EC REP CERTIFICATE

CMC MEDICAL DEVICES & DRUGS SL
NO. CMC/CE/2020/14092020.12

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of

ZHEJIANG HUACAN MEDICAL CO.,LTD
NO.233 SUFU ROAD,SUXI TOWN,YIWU,ZHEJIANG

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.
The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 93/42/EEC on medical devices as amended.

The products in Annex I was registered in Spanish MOH with number **RPS/2146/2020**

CE

Issued on: 14/09/2020

Valid until: 13/09/2021

Authorized Signatory
CMC Medical Devices & Drugs SL

EC REP CERTIFICATE

ANNEX I Medical Device Product

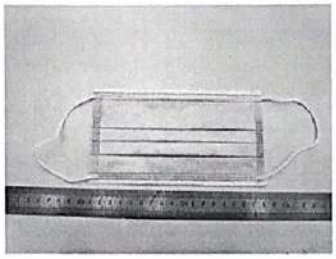
Disposable Medical Mask

CE

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer:	ZHEJIANG HUACAN MEDICAL CO.,LTD NO.233 SUFU ROAD,SUXI TOWN,YIWU,ZHEJIANG
EC Authorized Representative:	CMC Medical Devices & Drugs S.L C/Horacio Lengo N° 18 CP 29006, Málaga-Spain

We declare under our sole responsibility that

the medical device:	Disposable Medical Mask Type IIR Model: Planar ear loop
UMDNS code:	12447
Standard:	EN 14683:2019+AC:2019 Type IIR
Product photograph	
Basic UDI-DI:	/
Trade name:	/
of class:	**Class I** nach Anhang VIII der Verordnung EU 2017/745 (MDR) / according to annex VIII of Regulation EU 2017/745(MDR)

Meets the provisions of the Regulation EU 2017/745(MDR). The declaration is valid in connection with the "final inspection report" of the device.

Conformity assessment procedure:	Annex II, Annex III of EU 2017/745
Declaration of Conformity is valid until: /	2021-09-09

Yiwu, 2020-09-09

Place, date /

Fang Feixiang, Management representative

Name and function

ZHEJIANG HUACAN MEDICAL CO.,LTD
NO.233 SUFU ROAD,SUXI TOWN,YIWU,ZHEJIANG

THIS REPORT CANCELS AND SUPERSEDES THE TEST REPORT NO. SL520352616375O1TX
DATE: Jul 16, 2020 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)Face mask (Disposable medical mask)
Sample Color	:	(A)blue
Lot No.	:	20200602
Sample Receiving Date	:	Jun 28, 2020
Testing Period	:	Jun 28, 2020 - Jul 16, 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).
Test Performed	:	Selected test(s) as requested by applicant

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

Sara Guo (Account Executive)

Dongjing Liu / Hailian Xuan (Authorized Signatory)

3rd Building, No.889, Yishan Road, Xuhui District Shanghai, China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgsgroup.com.cn
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64958763 e sgs.china@sgs.com

Test Result

EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods

Clause 5.2 Performance Requirement

Clause 5.2.2 Bacterial Filtration Efficiency (BFE)
(EN 14683:2019+AC:2019 Annex B)

Sample: A

Test Side	:	Inside
Test Area	:	Approximately 60 cm^2
Flow Rate	:	28.3 L/min
Pre-Conditioning	:	Minimum of 4 hours at 21±5°C and 85±5% R.H.
Dimensions of test specimen	:	175 mm x 170 mm
Positive Control Average	:	2496 CFU
Negative Monitor Count	:	< 1 CFU
Mean Particle Size	:	3.0 ±0.3μm
Test bacteria	:	Staphylococcus aureus ATCC 6538

Test Item	Specimen No.	Result
Bacterial Filtration Efficiency (BFE)	1	99.9%
	2	99.9%
	3	99.9%
	4	99.9%
	5	99.9%

Remark:
1) Performance Requirement: Type I≥95%, Type II≥98%, Type IIR ≥98%
2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.

Clause 5.2.3 Breathability
(EN 14683 :2019+AC:2019 Annex C)

Sample: A
Test Side : Randomly test in different location (1 around and 4 away from the centric point) on each of the 5 masks
Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
Test Area : 4.9 cm^2
Flow Rate : 8 l/min

Specimen No.	Test Area No.	Different Pressure for each tested area (Pa/cm^2)	The average value for each test specimen (Pa/cm^2)
49.81	1-1	57.1	53
	1-2	53.2	
	1-3	49.8	
	1-4	48.0	
	1-5	54.4	
2	2-1	52.2	49
	2-2	48.9	
	2-3	45.8	
	2-4	51.4	
	2-5	45.3	
3	3-1	48.0	50
	3-2	47.9	
	3-3	49.4	
	3-4	46.3	
	3-5	59.0	
4	4-1	56.0	49
	4-2	45.7	
	4-3	48.4	
	4-4	44.2	
	4-5	53.0	
5	5-1	43.7	50
	5-2	48.4	
	5-3	47.4	
	5-4	58.0	
	5-5	50.2	

Remark:
1) Performance Requirement: Type I<40 Pa/cm^2, Type II<40 Pa/cm^2, Type IIR<60 Pa/cm^2
2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.

Clause 5.2.4 Splash Resistance

(ISO 22609 :2004)

Sample: A

Test Blood Pressure : 16.0kPa

Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.

Distance of the mask to the tip of cannula : 300±10mm

Test Specimen#	Penetration on inside surface	Conclusion	Test Specimen#	Penetration on inside surface	Conclusion
1	None Seen	Pass	17	None Seen	Pass
2	None Seen	Pass	18	None Seen	Pass
3	None Seen	Pass	19	None Seen	Pass
4	None Seen	Pass	20	None Seen	Pass
5	None Seen	Pass	21	None Seen	Pass
6	None Seen	Pass	22	None Seen	Pass
7	None Seen	Pass	23	None Seen	Pass
8	None Seen	Pass	24	None Seen	Pass
9	None Seen	Pass	25	None Seen	Pass
10	None Seen	Pass	26	None Seen	Pass
11	None Seen	Pass	27	None Seen	Pass
12	None Seen	Pass	28	None Seen	Pass
13	None Seen	Pass	29	None Seen	Pass
14	None Seen	Pass	30	None Seen	Pass
15	None Seen	Pass	31	None Seen	Pass
16	None Seen	Pass	32	None Seen	Pass
Number of Pass:		32			
Overall result:		Acceptable			

Remark:

1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR: ≥16.0kPa
2) Test was conducted within 60s after removal from conditioning chamber.
3) An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show pass results.

Clause 5.2.5 Microbial Cleanliness

(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

Sample: A

Test Specimen#	Mask Weight(g)	Total Bioburden, (CFU/mask)	Total Bioburden, (CFU/g)
1#	3.52	30	8.52
2#	3.58	15	4.19
3#	3.56	18	5.06
4#	3.54	9	2.54
5#	3.51	39	11.11

Remark: Performance Requirement: Type I≤30 CFU/g, Type II≤30 CFU/g, Type IIR≤30 CFU/g

3rd Building,No.889,Yishan Road,Xuhui District Shanghai,China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgsgroup.com.cn
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64958763 e sgs.china@sgs.com

Sample Photo

The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report

3rd Building, No.889, Yishan Road, Xuhui District Shanghai, China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgsgroup.com.cn
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64958763 e sgs.china@sgs.com

AGREEMENT EC REP
CMC MEDICAL DEVICES

This Agreement made on Sep 09, 2020 between ZHEJIANG HUACAN MEDICAL CO.,LTD Located in NO.233 SUFU ROAD,SUXI TOWN,YIWU,ZHEJIANG (hereinafter referred to as "COMPANY") and **M/s CMC Medical Devices & Drugs S.L.** located in C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain (hereinafter referred to as "Authorized Representative")

Have agreed as follows with regard to the handling of all products (hereinafter called "Products") manufactured by Company and sold to EU in order to comply to the requirements set out in the COUNCIL DIRECTIVE 93/42/EEC Concerning Medical Devices (MDD), Regulation (EU) 2017/745 or 98/79/EC, Regulation (EU) 2017/746 concerning in vitro diagnostic medical devices (as per applicability) and latest version of "Guidelines on a Medical Devices Vigilance System".

Appointment
Company hereby appoints Authorized Representative, who accepts such appointment, as a representative for the "Business Area" and "Product Categories" set out in Appendix A. The responsibility of both parties is as stated hereafter. Service of European Authorized Representative cover the MDD 93/42/EEC or 98/79/EEC. The service will cover the new Regulation (EU) 2017/745 and (EU)2017/746 on medical devices and in vitro diagnostic when this regulation take effect.

Claim Handling
Authorized Representative shall notify company about any received claims and any change of laws and regulations related to company's products set out in Appendix A. Company is the immediate responsible person for the claim handling and regulation compliance.

Accident Handling
On receiving information of an incident (accident), as defined in the MDD 93/42/EEC, Regulation (EU) 2017/745 or 98/79/EC, Regulation (EU) 2017/746 (as per applicability) and MEDDEV 2.12-1 "Guidelines on a Medical Devices Vigilance System", the following procedures shall be applied:

Authorized Representative shall notify occurrence of an incident in its business area to Company immediately upon receiving of incident.
Upon receiving information of any incident Company shall perform the necessary analysis of the situation immediately and send the incident report to Authorized Representative according to the requirements of latest version of "Guidelines on a Medical Devices Vigilance System". In that way Authorized Representative can submit the report to the relevant Competent Authority as defined in the timescale of latest version of "Guidelines on a Medical Devices Vigilance System".

If applicable, based on the report Company shall instruct Authorized Representative of the necessary countermeasures to be taken. Authorized Representative shall inform the relevant Competent Authority and customer as required in the countermeasure plan issued by Company.

Responsibilities on Technical Documentation:

i. Company shall establish necessary procedures to prepare and maintain Technical Documentation including the Declaration of Conformity for the "Product Categories" set out in Appendix A to be able to comply with the MDD and MDR requirements.
ii. Company shall transfer the agreed Technical Documentation and Declaration of Conformity to Authorized Representative upon request.
iii. Company shall have the responsibility to provide to Authorized Representative any additional documentation as required by the Competent Authority or Notified Body.
iv. The authorized representative shall provide a copy of this agreement to the competent authority, upon request.

Instruction Manual (If applicable)
Company shall be responsible for the content of instruction (user's) manuals, and shall ensure that English language instruction manuals are available to Authorized Representative. Company shall ensure that the required local language instruction manuals are provided to the customers.

Registration

The Authorized Representative shall register or notify the products set out in Appendix A to the Competent Authority of the member state in which he has his registered place of business.

Company shall have all data allowing for identification of concerned devices together with the label and the instruction for use available to authorized representative upon request by competent authority.

Tasks to be performed by Authorized Representative:

i. Verify that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the company;
ii. Keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, available for the competent authorities for a period of at least 10 years after the last device covered by the eu declaration of conformity has been

placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market;

iii. Comply with the registration obligations laid down in article 31 of MDR/2017/745 OR art 28 of MDR /2017/746 and verify that the company has complied with the registration obligations laid down in articles 27 and 29 MDR/2017/745 OR art 24 and 26 of MDR/2017/746;

iv. In response to a request from a competent authority, provide that the competent authority with all the information and documentation necessary to demonstrate the conformity of a device, in an official union language determined by the member state concerned.

v. Forward to the company any request by a competent authority of the member state in which the authorized representative has its registered place of business for samples, or access to a device and verify that the competent authority receives the samples or is given access to the device;

vi. Cooperate with the competent authorities on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;

vii. Terminate this agreement if the company acts contrary to its obligations under this regulation;

viii. Authorized representatives will have permanently and continuously at their disposal at least one person responsible for regulatory compliance (PRRC) who possesses the requisite expertise regarding the regulatory requirements for medical devices in the Union.

Obligations of Manufacturer Company:

i. COMPANY must comply with all the requirements specified in Article 10 MDR - Regulation 2017/745 or art 10 MDR 746/2017 regarding general obligations of manufacturers.

ii. COMPANY shall procure and maintain at all times during the term of this Agreement a Product liability insurance covering the products placed on the European market. This liability insurance should include "EAR" as well. This insurance, however, will not protect "EAR" against liability which results from its unauthorized Activities, wrongful or negligent acts of omission, or breach of this Agreement.
This agreement will not be valid if the manufacturer does not meet this requirement.

Other Obligations of Authorized Representative & Company:

i. The authorized representative shall provide all documentation and information that a market surveillance authority may require for the purpose of market surveillance.

ii. The authorized representatives shall rescind his contract with the company if the latter does not provide him with the access to the necessary information.

iii. Company shall keep authorized representative informed in all matters that may be connected to the devices placed on the market in the EU. At the minimum, the exchange of information concerning paragraphs a) to c) hereunder shall be informed.

a) Safeguard Clause

i. "Where a Member State ascertains that any of the medical devices specified in Appendix A, when correctly used for their intended purpose may compromise the health and/or safety of patients, users or, where applicable, other persons, or the safety of property, it shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service." If the relevant Competent Authority contacts the authorized representative, he should immediately communicate such measures to the company and advise the company as to the implications of this decision.

ii. When the Commission finds that national measures taken under the Safeguard Clause "are unjustified, it shall immediately so inform the Member State which took the measures and the company or authorized representative". If the relevant Competent Authority contacts the authorized representative, he should immediately communicate such information to the company and advise the company as to the implications of this decision.

b) Vigilance

i. In case of an incident and If the relevant Competent Authority contacts the authorized representative, he should immediately communicate such information to the company and advise the company as to the implications of this decision.

ii. The company should ensure that the involved authorized representative is kept informed of incident reports and Field Safety Corrective Actions.

c) Serious adverse events during clinical investigation, i.e. in the premarket phase

i. According to Article 80 of MDR 745/2017 and art 76 of 746/2017, "all serious adverse events must be fully recorded and immediately notified to all Competent Authorities of the Member States in which the clinical investigation is being performed by the sponsor".

ii. Authorized representative should inform the company of decisions of a Member State in respect of refusal or restriction of the placing the devices specified in Appendix A in the market.

(Appendix A)

Product list:

Disposable Medical Mask
Medical Surgical Mask
Medical Protective Mask
Disposable Face Mask

The following countries represent Authorized Representative's Business Area:

EUROPEAN COMMUNITY TERRITORY

Annual Fee: EC REP fee will be paid by Shanghai Ling Shi He Medical Technology Co., Ltd to CMC Medical Devices & Drugs S.L

Validity of Agreement: This agreement shall stand valid from Sep 09, 2020 to Sep 08, 2021. The Company shall apply for renewal of the agreement at least 30 days prior to expiry of this agreement.

ZHEJIANG HUACAN MEDICAL CO., LTD (COMPANY)

Authorized Signatory

China on Sep 09 2020.

CMC MEDICAL DEVICES & DRUGS S.L.
(EC REP AUTHORIZED REPRESENTATIVE)

Authorized Signatory

Spain on Sep 09, 2020.