

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

This is to certify that:

Langshi Garments & Weaving  
Co.,Ltd. Jinjiang  
Sanou Industrial Zone, Yinglin  
Jinjiang  
Fujian  
362200  
China

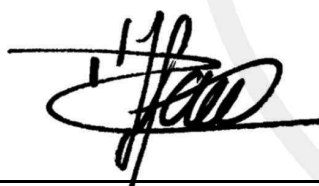
Holds Certificate Number:

CE 728635

In respect of:

**For the manufacture of particulate respirators to technical specification to satisfy Annex II of the PPE 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):

Drs. Dave Hagenaaers, Managing Director

Previous Notified Body: BSI 0086

First Issued: 2020-07-23

Latest Issue: 2020-07-23

Effective Date: 2020-07-23

Expiry Date: 2021-07-23

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

No. CE 728635

## Product manufactured by:

Langshi Garments & Weaving Co.,Ltd.  
Jinjiang  
Sanou Industrial Zone, Yinglin  
Jinjiang  
Fujian  
362200  
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:

<b>Product type:</b>	Particulate filtering half masks for use by Healthcare professionals.
<b>Model and classifications:</b>	MSK2 FFP2
<b>Technical Specification:</b>	Technical specification to satisfy Annex II of the PPE Regulation (EU) 2016/425. BSI's PPE for Healthcare Professionals 2020/403 – RPE Technical Specification.

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A member of BSI Group of Companies.

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

No. CE 728635

## Certificate Administration Details:

### Certificate Amendment Record and BSI internal Review relating to this Certificate

Issue date	Comments	BSI Review No.
July 2020	First issue.	2797:20:3204352

## Certificate validity

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspects of the overall quality system utilized in the manufacture of the products, failure to do so could invalidate the Certificate in respect of product manufactured after the introduction of such changes.

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## Section 9

### EU Declaration of Conformity


#### EU DECLARATION OF CONFORMITY

1. PPE (product, type, batch or serial number): MODEL MSK2,product code:2020PM02
2. Name and address of the manufacturer and, where applicable, his authorised representative: Langshi Garments & Weaving Co.,Ltd.Jinjiang/Sanou Industrial Zone,Yinglin,Jinjiang,Fujian,China
3. This declaration of conformity is issued under the sole responsibility of the manufacturer:Langshi Garments & Weaving Co.,Ltd.Jinjiang
4. Object of the declaration (identification of PPE allowing traceability; where necessary for the identification of the PPE, a colour image of sufficient clarity may be included): MODEL MSK2 Particulate Respirator
5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation: PPE Regulation 2016/425
6. References to the relevant harmonised standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared: EN149:2001+A1:2009
- 7.Where applicable, the notified body BSI Group NB 0086 performed the EU type-examination (Module B) and issued the EU type-examination certificate CE 600016 EU Type Examination Certificate.
8. Where applicable, the PPE is subject to the conformity assessment procedure -conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the notified body BSI Group NB number:2797.
9. Additional information:

Signed for and on behalf of: Langshi Garments & Weaving Co.,Ltd.Jinjiang

3. (place and date of issue): Sanou Industrial Zone,Yinglin,Jinjiang,Fujian,China

(name, function) Sam Ouyang,Manager

(signature): 

# Test Report 3248298.


Langshi Garments & Weaving Co. Ltd.

## Introduction.

This report has been prepared by Ben Hobbs and relates to the activity detailed below:

Job/Registration Details	Client Details
<b>Job number:</b> 3248298 Job type: Testing Samples Submitted Start Date: 06/06/2020 Test type: Type Sample ID: 10190967 <b>Registration:</b> CE 728634 Scheme: Negative pressure RPE Protocol: PP123 Scheme Manager: Nathan Shipley	Langshi Garments & Weaving Co., Ltd. Jinjiang Sanou Industrial Zone Yinglin Jinjiang Fujian 362200 China

The report has been approved for issue by T Wicksey – Senior Test Engineer

Approved For Issue	
	Issue Date: 30 June 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 3 June 2020 and the testing was started on 6 June 2020.

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

## Test Samples.

Sample ID	ER Number	Description
1 to 19	10190967	Model: KN95 mask

## Description of Test Samples.

Sample Description
Model: KN95. COVID-19 masks for use by healthcare workers

## 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.

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Hertfordshire  
HP2 4SQ



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	<p><b>Practical performance</b></p> <p>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.</p> <p>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.</p> <p>Test in accordance with clause 8.4 of the standard.</p> <p><b>Testing in accordance with BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers</b></p> <p>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:</p> <p>a) head harness comfort; b) security of fastenings; c) field of vision; d) any other comments reported by the wearer on request.</p>	Pass

**Table A:** Practical performance

Test candidate	Sample	Comments				Assessment
		Head harness comfort	Security of fastenings	Field of vision	Any other comments	
RF1	1 AR	OK	OK	OK	None	Pass
JS3	2 AR	OK	OK	OK	None	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 (%)						Assessment
			A	B	C	D	E	Average	
			Walking	Walking with head side to side	Walking with head up & down	Walking and talking	Walking		
JB1	3	AR	5.0281	7.3048	10.0191	7.0132	7.0601	7.2850	Pass
AH1	4	AR	6.5032	6.5831	7.3376	4.3008	7.4447	6.4339	Pass
JS3	5	AR	3.1955	3.3215	5.1665	2.7727	3.7286	3.6369	Pass
BH1	6	AR	7.3943	7.9196	7.0189	5.4025	9.4578	7.4386	Pass
CB1	7	AR	3.7106	3.8195	4.1821	4.2392	5.0839	4.2071	Pass

# Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
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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	Actual
8	AR	95	< 6	1.1782
9	AR			1.2865
10	AR			1.2686

**Table D:** Clause 8.11 - Paraffin oil penetration test

Sample number	Pre-test condition	Flow through filter (l/min)	Penetration (%)	
			Limit	Actual
11	AR	95	< 6	2.1190
12	AR			1.8915
13	AR			2.5045

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 <sub>2</sub> (%)	
		Limit	Measured
14	AR	< 1.0	0.49
15	AR		0.54
16	AR		0.44

# Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
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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)

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	0.40
18	AR			0.41
19	AR			0.35
17	AR	95	< 2.4	1.23
18	AR			1.32
19	AR			1.19

**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	2.10
18	AR			2.23
19	AR			2.03

## Appendix A. – Test Panel Data

Test Candidate	Facial Dimensions (mm)					Sex
	Length of face	Width of face	Face depth	Width of mouth	Head Circumference	
JB1	114	144	108	59	574	Male
JS3	126	134	124	49	600	Male
BH1	114	139	120	50	570	Male
CB1	117	147	130	57	566	Male
AH1	108	124	130	46	570	Male
RF1	104	122	121	55	549	Male

Note: All candidates were clean shaven

## Product photographs.



Front view



Side View



Inside View

\*\*\*End of Report\*\*\*