CE

DECLARATION OF CONFORMITY

According to Medical Device Regulation (MDR) 2017/745 Annex II and Annex III.

Manufacturer:

Name:Zhejiang The Purples Protective Products Co.,Ltd
Address: Floor 1, No.45, Suhua Street, Suxi Town, Yiwu City, Zhejiang Province, China.
Telephone:18305890175
E-mail：2187672261@qq.com

Whose Authorized Representative:

Name:：Lotus NL B.V.
Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.
E-mail：peter@lotusnl.com

We, the manufacturer, herewith declare that the products

Product Name	Medical Device	Device Class	Model	UMDNS Code	Standard
Single-use face mask(non-sterile)	Masks	I, Rule12 (Annex IX of MDD)	TP-001	12447	EN 14683 Type IIR

meet the provisions of the Medical Device Directives 93/42/EEC. which apply to them.

Conformity Assessment Route: Annex V II according to Directives 93/42/EEC.

Applicable Standards:

ISO 13485:2016
ENISO 10993-5：2009
EN 1041:2008
EN 15223-1:2016
ISO 14971:2019
ENISO 10993-10：2013
EN 29073-1:1992
ISO 10993-1：2018
EN 14683:2019+AC
EN ISO 9073-15-2008

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Medical Device Directives 93/42/EEC.We agree to develop, implement and maintain a documented post-production monitoring process.

Name of authorized signatory: Zeng Yuqing

Position held in the company: General Manager

Place: Zhejiang, China

Signature:

Date:

Seal/Stamp:

Zhejiang The Purples Protective Products Co.,Ltd

Test Report **SL52025244048101TX** **Date:April 21,2020**

ZHEJIANG THE PURPLE'S PROTECTIVE PRODUCTS CO.,LTD
1/F, NORTH ZONE, BUILDING B, NO.66, QUNYING ROAD, HOUZHAI, YIWU, ZHEJIANG PROVINCE

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

Sample Description	:	(A)Face mask
Style No.	:	TP-001
Composition	:	(A)NONWOVEN MELT-BLOWN FABRIC
Sample Color	:	(A)blue
Manufacturer	:	ZHEJIANG THE PURPLE'S PROTECTIVE PRODUCTS CO.,LTD
Proposed Care Instruction	:	-
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Apr 02,2020
Testing Period	:	Apr 02,2020 - Apr 21,2020
Test Result(s)	:	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

Medical Face Masks-Requirements and Test Methods
(EN 14683:2019)

Clause 5.2.2 Bacterial filtration efficiency (BFE)"@

	1#	2#	3#	4#	5#
(BFE), %	99.9	99.2	99.8	99.6	99.7

Remark: Performance Requirement: Type I>95%, Type II>98%, Type IIR >98%
**": The test was carried out by external laboratory assessed as competent
@: These test methods are not in CNAS accredited scope

Clause 5.2.3 Breathability
(EN 14683 :2019 Annex C, Flow rate 8 l/min)

	1#	2#	3#	4#	5#
Differential pressure △P (Pa/cm²)	59.9	58.7	58.1	58.6	57.3
Recommended Level:		Type IIR			

Remark: Performance Requirement: Type I<40 Pa/cm², Type II<40 Pa/cm², Type IIR<60 Pa/cm²

Clause 5.2.4 Splash Resistance
(ISO 22609 :2004, Pressure 16.0 kPa)

Penetration on inside surface

1#	2#	3#	4#	5#	6#	7#	8#
Pass	Pass	Pass	Fail	Pass	Pass	Pass	Pass
9#	10#	11#	12#	13#	14#	15#	16#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
17#	18#	19#	20#	21#	22#	23#	24#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
25#	26#	27#	28#	29#	30#	31#	32#
Pass	Pass	Fail	Pass	Pass	Pass	Pass	Pass

Number of Pass: 30
Overall result: Acceptable

Remark:
1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR:≥16.0kPa
2) Distance of the medical face mask target area surface to the tip of cannula is 300±10mm.
3) Condition and Test temperature (21±5)° C, relative humidity (85±10)%
4) 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

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Clause 5.2.5 Microbial Cleanliness
(EN 14683: 2019 Annex D)

	1#	2#	3#	4#	5#
CFU/g	9	8	8	6	6

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

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

Test Report **SL52025244045101TX** **Date:July 03,2020**

ZHEJIANG THE PURPLE'S PROTECTIVE PRODUCTS CO.,LTD
1/F, NORTH ZONE, BUILDING B,NO.66, QUNYING ROAD, HOUZHAI, YIWU, ZHEJIANG PROVINCE

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

Sample Description	:	(A)Face mask
Style No.	:	TP-001
Composition	:	(A)NONWOVEN MELT-BLOWN FABRIC
Sample Color	:	(A)BLUE
Manufacturer	:	Zhejiang The Purple's Protective Products Co.,Ltd
Lot No./Batch No.	:	Not provided
Proposed Care Instruction	:	-
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Apr 02, 2020
Testing Period	:	Apr 02, 2020- Jul 03, 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).

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

Sara Guo (Account Executive)

Dongjing Liu (Authorized Signatory)

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Test Result

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

Clause 5.2 Performance Requirement

Clause 5.2.6 Biocompatibility
(ISO 10993-1)

Tests for in vitro cytotoxicity (test on extracts)
(ISO 10993-5:2009)

TEST METHOD(S):
ISO 10993-5:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
Test Article: The sample preparation was in accordance with ISO 10993-12:2002. Extration condition is 24h at 37℃ in culture medium. The volume of extract is determined by the standard surface area.
Cell lines: L-929 cells (mouse fibroblast)
Medium: 1640 medium（Gibco） with 10% FBS
Chromogenic reagent: MTT
Negative control: Polyethylene
Positive control: Phenol diluted solution (5g/L)
General Procedure: The prepared cell suspension was seeded in 96-well culture plate, set blank control, negative control, the positive control and the test sample group, inoculated with 100μL of cell suspension per well. Set CO^2 incubator (5% CO^2, the same below) 37 ℃ cultured for 24 h , discard the original culture medium. Adding fresh cell culture medium in blank control group, added extracts of the negative control in negative control group, added positive control solution or positive control extracts in the positive control group, added the extracts of the experimental material in the test sample. The test volume is 100μL per well, set CO^2 incubator cultured for 24h. Observed cell morphology under the microscope. Added 20μL 5g/L MTT solution, cultured 4h, discarded liquid, added 150μL DMSO and shaken 10min. Measure the absorbance at 570 nm and 630 nm and RGR was calculated, to determine the cytotoxic response.

TEST RESULT(S):
The cell viability is 97%, cell growth state in blank control,negative control and positive control is normal

Attached table: Test result

	Viability of the test sample/%
Parallel sample 1	94
Parallel sample 2	98
Parallel sample 3	100

CONCLUSION:
The sample is non cytotoxic effect.
According to the ISO 10993.5-2009, the result of cell viability ≥70% is considered non cytotoxic effect.

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Animal Skin Irritant Test*
(ISO 10993.10-2010)

Test animal

Three healthy conventional New Zealand White Rabbits, female, 2.0-3.0 kg each, supplied by Shanghai KeShuo Experiment Animal Co., LTD, Certificate No. SCXK(Hu)2017-0013. The animal feed were supplied by JiaShan chenchen food Co., LTD, license No. Zhe Feed Approval(2014)06017

Test environment

Rabbit room of conventional condition. Certificate No. SYXK(Hu)2019-0033, room temperature 18-23℃, relative humidity 45-65%

Test Results

Tab.1

Rabbit Number	response	Observation time					
		24 h		48 h		72 h	
		Sample S	Contrast C	Sample S	Contrast C	Sample S	Contrast C
4253#	Erythema	0	0	0	0	0	0
	Edema	0	0	0	0	0	0
4254#	Erythema	0	0	0	0	0	0
	Edema	0	0	0	0	0	0
4255#	Erythema	0	0	0	0	0	0
	Edema	0	0	0	0	0	0

The Primary Irritation Score of the sample was 0.

Tab.2 Primary irritation index categories in a rabbit

Mean score	Response category
0~0.4	Negligible
0.5~1.9	Slight
2~4.9	Moderate
5~8	Severe

Conclusions

According to Primary irritation index categories in a rabbit, the sample was found to be a negligible irritant to rabbits' skin

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Skin Sensitisation test*
(ISO 10993-10:2010)

Test environment

Animal room of conventional condition. Certificate No. SYXK(Hu) 2019-0033, room temperature 20-22℃, relative humidity 45-65%.

Experimental animals

Guinea pigs，female，300-500g,, supplied by Shanghai KeShuo Experiment Animal Co.，LTD, Certificate No. SCXK (Hu)2017-0013). The animal feed were supplied by Jiangsu Xietong Medical bio-engineering Co. LTD. License No: Su Feed Approval(2014) 01008

Test results

Delayed hypersensitivity tests results of face mask

Group	Time(h)	Skin response				Sensitization rate %
		0	1	2	3	
Normal saline	24	5	0	0	0	0
	48	5	0	0	0	0
The test article	24	10	0	0	0	0
	48	10	0	0	0	0

Magnusson and Kligman scale Patch test reaction Grading scale

Patch test reaction	Scoring
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and swelling	3

Conclusions

Under the conditions of the study, the test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig

Remark:

* This test standard is not within the accredited scope in SGS Shanghai testing centre, it is carried out by external laboratory accredited by CNAS (China National Accreditation Service for Conformity Assessment) L1009.

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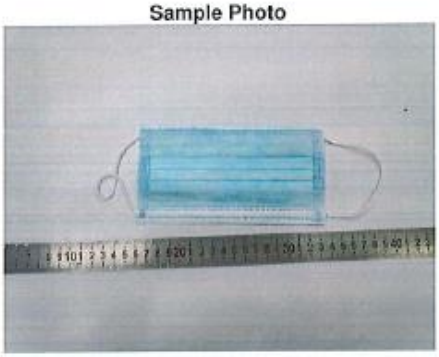
Sample Photo



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

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