DHSC Terms and Conditions for the Supply of Goods

The Authority	**Department of Health and Social Care** 1st Floor South, 39 Victoria Street, London, SW1H 0EU
The Supplier	**Chemical Intelligence Limited** 57A London Road, Harston, Cambridge, CB22 7QJ Registered Company Number: 08187340
Date	25/04/2020
Type of Goods	Personal Protective Equipment – Type IIR Face Masks

This Contract is made on the date set out above subject to the terms set out in the Order Form and schedules ("**Schedules**") contained in the document (DHSC Contract for Goods - Terms and Conditions April 2020.pdf) The Authority and the Supplier undertake to comply with the provisions of the Order Form and the Schedules in the performance of this Contract.

The Supplier shall supply to the Authority, and the Authority shall receive and pay for, the Goods on the terms of this Contract. For the avoidance of doubt, the Contract consists of the terms set out in the Order Form and the Schedules, together with the annexes as stated.

The Definitions in Schedule 3 apply to the use of all capitalised terms in this Contract.

Schedules

Schedule 1	Key Provisions
Schedule 2	General Terms and Conditions
Schedule 3	Definitions and Interpretations
Schedule 4	Additional Special Conditions

Schedules 2, 3 and 4 are contained in the document DHSC Contract for Goods - Terms and Conditions April 2020.pdf

Order Form

1. Contract Reference	Case DA6A
2. Date **3.**	24.04.2020
4. Buyer	Department of Health & Social Care, 1st Floor South, 39 Victoria Street, London, SW1H 0EU
5. Supplier	Chemical Intelligence Limited Registered Office: 57A London Road, Harston, Cambridge, CB22 7QJ Registered Company Number: 08187340
6. The Contract	The Supplier shall supply the deliverable described below on the terms set out in this Order Form and the Schedules and any Annex and Appendices. Unless the Contract otherwise requires, capitalised expressed used in this Order Form have the same meanings as in Schedule 3. In the event of any conflict between this Order Form and the Schedules, this Order Form shall prevail. Please do not attach any supplier terms and conditions to this Order Form as they will not be accepted by the Buyer and may delay conclusion of the Contract.
7. Deliverables	(Goods) Type IIR Face Masks Delivered in accordance with the following instructions: Delivery Address: **NHS Supply Chain c/o Clipper Logistics** Daventry Distribution Centre Danes Way DIRFT Daventry NN6 7GX [redacted] Date(s) of Delivery: as set out in Annex A.

8. Specification	The specification of the Deliverables is as set out in Annex B.
9. Term	The Term shall commence on on placement of Purchase Order 001 at Annex A. And the Expiry Date shall be upon delivery of the Purchase Order(s), unless it is otherwise extended or terminated in accordance with the terms and conditions of the contract. The Buyer may extend the Contract for a period of up to 3 months by giving not less than 5 Business days notice in writing to the supplier prior to the Expiry Date. The terms and conditions of the Contract shall apply throughout any such extended period.
10. Charges	The Charges for the Deliverables shall be set out in Annex A.
11. Payment	All invoices must be emailed quoting a valid purchase order number to the following email address COVID-19FinanceOperations@dhsc.gov.uk. The Authority agrees to pay the Supplier the value of the Goods as set out in Line 01 of the Purchase Order Form 001 at Annex A (50% of the total order value) upon the commencement of this Contract and presentation of a valid invoice. Upon delivery and presentation of a valid invoice; the Authority agrees to pay the remaining unit costs as specified at Line 02 of Purchase Order 001 at Annex A. Within 10 Business Days of receipt of your countersigned copy of the Contract, we will send you a unique Purchase Order number (the **"PO Number"**). You must in receipt of a valid PO Number before submitting an invoice. To avoid delay in payment it is important that the invoice is compliant and that it includes a valid PO Number, PO item number (if applicable) and the details (name and telephone number) of your Buyer contact (i.e. Contract Manager). Non-compliant invoices will be sent back to you, which may lead to a delay in payment. If you have a query regarding an outstanding payment please contact our Accounts Payable section by email to COVID-19FinanceOperations@dhsc.gov.uk.
12. Buyer Authorised Representative(s)	For general liaison your contact will continue to be: [redacted] Department of Health and Social Care 39 Victoria Street, London, SW1H 0EU

13. Seller's Authorised Representative(s)	For general liaison your contact will continue to be [redacted]	
14. Address for notices	**Buyer:** Department of Health and Social Care 39 Victoria Street, London, SW1H 0EU	**Supplier:** Chemical Intelligence Limited 57A London Road, Harston, Cambridge, CB22 7QJ FAO : [redacted]
15. Key personnel	[redacted] Department of Health and Social Care 39 Victoria Street, London, SW1H 0EU	**Supplier:** [redacted] Chemical Intelligence Limited Registered Office: 57A London Road, Harston, Cambridge, CB22 7QJ Email: [redacted]
16. Procedures and Policies	The Buyer may require the Supplier to ensure that any person employed in the delivery of the Deliverables has undertaken a Disclose and Barring Service check. The supplier shall ensure that no person who discloses that he/she has a conviction that is relevant to the nature of the Contract, relevant to the work of the Buyer, or is of a type otherwise advised by the Buyer (each such conviction a "**Relevant conviction**"), or is found by the Supplier to have a Relevant Conviction (whether as a result of a police check, a Disclosure and Barring Service check or otherwise) is employed or engaged in the provision of any part of the Deliverables.	

Signed by the authorised representative of THE AUTHORITY

Name:	[redacted]	Signature:	[redacted]
Position:	Deputy Director	Date	25th April 2020

Signed by the authorised representative of THE SUPPLIER

Name:	[redacted]	Signature	[redacted]
Position:	CEO	Date	24th April 2020

Schedule 1

Key Provisions

Standard Key Provisions

1 Application of the Key Provisions

1.1 The standard Key Provisions at Clauses 1 to 2 of this Schedule 1 shall apply to this Contract.

1.2 The optional Key Provisions at Clauses 3 to 12 of this Schedule 1 shall only apply to this Contract where they have been checked and information completed as applicable.

1.3 Extra Key Provisions shall only apply to this Contract where such provisions are set out at the end of this Schedule 1.

2 Order of precedence

2.1 Subject always to Clause **Error! Reference source not found.** of Schedule 3 should there be a conflict between any other parts of this Contract the order of priority for construction purposes shall be:

2.1.1 Order Form

2.1.2 Schedule 1: Key Provisions;

2.1.3 Schedule 2**Error! Reference source not found.**: General Terms and Conditions;

2.1.4 Schedule 3: Definitions and Interpretations;

2.1.5 any other documentation forming part of the Contract in the date order in which such documentation was created with the more recent documentation taking precedence over older documentation to the extent only of any conflict.

2.2 For the avoidance of doubt, the Order Form shall include, without limitation, the Authority's requirements in the form of its specification and other statements and requirements, the Supplier's responses, proposals and/or method statements to meet those requirements, and any clarifications to the Supplier's responses, proposals and/or method statements as included in these Terms and Conditions. Should there be a conflict between these parts of the Order Form, the order of priority for construction purposes shall be (1) the Authority's requirements; (2) any clarification to the Supplier's responses, proposals and/or method statements, and (3) the Supplier's responses, proposals and/or method statements

3 Quality assurance standards ☒ (only applicable to the Contract if this box is

checked and the standards are listed)

3.1 The quality assurance standards as set out in Annex B shall apply, as appropriate, to the manufacture, supply, and/or installation of the Goods.

4 Purchase Orders ☒ (only applicable to the Contract if this box is checked)

4.1 The Authority shall issue a Purchase Order to the Supplier in respect of any Goods to be supplied to the Authority under this Contract. The Supplier shall comply with the terms of such Purchase Order as a term of this Contract. For the avoidance of doubt, any actions or work undertaken by the Supplier under this Contract prior to the receipt of a Purchase Order covering the relevant Goods shall be undertaken at the Supplier's risk and expense and the Supplier shall only be entitled to invoice for Goods covered by a valid Purchase Order.

5 Time of the essence ☐ (only applicable to the Contract if this box is checked)

5.1 Time is of the essence as to any delivery dates under this Contract and if the Supplier fails to meet any delivery date this shall be deemed to be a breach incapable of remedy for the purposes of Clause 12.4 of Schedule 2.

6 Specific time periods for inspection ☐ (only applicable to the Contract if this box is checked and Clause 12.1 of this Schedule 1 is completed)

6.1 The Authority shall visually inspect the Goods within **[*time period during which any inspection must be carried out*]** of the date of delivery of the relevant Goods.

7 Specific time periods for rights and remedies under Clause 4.6 of Schedule 2 ☐ (only applicable to the Contract if this box is checked and Clause 7.1 of this Schedule 1 is completed)

7.1 The Authority's rights and remedies under Clause 4.6 of Schedule 2 shall cease **[*12 months*]** from the date of delivery of the relevant Goods.

8 Termination for convenience ☐ (only applicable to the Contract if this box is checked and Clause 8.1 of this Schedule 1 is completed)

8.1 The Authority may terminate this Contract by issuing a Termination Notice to the Supplier at any time on **[*one (1)/three (3)/six (6) months'*]** written notice. **[**Such notice shall not be served within [one (1)] year of the Commencement Date**]**.

8.2 Should the Authority terminate this Contract in accordance with Clause 8.1 of this Schedule 1, then the Authority shall pay to the Supplier the termination sum calculated in accordance with Schedule [**insert schedule number**.]

9 Right to terminate ☐ (only applicable to the Contract if this box is checked)

9.1 Either Party may terminate this Contract by issuing a Termination Notice to the other Party if such other Party commits a material breach of this Contract in circumstances where it is served with a valid Breach Notice having already been served with at least [two (2)] previous valid Breach Notices within the last twelve (12) calendar month rolling period as a result of any previous material breaches of

this Contract which are capable of remedy (whether or not the Party in breach has remedied the breach in accordance with a Remedial Proposal). The twelve (12) month rolling period is the twelve (12) months immediately preceding the date of the [third] Breach Notice.

10 Consigned Goods ☐ (only applicable to the Contract if this box is checked)

10.1 Provided that such Consignment Request is consistent with the forecast requirement for the Goods (as set out in the Order Form and/or as calculated in accordance with any relevant processes set out in this document and/or as otherwise agreed by the Parties in writing), the Supplier shall deliver the Consigned Goods in accordance with Clause 2 of Schedule 2 in response to a Consignment Request for their eventual purchase and use by the Authority in accordance with the terms set out in this Contract.

10.2 For the avoidance of doubt, Clause 4 of Schedule 2 shall apply to the inspection, rejection, return and recall of the Consigned Goods.

10.3 The Authority shall, or shall procure that its third party provider shall, maintain any storage facilities throughout the term of this Contract where the Consigned Goods are to be stored in such manner that such storage facilities remain suitable to store the Consigned Goods.

10.4 Prior to the Consigned Goods being taken into use by the Authority, the Authority shall ensure that:

10.4.1 the Consigned Goods are stored at the storage facilities in such a manner as to protect them from damage or deterioration;

10.4.2 the Consigned Goods in its possession remain readily identifiable as the Supplier's property;

10.4.3 any identifying marks or packaging on or relating to the Consigned Goods are not removed, defaced or obscured; and

10.4.4 the Consigned Goods are kept in satisfactory condition in accordance with any reasonable and necessary instructions from the Supplier from time to time.

10.5 The Authority shall keep accurate stock records in relation to any Consigned Goods and shall provide the Supplier with a sales report ("**Sales Report**") each [**week/month/quarter/other agreed period**] detailing current stock levels and the Consigned Goods taken into use by the Authority. For the avoidance of doubt, a sale will take place at the point any Consigned Goods are taken into use by the Authority.

10.6 On receipt of the Sales Report, the Supplier may invoice the Authority the Contract Price for all of the Consigned Goods taken into use by the Authority (as set out in that Sales Report).

10.7 Each [***week/month/quarter/other agreed period***] the Authority shall take into use and purchase at the Contract Price at least the minimum quantity of Consigned Goods specified in the Order Form for such period (if any) ("**Minimum Quantity**"). If the Supplier fails to supply the Authority with any Consigned Goods required by the Authority (including, without limitation, where the Authority obtains substitute

goods from a third party as a result), the Minimum Quantity for the period in question shall be reduced by the quantity of the Consigned Goods that the Supplier fails to supply. Except to the extent that the Authority's failure to purchase the Minimum Quantity during any given period is caused by the Supplier's default or a Force Majeure Event, if the Authority purchases less than the Minimum Quantity for a given period, the Supplier may charge the Authority for any shortfall between:

10.7.1 the Contract Price of the Minimum Quantity in the relevant period; and

10.7.2 the Contract Price for Consigned Goods purchased by the Authority in that period.

10.8 The Authority (on a first in first out basis) may return to the Supplier any Consigned Goods that it is unable to use ("**Returned Goods**") by giving written notice to that effect ("**Returns Notice**"). Upon receipt of a Returns Notice, the Supplier shall collect the Returned Goods at the Supplier's risk and expense within ten (10) Business Days of the date of the Returns Notice. If the Supplier requests and the Authority accepts that the Returned Goods should be disposed of by the Authority rather than returned to the Supplier, the Authority may invoice the Supplier for the costs associated with the disposal of the Returned Goods and the Supplier shall pay any such costs.

10.9 Risk in respect of any Returned Goods shall pass to the Supplier on the earlier of: (a) collection by the Supplier; or (b) immediately following the expiry of ten (10) Business Days from the date of the Returns Notice related to such Returned Goods. If Returned Goods are not collected within ten (10) Business Days of the date of the relevant Returns Notice, the Authority may return the Returned Goods to the Supplier at the Supplier's risk and expense and/or charge the Supplier for the cost of storage from the expiry of ten (10) Business Days from the date of the relevant Returns Notice. The Authority may invoice the Supplier for such return expenses and/or storage costs and the Supplier shall pay any such expenses or costs.

10.10 The Consigned Goods shall at all times be subject to the direction and control of the Supplier, and the Supplier may (at the Supplier's risk and expense), upon (10) Business Days written notice to the Authority, collect (on a first in first out basis) any Consigned Goods that have not been taken into use by the Authority within [***period***] of their delivery to the Authority and/or which have a remaining shelf life of less than [***period***].

10.11 The Authority acknowledges that it holds Consigned Goods in its possession as bailee for the Consignor until such time as ownership passes in accordance with Clause 3.2 of Schedule 2.

10.12 On the termination or expiry of this Contract for whatever reason, all Consigned Goods not taken into use by Authority as at the point of such termination or expiry shall be deemed Returned Goods. Such Returned Goods shall be deemed the subject of a Returns Notice that shall be deemed to have been received by the Supplier with a notice date the same as the date of the expiry or earlier termination of this Contract. Clauses 12.8 and 12.9 of this Schedule 1 shall then apply accordingly and this Clause, together with Clauses 12.8 and 12.9 of this Schedule 1, shall survive the expiry or earlier termination of this Contract for these purposes.

11 Electronic product information ☐ (only applicable to the Contract if this box is checked)

11.1 Where requested by the Authority, the Supplier shall provide the Authority the Product Information in such manner and upon such media as agreed between the Supplier and the Authority from time to time for the sole use by the Authority.

11.2 The Supplier warrants that the Product Information is complete and accurate as at the date upon which it is delivered to the Authority and that the Product Information shall not contain any data or statement which gives rise to any liability on the part of the Authority following publication of the same.

11.3 If the Product Information ceases to be complete and accurate, the Supplier shall promptly notify the Authority in writing of any modification or addition to or any inaccuracy or omission in the Product Information.

11.4 The Supplier grants the Authority a perpetual, non-exclusive, royalty free licence to use and exploit the Product Information and any Intellectual Property Rights in the Product Information for the purpose of illustrating the range of goods and services (including, without limitation, the Goods) available pursuant to the Authority's contracts from time to time.

11.5 Before any publication of the Product Information (electronic or otherwise) is made by the Authority, the Authority will submit a copy of the relevant sections of the Authority's product catalogue to the Supplier for approval, such approval not to be unreasonably withheld or delayed. For the avoidance of doubt the Supplier shall have no right to compel the Authority to exhibit the Product Information in any product catalogue as a result of the approval.

11.6 If requested in writing by the Authority, and to the extent not already agreed as part of writing, the Supplier and the Authority shall discuss and seek to agree in good faith arrangements to use any Electronic Trading System

12 Supply of PPE Goods ☒ (only applicable to the Contract if this box is checked)

Regulatory Requirements

12.1 The Supplier acknowledges and understands that when procuring PPE the Authority is required to ensure the PPE Goods are compliant with and meet applicable legal and regulatory requirements.

12.2 The Supplier shall supply the PPE Goods to Authority in accordance with the terms of this Contract and in accordance with the relevant requirements of applicable laws and regulations applicable to the supply of PPE, including, as applicable, the EU PPE Regulation 2016/425, the Personal Protective Equipment (Enforcement) Regulations 2018 and the Medical Device Regulations 2002 (together the "**PPE Laws**").

12.3 Without prejudice to the generality of clause 12.2 the Supplier shall ensure for PEE Goods supplied:

12.3.1 the appropriate conformity assessment procedure(s) applicable to the PPE Goods have been followed;

12.3.2 all declarations of conformity and approvals required by PPE Laws are in place prior to the delivery of any PPE Goods to the Authority;

12.3.3 where required by PPE Laws, there is a CE mark affixed to the PPE Goods in accordance with the PPE Laws; and

12.3.4 where, necessary current EC-type examinations certificates are in place for the PPE Goods.

12.4 If there are any PPE Goods supplied to the Authority hereunder that require a CE mark under more than one set of regulations, due to the nature of those PPE Goods, including and not limited to:

- PPE Laws;
- Control of Lead at Work Regulations 2002;
- Ionising Radiations Regulations 2017;
- Control of Asbestos Regulations 2012;
- Control of Substances Hazardous to Health Regulations 2002; and
- any other relevant regulations,

the Supplier shall ensure that the CE marking for any such PPE Goods is affixed in accordance with the relevant requirements and shall indicate that the PPE Goods also fulfils the provisions of that other regulation or regulations.

Goods bought to the market before 21 April 2019

12.5 The Supplier shall provide details, including any EC-type examination certificates and approval decisions issued under Directive 89/686/EEC and Directive 93/42/EEC (if applicable), and corresponding national implementing legislation, of any PPE Goods supplied under this Contract that have been placed on the market before 21 April 2019 and products already in the distribution chain by that date confirming that these can continue to be supplied as PPE to the Authority until 21 April 2023, unless their certificate or approval will expire before that date.

Other Specific Requirements

12.6 The Supplier shall offer to the Authority spares and consumables required for any of the PPE Goods supplied to the Authority. The Supplier agrees any charging rate for the spares and consumables shall be inclusive of all packaging and standard delivery.

Annex A – Purchase Order Form

PURCHASE ORDER FORM No 001

Line Number	Specification	Delivery Date	Total Estimated Quantity	FIRM Price (£) Ex VAT	
				Per Item	Total
01	Type IIR Face Masks - 50% payment on contract	11 May 2020	[redacted]	£[redacted]	£[redacted]
02	Type IIR Face Masks - 50% Payment on delviery	11 May 2020	[redacted]	£[redacted]	£[redacted]
				Total Firm Price	£1,980,000.00

Test Report No.: 721653337
Report Date: 14 April 2020

SUBJECT	**Physical & Microbiological Test**
TEST LOCATION	**TÜV SÜD China** TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	**Sichuan Xinglin Medical Device Co., Ltd.**
CLIENT ADDRESS	Building 1-4, No.5 West Section of Yiyuan Road, Yuchan Street, Lu County,
TEST PERIOD	29-Mar-2020~08-Apr-2020

Prepared By

Bella Xu

(Bella Xu)
Report Drafter

Authorized By

Leo Liu

(Leo Liu)
Authorized Signatory

Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory , the client is not authorized to use the test results for unapproved propaganda.

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
TÜV SÜD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

TEST REPORT

Sample Description	:	Medical Face Mask for Single Use
Sample Quantity	:	[redacted]
Lot Number/Batch Code	:	/
Specification	:	/
Size	:	17.5CM-9.5CM
Type of Mask	:	Type IIR
Brand Name	:	/

Remark: The above information was provided by applicant.

Summary of Test Results

No.	Test Item	Test Standard	Judgement
1	Bacterial Filtration Efficiency (BFE) Test	EN 14683:2019+AC:2019(E) Annex B	Pass
2	Differential Pressure Test	EN 14683:2019+AC:2019(E) Annex C	Pass
3	Synthetic Blood Penetration Test	ISO 22609:2004	Pass
4	Microbial Cleanliness Test	EN 14683:2019+AC:2019(E) Annex D	Pass

Note: Pass = Meet customer requirements;
Fail = Fail customer requirements;
# = No comment;
N.D. = Not detected.

Photo of Samples

Chemical/Microbiology Laboratory:
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Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
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No.151 Heng Tong Road Shanghai
200 070 P.R.China

Restults

No.	Test Item	Test Result
1	Bacterial Filtration Efficiency (BFE) Test	Specimen 1#: 99.9% Specimen 2#: 99.7% Specimen 3#: 99.7% Specimen 4#: 99.7% Specimen 5#: 99.9%
2	Differential Pressure Test	49.0 Pa/cm^2
3	Synthetic Blood Penetration Test	Specimen 1#~13#: None seen
4	Microbial Cleanliness Test	Specimen 1#: <1 CFU/g Specimen 2#: 1 CFU/g Specimen 3#: 1 CFU/g Specimen 4#: 1 CFU/g Specimen 5#: 1 CFU/g

Bacterial Filtration Efficiency (BFE) Test

1. Purpose

For evaluating the bacterial filtration efficiency (BFE) of mask.

2. Sample description was given by client

Sample description : Medical Face Mask for Single Use
Specification : /
Lot Number : /
Sample Receiving Date : 2020-03-29

3. Test Method

EN 14683:2019+AC:2019(E) Annex B

4. Apparatus and materials

4.1 *Staphylococcus aureus* ATCC 6538.
4.2 Peptone water.
4.3 Tryptic Soy Broth(TSB).
4.4 Tryptic Soy Agar(TSA).
4.5 Bacterial filtration efficiency test apparatus.
4.6 Six-stage viable particle Anderson sampler.
4.7 Flow meters.

5. Test specimen

5.1 As requested by client, take a total of 5 test specimens.
5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5)°C and (85±5)% relative humidity.

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Regional Head Office:
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200 070 P.R.China

6. Procedure

6.1 Preparation of the bacterial challenge: Dilute the cultutre in peptone water to achieve a concentration of approximately 5×10^5 CFU/mL.
6.2 Adjust the flow rate through the Anderson sampler to 28.3 L/min.
6.3 Deliver the challenge to the nebulizer using a syringe pump. Purge tubing and nebulizer of air bubbles.
6.4 Perform a positive control run without a test specime to determine the number of viable aerosol particles being generated. The mean particle size (MPS) of the aerosol will also be calculated from the results of these positive control plates.
  6.4.1 Initiate the aerosol challenge by turning on the air pressure and pump connected to the nebulizer. Immediaterly begin sampling the aerosol using the Anderson sampler.
  6.4.2 Time the challenge suspension to be delivered to the nebulizer for 1 min.
  6.4.3 Time the air pressure and Anderson sampler to run for 2 min.
  6.4.4 At the conclusion of the positive control ran, remove plates from the Anderson sampler.
6.5 Place new agar plates into Anderson sampler and clamp the test specimen into the top of the Anderson sampler, with the inside of the specimen facing towards the bacterial challenge (test area: 77cm^2).
6.6 Repeat the challenge procedure for each test specimen.
6.7 Repeat a positive control after completion of the sample set.
6.8 Perform a negative control run by collecting a 2 min sample of air from the aerosol chamber. No bacterial challenge should be pumped into the nebulizer during the collection of the negative control.
6.9 Incubate agar plates at (37±2)°C for (20 to 52) h.
6.10 Count each of the six-stage plates of the Anderson sampler.

7. Calculation

Total the count from each of the six plates for the test specimens and positive controls, as specified by the manufacture of Anderson sampler. The filtration efficiency percentages are calculated as follows:

$$BFE=(C-T)/C\times100$$

T is the total plate count for the test specimen.

C is the mean of the total plate counts for the two positive controls.

8. Test results*

P Value / Stage Number	Positive Control (A)	Positive Control (B)	Negative Control	Specimen 1#	Specimen 2#	Specimen 3#	Specimen 4#	Specimen 5#
1	14	14	0	0	1	0	0	0
2	55	55	0	0	0	0	0	0
3	65	107	0	0	0	0	0	0
4	83	115	0	0	0	0	1	0
5	1341	1263	0	2	5	4	3	1
6	289	296	0	0	0	1	1	0
Total (*T*), CFU	1847	1850	<1	2	6	5	5	1
Average (*C*), CFU	$1.8x10^3 = (P_A+P_B)/2$							
BFE ,%				99.9	99.7	99.7	99.7	99.9
Requirements	≥ 98							
Remarks	*P* is the value of corresponding corrected particle counts as specified by the manufacturer of the cascade impactor. *T* is the total of *P* value for the test specimen. *C* is the mean of the total of *P* value of the two positive controls.							

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No.151 Heng Tong Road Shanghai
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Differential pressure Test

1.Purpose

The purpose of the test was to measure the differential pressure of masks.

2.Sample description was given by client

Sample description : Medical Face Mask for Single Use
Specification : /
Lot Number : /
Sample Receiving Date : 2020-03-29

3.Test Method

EN 14683:2019+AC:2019(E) Annex C

4. Apparatus and materials

Differential pressure testing instrument

5.Test specimen

5.1 Test specimen are complete masks or shall be cut from masks. Each specimen shall be able to provide 5 different circular test areas of 2.5 cm in diameter.
5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5) °C and (85±5)% relative humidity.

6. Procedure

6.1 Without a specimen in place, the holder is closed and the differential manometer is zeroed. The pump is started and the flow of air adjusted to 8 L/min.
6.2 The pretreated specimen is placed across the orifice (total area 4.9cm², test area diameter 25mm) and clamped into place so as to minimize air leaks.
6.3 Due to the presence of an alignment system the tested area of the specimen should be perfectly in line and across the flow of air.
6.4 The differential pressure is read directly.
6.5 The procedure described in steps 6.1-6.4 is carried out on 5 different areas of the mask and readings averaged.

Results:

Specimen	Test Results* (Pa/cm²)	Average (Pa/cm²)	Requirements	Judgement
1#	48.5	49.0	< 60	Pass
2#	48.5			
3#	49.0			
4#	49.0			
5#	50.0			

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Regional Head Office:
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No.151 Heng Tong Road Shanghai
200 070 P.R.China

Differential pressure Test

1.Purpose

The purpose of the test was to measure the differential pressure of masks.

2.Sample description was given by client

Sample description : Medical Face Mask for Single Use
Specification : /
Lot Number : /
Sample Receiving Date : 2020-03-29

3.Test Method

EN 14683:2019+AC:2019(E) Annex C

4. Apparatus and materials

Differential pressure testing instrument

5.Test specimen

5.1 Test specimen are complete masks or shall be cut from masks. Each specimen shall be able to provide 5 different circular test areas of 2.5 cm in diameter.
5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5) °C and (85±5)% relative humidity.

6. Procedure

6.1 Without a specimen in place, the holder is closed and the differential manometer is zeroed. The pump is started and the flow of air adjusted to 8 L/min.
6.2 The pretreated specimen is placed across the orifice (total area 4.9cm², test area diameter 25mm) and clamped into place so as to minimize air leaks.
6.3 Due to the presence of an alignment system the tested area of the specimen should be perfectly in line and across the flow of air.
6.4 The differential pressure is read directly.
6.5 The procedure described in steps 6.1-6.4 is carried out on 5 different areas of the mask and readings averaged.

Results:

Specimen	Test Results* (Pa/cm²)	Average (Pa/cm²)	Requirements	Judgement
1#	48.5	49.0	< 60	Pass
2#	48.5			
3#	49.0			
4#	49.0			
5#	50.0			

Chemical/Microbiology Laboratory:
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Synthetic Blood Penetration Test

1.Purpose

For evaluation of resistance of masks to penetration by a fixed volume of synthetic blood at a high velocity.

2.Sample description was given by client

Sample description	:	Medical Face Mask for Single Use
Specification	:	/
Lot Number	:	/
Sample Receiving Date	:	2020-03-29

3.Test Method

ISO 22609:2004

4.Apparatus and materials

4.1 Synthetic blood.
4.2 Tensiometer.
4.3 Synthetic blood penetration test apparatus:
4.4 Targeting plate.
4.5 Air pressure source.
4.6 Ruler.
4.7 Balance.
4.8 Controlled temperature and humidity chamber.

5.Test specimen

5.1 As requested by client, take a total of 13 test specimens.
5.2 Prior to testing, condition all test specimens for a minimum of 4h at (21±5)°C and (85±5) % relative humidity.

6.Procedure

6.1 Prepare the synthetic blood (40~44 mN/m) for the test.
6.2 Determine the density of the synthetic blood.
6.3 Fill the reservoir with new synthetic blood.
6.4 Position the test specimen 30.5 cm (12 in.) from the exit of the canula.
6.5 Set the reservoir pressure to the approximate pressure.
6.6 Place the targeting plate approximately 1 cm away from the mask.
6.7 Set the valve timer to 0.5 s. Collect and weigh the amount of fluid delivered (before the targeting hole).

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6.8 Set the valve timer to 1.5 s. Collect and weigh the amount of fluid delivered (before the targeting hole).

6.9 Calculate the difference in weight of the two spurts. For a test fluid with a density of 1.003, Table 1 gives the target difference in weight plus lower and upper limits for a velocity range within 2% of the target.

Table 1 Target weight difference

Fluid Pressure (mmHg)	Weight difference for 1s difference in spurt duration (g)		
	Min.	Target	Max.
120	3.002	3.063	3.124

6.10 Adjust the reservoir pressure and repeat steps 6.7 to 6.9 until the weight difference is within the target range.

6.11 Record the weight difference for the spurts exiting the nozzle.

6.12 Record the pressure in the reservoir.

6.13 Set the valve time to 0.5 s. Collect and weigh the amount of fluid passing through the targeting hole.

6.14 Set the valve time to 1.5 s. Collect and weigh the amount of fluid passing through the targeting hole.

6.15 The difference in weight between the 0.5 s and 1.5 s spurts through the targeting plate shall be within +2 % ~ -5 % of the difference in weight from the nozzle.

6.16 If the differential weight is less than 95 % of the weight difference exiting the nozzle, check the aim of the stream to make sure it is passing cleanly through the targeting hole.

6.17 If the differential weight is more than 102 % of the weight difference exiting the nozzle, repeat the weight measurements exiting the nozzle (steps 6.7 to 6.11).

6.18 For standard synthetic blood, the timer duration can be estimated using the formula:
(ρ is the density of the test fluid.) $t = 0.5 + (2 \times \rho - g \text{ at } 0.5 \text{ s}) / (g \text{ at } 1.5 \text{ s} - g \text{ at } 0.5 \text{ s})$.

6.19 Record the timer setting to use as the starting point for subsequent testing.

6.20 Mount a test specimen on the specimen holding fixture. If the mask contains pleats, spread the pleats out when mounting the mask onto the fixture to present a single layer of material as the target area.

6.21 Squirt the synthetic blood onto the test specimen for the calculated time. Ensure that the synthetic blood hits the target area of mask.

6.22 Inspect the inside surface for synthetic blood penetration within 10 s of squirting the synthetic blood against the target area.

6.23 Report the results (none / penetration) for each test specimen at the test pressure.

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Results:

Specimen	Test Results*	Requirements	Judgement
1#	None Seen	Pass Pressure at 16.0 kPa (120mmHg)	Pass
2#	None Seen		Pass
3#	None Seen		Pass
4#	None Seen		Pass
5#	None Seen		Pass
6#	None Seen		Pass
7#	None Seen		Pass
8#	None Seen		Pass
9#	None Seen		Pass
10#	None Seen		Pass
11#	None Seen		Pass
12#	None Seen		Pass
13#	None Seen		Pass

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Microbial Cleanliness Test

1. Purpose

The purpose of the test was to measure microbial cleanliness of mask.

2. Sample description was given by client

Sample description : Medical Face Mask for Single Use

Specification : /

Lot Number : /

Sample Receiving Date : 2020-03-29

3. Test Method

According to EN ISO 11737-1:2018 to determine the microbial cleanliness of mask material, and refer to the procedure as described in EN 14683:2019+AC:2019(E) Annex D

4. Apparatus and materials

4.1 Orbital shaker.
4.2 0.45 um filter.
4.3 Tryptic Soy Agar (TSA).
4.4 Sabouraud Dextrose Ager (SDA) with chloramphenicol.
4.5 Formula of Extraction Liquid: 1g/L peptone, 5g/L NaCl and 2g/L Tween 20.
4.6 Extraction apparatus.

5. Test specimen

5.1 As requested by client, take a total of 5 mask samples.
5.2 Mask samples for testing are provided in the original primary packaging.
5.3 Condition at (18 to 26)°C and (45 to 65)% relative humidity during testing.

6. Procedure

6.1 Five test specimens are selected from the top, bottom and 3 randomly chosen marks.
6.2 The mask is aseptically removed from the packaging and placed in a sterile 500 mL bottle containing 300 mL of extraction liquid.
6.3 The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm.
6.4 After extracting, 100mL of the extraction liquid is filtered through a 0.45 um filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 mL aliquot of the same extraction liquid is filtered in the same way and the filter plated on SDA for fungi enumeration.
6.5 The plates are incubated for 3 days at 30°C and 7 days at (20 to 25)°C for TSA and SDA plates respectively.
6.6 Calculate the colonies of each agar plate.

7. Calculation

For each test specimen calculate the microbial cleanliness as follows by counting the total colonies of the TSA and SDA plates.

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Results*:

Specimen	Colonies of the TSA Plate	Colonies of the SDA Plate	Microbial Cleanliness, (CFU/g)	Requirements	Judgement
1#	0	0	<1	According to EN ISO 11737-1:2018 the microbial cleanliness of the mask shall be ≤30 CFU/g tested.	Pass
2#	0	1	1		
3#	0	1	1		
4#	0	1	1		
5#	0	1	1		

Note:

1.*denotes this test was carried out by external laboratory assessed as competent.

2.This report is for internal use only such as internal scientific research ,education, quality control, product R&D.

-END OF THE TEST REPORT-

Chemical/Microbiology Laboratory:
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CONFIRMATION OF PRODUCT NOTIFICATION

This is to confirm that Zoustech S.L., has registered under the AEMPS (Spanish Agency for Medicines and Medical Devices), the following medical devices:

Number in the contract	Product name in English	Product name in Spanish
1	Medical Face Mask for Single Use (Non-Sterile)	Mascarilla médica de un solo uso (no estéril)

Manufacturer: SICHUAN XINGLIN MEDICAL DEVICE CO. LTD.

Address: No. 5 West Section of Yiyuan Road, Yuchan Street, Lu County, Luzhou _City, Sichuan Province, P.R. China

Registered under number: RPS/349/2020 (See attached the electronic notification)

The Manufacturer has declared that these devices comply with the regulation including all the general safety and performance requirements.

Zoustech has complied with its commitment of registering the above mentioned devices under the AEMPS and will not have any other further obligation, compromise or responsibility.

18 March, 2020

Mr. Rubén Valle Ibaseta
On behal of
ZOUSTECH SL

ZOUSTECH S.L.
Pso. Castellana, 141 – Planta 19
28049 Madrid – Spain
INSCRITA EN EL REGISTRO MERCANTIL DE MADRID, TOMO 35086, FOLIO 147, HOJA M-630984, INSCRIPCIÓN 1

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 095972 0010 Rev. 00

For the product(s)/product category (ies):

1. **Absorbent Cotton Type:**

   Cotton Ball, Cotton Roll, Cotton Bud

2. **Bandage Type:**

   Gauze Bandage, Elastic Bandage, Self-Adhesive Bandage

3. **Medical Adhesive Tape Type:**

   Adhesive Tape, Adhesive Plaster, Adhesive Dressing

4. **Gauze Type:**

   Lap Sponge, Gauze Swab, Gauze Ball, Gauze Cutting, Gauze Roll,
   Paraffin Gauze Swab, Vaginal Plugging Gauze for Medical Use

5. **Non-woven Type:**

   Non-woven Swab, Drape, Underpad, Face Mask, Surgical Gown Gown, Ball, Cap
   Burn Dressing, First Aid Kit, Paraffin Non-woven Swab, Dressing Kit for Medical Use

6. **Anti-embolism Stocking Type**

7. **Wound Dressing Type**

8. **Ostomy Applicances Type**

   One-piece ostomy bag, Two-piece ostomy bag, Ostomy Accessories

9. **Orthopaedic Support Type**

   Back Support, Knee Support, Ankle Support, Wrist Support, Finger Support, Elbow Support,
   Shoulder Support, Neck Support, Chest Support, Muscle Training Belt

10. **Absorbent Pad Type**

    Absorbent Pad, Non-adherent Pad

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Sichuan Xinglin Medical Device Co., Ltd.					
Declaration of Conformity **for Medical Face Mask for Single Use**					
ID No.	XL-CE-21-01	Version	1	Issue date	2020-03-16

1. Manufacturer

Manufacturer Name: Sichuan Xinglin Medical Device Co., Ltd.

Manufacturer Address: Building 1-4, No. 5 West Section of Yiyuan Road, Yuchan Street, Lu County, Luzhou City, Sichuan Province, P.R.China

Tel: 0830-8662222 Fax: 0830-8662222 E-mail: 454029559@qq.com

2. EC-representative

EC-representative Name: ZOUSTECH S.L.

EC-representative Address: Pso. Castellana, 141 - Planta 19, 28046 - Madrid, Spain

Tel: +34694426446 Fax: +34917915466 E-mail: legal@zoustech.eu

3. Product name: Medical Face Mask for Single Use

4. Model: Large, Small

5.Product picture:

6. UMDNS Code of product: 12458

7. Classification of product: MDD 93/42/EEC Class I (Rule 1)

8. Conformity assessment route: MDD 93/42/EEC Annex VII

We herewith declare that we follow the applicable directives: Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC, according to Rule 1 of Annex IX in MDD93/42/EEC, the face mask is Class I device, it can bear the mark CE

The product concerned has been designed and manufactured under a quality management system according to MDD93/42/EEC Annex VII.

Following the procedure relating to the EC Declaration of Conformity set out in MDD93/42/EEC Annex VII

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

We have completed European registration, the registration number is:

RPS/349/2020

The above mention declaration of conformity is exclusively under the responsibility of

Company: Sichuan Xinglin Medical Device Co., Ltd.

Address: Building 1-4, No. 5 West Section of Yiyuan Road, Yuchan Street, Lu County, Luzhou City, Sichuan Province, P.R.China

Signature of issuing person: [redacted]

Name: Qiong Wang

Title: General Manager

Location: Luzhou, Sichuan, China

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q6 101437 0003 Rev. 00

Holder of Certificate: **Sichuan Xinglin Medical Device Co., Ltd**
Building 1-4
No.5 West Section of Yiyuan Road
Yuchan Street
Lu County
646100 Luzhou City, Sichuan Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Sichuan Xinglin Medical Device Co., Ltd
Building 1-4, No.5 West Section of Yiyuan Road, Yuchan Street, Lu County, 646100 Luzhou City, Sichuan Province, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Production and Distribution of Dressing Change Bag for Single Use, Nasal Oxygen Tube for Single Use, Sputum Suction Tube for Single Use, Sputum Suction Tube Bag for Single Use, Oxygen Supply Sputum Suction Tube Pack for Single Use, Gastric Tube for Single Use, I.V. Catheter for Single Use**

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.: SH18141501

Valid from: 2019-04-25
Valid until: 2022-04-24

Date, 2019-04-25

[redacted]

Page 1 of 1
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

A4 / 07.17

beare

MEDICAL FACE MASK FOR SINGLE USE

Order No.:
Product Code: BMD 2
Expiry Date: April 2022

EC REP ZOUSTECH S.L.,
Pso. Castellana, 141-Planta 19,
28046 Madid, SPAIN
legal@zoustech.eu

SUPPLIED IN AUSTRALIA BY:

CE

Order No.:
Product Code: BMD 2
Expiry Date: April 2022

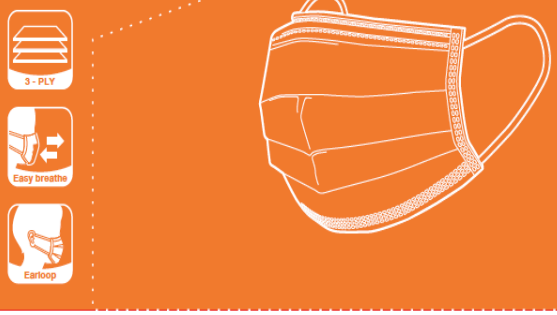
Specification: 17.5cm-9.5cm
Manufacture Date: April 2020
Qty: 2000pcs
Volume: 560 x 400 x 430mm
Weight:

MEDICAL FACE MASK FOR SINGLE USE

LEVEL 2 BARRIER

beare

50 PCS



MEDICAL FACE MASK FOR SINGLE USE

LEVEL 2 BARRIER

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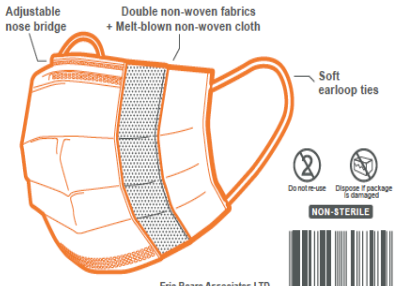
- 3-ply face mask with ear loop - Type II R
- Bacterial filtration efficiency (BFE) ≥ 98%
- Filter dust, pollen, virus and bacteria
- EN 14683:2019+AC:2019 Annex B/C/D
- ISO 22609:2004



BMD 2
Made in China
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CE

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E-mail: admin@ericbeare.com
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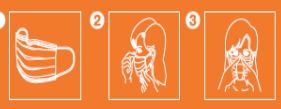
MEDICAL FACE MASK FOR SINGLE USE

LEVEL 2 BARRIER



Keep dry. Key away from sunlight.
Do not use if package is damaged.
Masks should be disposed of in accordance with local policies and procedures.

REF
LOT

Sichuan Xinglin Medical Device Co., Ltd.
Building 1-4, No.5 West Section of Yinyuan Road, Yuchan Street, Lu County,
Luzhou City, Sichuan Province, P.R.China Tel: 0830-8622222 Fax: 0830-8622222

Qty: 50 PCS

Specification: 17.5cm-9.5cm

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