DHSC Terms and Conditions for the Supply of Goods

The Authority	**Department of Health and Social Care** 39 Victoria Street, London, SW1H 0EU, UK
The Supplier	P1F LIMITED [redacted]
Date	**30 April 2020**
Type of Goods	Type IIR Face Masks [EN14683:2019] manufactured by Beijing Biosis Healing Biological Technology Co.Ltd - 3ply 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	DHSC/Case 6058
2. Date	30 April 2020
3. Buyer	**Department of Health and Social Care** 39 Victoria Street, London, SW1H 0EU UK

<table>
<tr><td>4. Supplier</td><td>P1F LIMITED [redacted]</td></tr>
<tr><td>5. The Contract</td><td>The Supplier shall supply the deliverable described below on the terms set out in this Order Form and the Schedules and any Annexes.

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.</td></tr>
<tr><td>6. Deliverables</td><td>Description:

<table>
<tr><th>Item</th><th>Qty</th><th>Unit price</th><th>Contract Value (in GBP)</th></tr>
<tr><td>Item 1 - Type IIR Face Masks [EN14683:2019] manufactured by Beijing Biosis Healing Biological Technology Co.Ltd - 3ply Type IIR Face Masks</td><td>[redacted]</td><td></td><td>[redacted]</td></tr>
<tr><td>Item 2 - Type IIR Face Masks [EN14683:2019] manufactured by Beijing Biosis Healing Biological Technology Co.Ltd - 3ply Type IIR Face Masks</td><td>[redacted]</td><td>[redacted]</td><td>[redacted]</td></tr>
<tr><td>TOTAL</td><td></td><td></td><td>£7,590,000</td></tr>
</table>

The Supplier warrants that it will carry out inspections of the Goods at the point of manufacture and in any case prior to delivery of the Goods at the delivery address. Such inspection</td></tr>
</table>

shall be carried out by suitably training and qualified personnel of the Supplier or its representatives.

Delivered in accordance with the following instructions:
Delivery Address(es): airport in China to be designated by Buyer and delivery of Goods to On-Time representatives in China.

Dates of Delivery:

Tranche	Loading Date	Quantity	Delivery
1	30/04/2020	[redacted]	EXW
2	08/06/2020		EXW
3	15/06/2020		EXW
4	22/06/2020		EXW
5	29/06/2020		EXW
Total			

Suppliers to send ADVANCE SHIPPING NOTICES to the following email address:

[redacted]

They should also copy the email to their contact at On-Time (China freight agent)

The following detail needs to be included within the notice.

- Supplier Name (and code)
- Purchase Order No.
- Part No. / NPC Code (NHS specific code)
- Product Description (as complete as possible, ideally as NHS product listing)
- Quantity (total)
- Pack Qty / Packs per pallet
- No. of pallets
- Quality status (i.e. approved, certification status etc.)
- Any product expiration dates
- Any other contract reference

Clipper group will receive shipping and delivery details from Uniserve once these have been arranged.

Delivery Address:

NHS Supply Chain c/o Clipper Logistics
Daventry Distribution Centre
Danes Way
DIRFT
Daventry
NN6 7GX

<table>
<tr><td>7. Specification</td><td>The specification of the Deliverables is as set out in Annex A. Evidence is required to demonstrate compliance with the required standard is an EC Declaration of Conformity and supporting Test Report.</td></tr>
<tr><td>8. Term</td><td>The Term shall commence on: 30 April 2020

And the Expiry Date shall be upon delivery of the all four batch of Goods described in the table at Section 6 above, 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.</td></tr>
<tr><td>9. Charges</td><td>The Charges for the Deliverables are set out below.

<table>
<tr><th>Item</th><th>Qty</th><th>Unit price</th><th>Contract Value (in GBP)</th></tr>
<tr><td>Item 1 - Type IIR Face Masks [EN14683:2019] manufactured by Beijing Biosis Healing Biological Technology Co.Ltd - 3ply Type IIR Face Masks</td><td></td><td></td><td></td></tr>
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<tr><td>TOTAL</td><td></td><td></td><td>£7,590,000</td></tr>
</table>
</td></tr>
<tr><td>10. Payment</td><td>The parties agree that:</td></tr>
</table>

Item	Contract Value (in GBP £)	Units per week
Pre-payment (100% of Item 1 and 70% of Item 2)	[redacted]	
1st delivery payment		
2nd delivery payment		
3rd delivery payment		
4th delivery payment		
5th delivery payment		
TOTAL	**£7,590,000**	[redacted]

(a) The Supplier may issue an invoice for the pre-payment in the table above immediately on the signature of this Order Form and such invoice shall be paid immediately on signature of this Order Form;

(b) The Supplier may issue further invoices upon each delivery of the Goods at the Delivery Address set out in Section 6 above. Such subsequent invoices shall represent the remaining 50% of the relevant Charges payable by the Authority for the Goods actually delivered (as set out in the table above) and such invoices shall be paid by the Authority in accordance with the payment terms set out at clause 6.6 of Schedule 2 provided always that such invoice is undisputed and validly issued in accordance with the invoicing requirements set out below and elsewhere in this Contract.

The parties agree that the payment terms set out above shall apply only in respect of this Order Form, and that nothing set out herein shall relieve the Supplier of its obligations to comply with, or otherwise vary the remaining terms of this Order Form or any other provision of this Contract.

The Supplier acknowledges and agrees that any advance payment of Charges as set out in this Order Form may be recovered by the Authority in accordance with the terms and conditions (including (without limitation) in the event that the Goods are delivered late or are rejected or otherwise in the event of the expiry or early termination of this Contract prior to the acceptance of any such Goods by the Authority).

All invoices must be sent quoting a valid purchase order number to the following email address [redacted]

	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 us by email, marking for the attention of our Accounts Payable section and send to the following email address [redacted]	
11. Buyer Authorised Representative(s)	For general liaison your contact will continue to be: [redacted] E-mail: [redacted] Mobile: [redacted]	
12. Seller's Authorised Representative(s)	For general liaison your contact will continue to be [redacted] or, in their absence, [redacted]	
13. Address for notices	**Buyer:** **Department of Health and Social Care** 39 Victoria Street, London, SW1H 0EU, UK	Supplier: **P1F LIMITED** [redacted] Fieldfisher Riverbank House, 2 Swan Lane, London, EC4R 3TT, UK
14. Key personnel	**Buyer:** **Department of Health and Social Care** 39 Victoria Street, London, SW1H 0EU, UK	Supplier: [redacted]
15. 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:	[redacted]	Date	30th April 2020

Signed by the authorised representative of THE SUPPLIER

Name:	[redacted]	Signature	[redacted]
Position:	[redacted]	Date	30 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 1.9 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: 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 following quality assurance standards shall apply, as appropriate, to the manufacture, supply, and/or installation of the Goods:

EN14683:2019- 3ply Type IIR Face Masks

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(i) of Schedule 2.

6 Specific time periods for inspection ☒ (only applicable to the Contract if this box is checked and Clause 6.1 of this Schedule 1 is completed)

6.1 The Authority shall visually inspect the Goods within 60 days 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 three (3) months written notice.

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 **Error! Reference source not found.** 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 – Technical Specification

This Annex sets out details of the technical specification of the Goods including photographs and certificates.

The Supplier has provided the Buyer with a document produced by BIOSIS HEALING referenced ‘Medical Surgical Mask Introduction’ which align with the European Standard EN14683 IIR/Chinese medical standard of YY 0469-2011, which provides information relating to the specification of the Goods supplied under this Contract.

中华人民共和国
PEOPLE’S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号： 京兴食药监械出20200200
Certificate NO.

产品名称 ：医用外科口罩
Product(s):Medical Surgical Mask

规格型号：BH-EGF-12x7、BH-EGF-14.5x9、BH-EGF-17.5x9.5、BH-BDF-12x7、BH-BDF-14.5x9、BH-BDF-17.5x9.5
Model:BH-EGF-12x7、BH-EGF-14.5x9、BH-EGF-17.5x9.5、BH-BDF-12x7、BH-BDF-14.5x9、BH-BDF-17.5x9.5

产品注册或备案凭证号: 京械注准20202140092
Registration certificate(s)

生产企业： 北京博辉瑞进生物科技有限公司
Manufacturer：Beijing Biosis Healing Biological Technology Co., Ltd

生产企业住所：北京市大兴区中关村科技园区大兴生物医药产业基地药谷一号国际研发孵化园6#厂房西侧
Address of manufacturer:No.6 plant west, Valley No.1 Bio-medicine Industry Park, Daxing District, 102600 Beijing, PEOPLE'S REPUBLIC OF CHINA

生产许可或备案凭证号:京食药监械生产许20130033号
Manufacturing License(s)

兹证明上述产品已准许在中国生产和销售。
This is to certify that the above products have been registered to be manufactured and sold in China.

证明有效日期至： 2020-06-18
This certification valid until：2020-06-18

备注：
Remark：

（出具单位盖章）

Declaration of Conformity

Manufacturer Address BEIJING BIOSIS HEALING BIOLOGICAL TECHNOLOGY CO., LTD
No.6 plant west, Valley No.1 Bio-medicine Industry Park, Daxing District,
102600 Beijing, PEOPLE'S REPUBLIC OF CHINA.

European Representative SHANGHAI INTERNATIONAL HOLDING CORP.GMBH (EUROPE)
EIFFESTRASSE 80, 20537 HAMBURG, GERMANY

We, the manufacturer, herewith declare that the products

Medical Surgical Mask

BH-EGF- (12×7,14.5×9,17.5×9.5)

BH-BDF- (12×7,14.5×9,17.5×9.5)

meet the provisions of Directive 93/42/EEC and 2007/47/EC which apply to them. The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE

WE, AS THE MANUFACTURER,
ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY

Valid from: 2020 - 03 - 03
Valid until: 2024 - 05 - 27

Standard NO. EN 14683-2014 **Type** IIR

Bo Zhao

Signature of General DIrector

Declaration of Conformity

Manufacturer Address BEIJING BIOSIS HEALING BIOLOGICAL TECHNOLOGY CO., LTD
No.6 plant west, Valley No.1 Bio-medicine Industry Park, Daxing District,
102600 Beijing, PEOPLE'S REPUBLIC OF CHINA.

European Representative SHANGHAI INTERNATIONAL HOLDING CORP.GMBH (EUROPE)
EIFFESTRASSE 80, 20537 HAMBURG, GERMANY

We, the manufacturer, herewith declare that the products

Medical Surgical Mask

BH-EGF- (12×7,14.5×9,17.5×9.5)

BH-BDF- (12×7,14.5×9,17.5×9.5)

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CE

WE, AS THE MANUFACTURER,
ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY

Valid from: 2020 - 03 - 03
Valid until: 2024 - 05 - 27

Standard NO. EN 14683-2014 **Type** IIR

Bo Zhao

Signature of General DIrector

8.Test results

Test Items*		Test Results	Test Methods
Different Pressure Test (Pa/cm^2)	1	39.4	EN 14683:2019
	2	37.9	
	3	41.5	
	4	40.6	
	5	38.7	

Note: The test report is the test results issued by the testing institution as requested by the consignor, it shall not determine the legitimacy of the product.

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

Bacterial Filtration Efficiency (BFE) Test

1. Purpose

For evaluating the Bacterial Filtration Efficiency (BFE) of medical face mask material.

2. Sample description was given by the client

Medical Surgical Mask
Type : BH-EG-17.5X9.5
Lot : 620021301

3. References

EN 14683:2019 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.

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 throuth 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 form 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 in contact with the challenge.
6.6 Repeat the challenge procedure for each test specimen.
6.7 Repeat a positive control after completion of the sample set.

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Synthetic Blood Penetration Test for Masks

1.Purpose

For evaluating the resistance of medical face masks to penetration by a fixed volume of synthetic blood at a high velocity.

2.Sample description was given by the client

Medical Surgical Mask
Type : BH-EG-17.5X9.5
Lot : 620021301

3.References

EN 14683:2019
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.

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

Table 1 Target weight differences

Fluid Pressure (mmHg)	Weight difference for 1 s difference in spurt duration (g)		
	Min.	Target	Max.
80	2.456	2.506	2.556
120	3.002	3.063	3.124
160	3.466	3.537	3.607

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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Cleanliness of Microbial (Bioburden) Test for Masks

1. Purpose

For determination of a population of microorganisms.

2. Sample description was given by the client

Medical Surgical Mask
Type : BH-EG-17.5X9.5
Lot : 620021301

3. References

EN 14683:2019
EN ISO 11737-1:2018

4. Apparatus and materials

4.1 Orbital shaker
4.2 Sterile 500 mL bottle
4.3 Extraction liquid (1 g/L Peptone, 5 g/L NaCl and 2 g/L Tween 20)
4.4 Tryptone soya agar (TSA)
4.5 Sabouraud dextrose agar (SDA) with chloramphenicol
4.6 Filtration equipment
4.7 Sterilized membrane (0.45μm)

5. Test specimen

5.1 As requested by client, take a total of 5 masks.

6. Procedure

6.1 Weight each mask prior testing.
6.2 The full mask is aseptically removed from the packaging and placed in a stomacher bag.
6.3 Pour into 100 mL extraction liquid and process 5 min in a stomacher individually by highest speed.
6.4 After this extraction step, 100 mL of the extraction liquid is filtered through a 0.45μm filter and laid down on a TSA plate for the total visable aerobic microbial count. Another 100mL aliquot of the same extraction liquid is filtered in the same way and the filter plated on SDA with chloramphenicol for fungi enumeration.Additionally,plate 10mL,1mL and 0.1mL of the extraction liquid both for TSA and SDA with chloramphenicol.
6.5 The plates are incubated for 3 d at 30°C and 7d at 25 °C for TSA and SDA plates respectively.
6.6 The colonies formed on incubation are counted.

7. Calculation

The total bioburden is expressed by addition of the TSA and SDA counts. Microbial cleanliness is based on the mask weigh, which is the total bioburden per gram tested.

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8. Test results

Test Items*		Test Results	Test Methods
Microbial cleanliness (CFU/g)	1	9.6	EN 14683:2019 EN ISO 11737-1:2018
	2	5.2	
	3	2.6	
	4	1.7	
	5	0.9	

Note:

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

2.This report is for internal use only by the client.

-END OF THE TEST REPORT-

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BIOSIS HEALING

CE

20 PC

Medical Surgical Mask

For medical staff in a medical environment

Conform to EN14683 Type IIR
Conform to Directive 93/42/EEC

Model Specifications	Length(±1cm)	Width(±1cm)
BH-EGF-12×7	12	7
BH-EGF-14.5×9	14.5	9
BH-EGF-17.5×9.5	17.5	9.5
BH-BDF-12×7	12	7
BH-BDF-14.5×9	14.5	9
BH-BDF-17.5×9.5	17.5	9.5

Instruction:
Place the mask on the face, press the nose-clip with the middle fingers of both hands. Make sure the mask cover from nose to end of jaw.

Produced date:
Validity: 2 years

Manufacturer LOT Production Lot Number
EC REP Authorised Representative In The European Community

Name: Beijing Biosis Healing Biological Technology Co.,Ltd
Address: No.6 plant west, Valley No.1 Bio-medicine Industry Park, Daxing District, 102600 Beijing, China
Tel: 86-10-61252660 **Fax**: 86-10-61252030
Web: www.biosishealing.com

EC REP **Name**: Shanghai International Holding Corp.GmbH(Europe)
Address: Eiffestrasse 80,20537 Hamburg,Germany
Tel: +49-40-2513175 **Fax**: +49-40-255726

国家食品药品监督管理局北京医疗器械质量监督检验中心

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 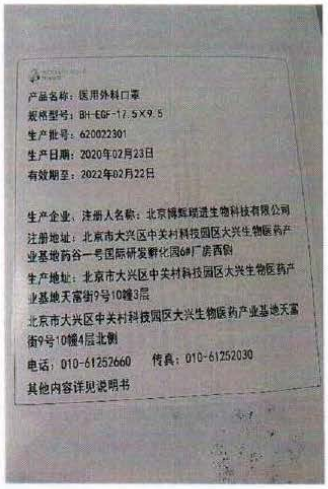 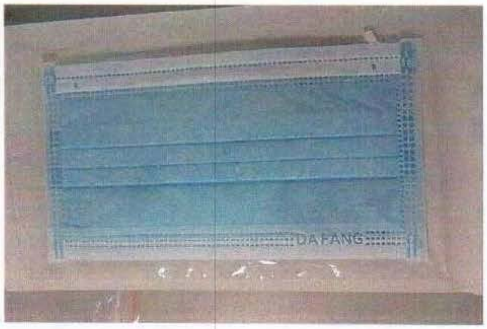
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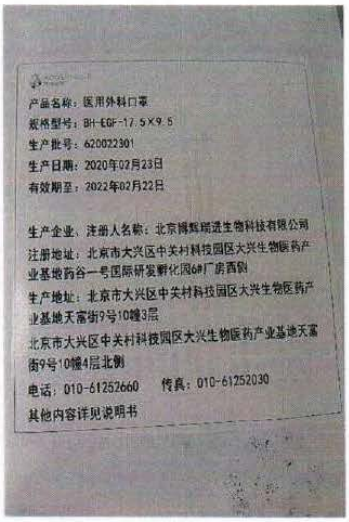

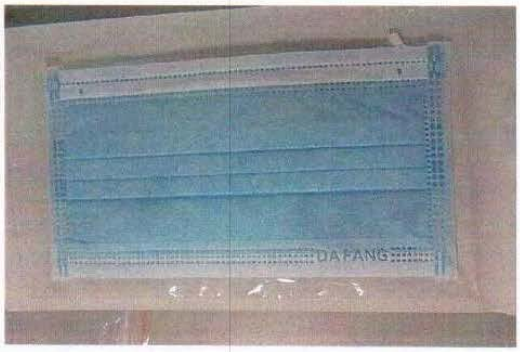

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