the certificate was audited and certified by “TÜV Rheinland Shenzhen Ltd.“.

Certificate scope:

- MDD Annex V:

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

Show certificate data...

Further information by the certificate holder:	The certificate holder has not provided further information.
Contact to the certificate holder:	**Zhejiang Hongyu Medical Commodity Co.,Ltd** No.668 ChanHua Road, Fotang Town Industrial Functional Area Yiwu City, 322002 Zhejiang China (Mainland)

Further Information

- Website of Zhejiang Hongyu Medical Commodity Co.,Ltd
- All certified management systems of Zhejiang Hongyu Medical Commodity Co.,Ltd
- Request more information on Zhejiang Hongyu Medical Commodity Co.,Ltd

EU DECLARATION OF CONFORMITY

Manufacturer

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

Declares that the new PPE described hereafter

Protective Face Mask
HY1117

is in conformity with the provisions of regulation （EU） 2016/425 of the European parliament and of the council of 9 March 2016 on Personal protective equipment, and Conformity with the requirements of above regulation is testified by complete adherence to the following technical specifications:

EN 149: 2001+A1:2009

Is identical to the PPE which is the subject of EU type-examination for Regulation (EU) 2016/425 issued by SGS Fimko Oy, Takomotie 8, FI-00380 Helsinki, Finland, Notified Body number: 0598

Is identical to the PPE which is subject to the procedure set out in module C2 of Regulation(EU)2016/425 Personal Protective Equipment under the supervision of the notified body SGS Fimko Oy, Takomotie 8,FI-00380 Helsinki, Finland, Notified Body number:0598

The product(s) of the declaration described above is in conformity with the requirement of following test reports:

Report No. : SL52035284826801TX

Place : Yiwu
DATE :August 07 2020

Name
On behalf of Company

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.

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

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description	:	(A-G)Nonwoven
Buyer	:	ZHEJIANG HONGYU MEDICAL COMMODITY CO.,LTD
SGS Internal Ref.No.	:	NBHL2103002326OT
Sample Color	:	(A)Red; (B)blue; (C)gray; (D)pink; (E)black; (F)green; (G)golden
Style No.	:	nonwoven
Country of Origin	:	China
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Mar 03, 2021
Testing Period	:	Mar 03, 2021 - Mar 08, 2021
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

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Test Result

Azo Dyes (Direct Reduction & Colorant Extraction)

Textile: According to EN ISO 14362-1:2017 – Analysis was conducted with GC-MS/HPLC-DAD.

Test Item(s)	Cas No	Result (mg/kg)			
		A+B+C		D+E	
		Direct Reduction	Colorant Extraction	Direct Reduction	Colorant Extraction
4-Aminobiphenyl	92-67-1	ND	ND	ND	ND
Benzidine	92-87-5	ND	ND	ND	ND
4-Chlor-o-toluidine	95-69-2	ND	ND	ND	ND
2-Naphthylamine	91-59-8	ND	ND	ND	ND
o-Aminoazotoluene	97-56-3	ND	ND	ND	ND
5-Nitro-o-Toluidine/2-Amino-4-Nitrotoluene	99-55-8	ND	ND	ND	ND
4-Chloroaniline	106-47-8	ND	ND	ND	ND
4-Methoxy-m-Phenylenediamine/2,4-Diaminoanisole	615-05-4	ND	ND	ND	ND
4,4'-Diaminodiphenylmethane, MDA	101-77-9	ND	ND	ND	ND
3,3'-Dichlorobenzidine	91-94-1	ND	ND	ND	ND
3,3'-Dimethoxybenzidine	119-90-4	ND	ND	ND	ND
3,3'-Dimethybenzidine	119-93-7	ND	ND	ND	ND
4,4'-methylenedi-o-Toluidine/3,3'-Dimethyl-4,4'-Diaminodiphenylmethane	838-88-0	ND	ND	ND	ND
p-Cresidine	120-71-8	ND	ND	ND	ND
4,4'-Methylene-bis-(2-chloroaniline)	101-14-4	ND	ND	ND	ND
4,4'-Oxydianiline	101-80-4	ND	ND	ND	ND
4,4'-Thiodianiline	139-65-1	ND	ND	ND	ND
o-Toluidine	95-53-4	ND	ND	ND	ND
4-Methyl-m-Phenylenediamine/2,4-Toluylendiamine, TDA	95-80-7	ND	ND	ND	ND
2,4,5-Trimethylaniline	137-17-7	ND	ND	ND	ND
4-Aminoazobenzene	60-09-3	ND	ND	ND	ND
O-Anisidine	90-04-0	ND	ND	ND	ND
Conclusion		#	#	#	#

Test Item(s)	Cas No	Result (mg/kg) F+G	
		Direct Reduction	Colorant Extraction
4-Aminobiphenyl	92-67-1	ND	ND
Benzidine	92-87-5	ND	ND
4-Chlor-o-toluidine	95-69-2	ND	ND
2-Naphthylamine	91-59-8	ND	ND
o-Aminoazotoluene	97-56-3	ND	ND
5-Nitro-o-Toluidine/2-Amino-4-Nitrotoluene	99-55-8	ND	ND
4-Chloroaniline	106-47-8	ND	ND
4-Methoxy-m-Phenylenediamine/2,4-Diaminoanisole	615-05-4	ND	ND
4,4'-Diaminodiphenylmethane, MDA	101-77-9	ND	ND
3,3'-Dichlorobenzidine	91-94-1	ND	ND
3,3'-Dimethoxybenzidine	119-90-4	ND	ND
3,3'-Dimethybenzidine	119-93-7	ND	ND
4,4'-methylenedi-o-Toluidine/3,3'-Dimethyl-4,4'-Diaminodiphenylmethane	838-88-0	ND	ND
p-Cresidine	120-71-8	ND	ND
4,4'-Methylene-bis-(2-chloroaniline)	101-14-4	ND	ND
4,4'-Oxydianiline	101-80-4	ND	ND
4,4'-Thiodianiline	139-65-1	ND	ND
o-Toluidine	95-53-4	ND	ND
4-Methyl-m-Phenylenediamine/2,4-Toluylendiamine, TDA	95-80-7	ND	ND
2,4,5-Trimethylaniline	137-17-7	ND	ND
4-Aminoazobenzene	60-09-3	ND	ND
O-Anisidine	90-04-0	ND	ND
Conclusion		**#**	**#**

Requirement: 30mg/kg

Note:
ND = Not Detected

Reporting Limit = 5 mg/kg (for individual compound)

Remark:
+Direct reduction refers to the extraction and reduction according to EN ISO 14362-1:2017 clause 10.2 and relevant clauses.

+Colorant extraction refers to the colourant extraction and subsequent reduction according to ISO 14362-1:2017 Clause 10.1 and relevant clauses

4-Aminodiphenyl (CAS No. 92-67-1), 2-Naphthylamine (CAS No. 91-59-8) and 2,4-Diaminoanisole (CAS No. 615-05-4) can be indirectly generated from some colorants which do not contain these amines azo bound. The use of banned azo colorants cannot be reliably ascertained without additional information.

In case PU is used, e.g. PU Foams or coatings, it cannot be ruled out that MDA (CAS No. 101-77-9) and TDA

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(CAS No. 95-80-7) can be released from PU material, not from banned azo colorant. Similarly, for pigment prints, MDA will be released from a chemical fixing agent.

EN ISO 14362-1:2017 will enable further cleavage of 4-AAB (CAS No. 60-09-3) to non-forbidden amines: aniline and p-phenylenediamine. If aniline and/or p-phenylenediamine is not found, 4-AAB is considered as “n.d.” (i.e. <5.0 mg/kg). Otherwise, EN ISO 14362-3:2017 will be employed to verify the presence of 4-AAB.

pH Value

(ISO 3071:2005; 0.1mol/L KCL extraction)

-	Unit	**A**	**B**	**C**
pH Value	-	6.3	6.4	6.2
-	Unit	**D**	**E**	**F**
pH Value	-	6.1	6.0	6.1
-	Unit	**G**		
pH Value	-	6.1		

Note:
1) pH value of extraction medium: 5.7
2) Temperature of the extraction solution: 20.3ºC

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Sample Photo

End of Report

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Back

Certificate No. DD 2253563-1

Certificate Number:	DD 2253563-1
Certificate Holder:	**Zhejiang Hongyu Medical Commodity Co.,Ltd** No.668 ChanHua Road, Fotang Town Industrial Functional Area Yiwu City, 322002 Zhejiang China (Mainland)
Scope:	Aspects of manufacture concerned with securing and maintaining sterile conditions of Medical Face Masks, PVA Swabs
Certificate Type:	MDD Annex V

Further Information

- Request more information on Zhejiang Hongyu Medical Commodity Co.,Ltd
- All certified management systems of Zhejiang Hongyu Medical Commodity Co.,Ltd

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