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 (as custodian for "THE MASKS FOR NHS HEROES CHARITABLE TRUST: Registered Charity Number 1189289 ")
Date	**18/05/2020**
Type of Goods	PPE - Type IIR Face Masks [EN14683:2019] (non-sterile) manufactured by Henan Yubei Sanitary Materials 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**") below. 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
Error! Reference source not found.	General Terms and Conditions
Schedule 3	Definitions and Interpretations
Schedule 4	Additional Special Conditions

Order Form

1. Contract Reference	DHSC / Case 15587
2. Date	18/05/2020
3. Buyer	**Department of Health and Social Care** 39 Victoria Street, London, SW1H 0EU UK
4. Supplier	**P1F LIMITED** (acting as custodian for "THE MASKS FOR NHS HEROES CHARITABLE TRUST: Registered Charity Number 1189289 ") Fieldfisher Riverbank House, 2 Swan Lane, London, EC4R 3TT, UK

	Company Registration Number: [redacted]
5. The Contract	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.
6. Deliverables	

Item	NPC (internal DHSC use)	Qty	Unit price in £	Contract Value in £
Type IIR Face Masks [EN14683:2019] (non-sterile) manufactured by Henan Yubei Sanitary Materials Co Ltd - 3ply Type IIR Face Masks	[redacted]	[redacted]	[redacted]	£259,000.00
TOTAL		[redacted]		**£259,000.00**

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 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. The Supplier shall be responsible for liaising with the Buyer and its representatives to arrange delivery of such goods.

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.

Date(s) of Delivery:

	<table><tr><th>Item</th><th>Loading Date</th><th>Units</th></tr><tr><td>Delivery 1 - as soon as arranged with Uniserve</td><td>[redacted]</td><td>[redacted]</td></tr></table> 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. o Supplier Name (and code) o Purchase Order No. o Part No. / NPC Code (NHS specific code) o Product Description (as complete as possible, ideally as NHS product listing) o Quantity (total) o Pack Qty / Packs per pallet o No. of pallets o Quality status (i.e. approved, certification status etc.) o Any product expiration dates o 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 Packaging Instructions: [redacted]
7. Specification	The specification of the Deliverables is as set out in Annex A. Evidence is required to demonstrate compliance with the required standard [EN14683:2019] is an EC Declaration of Conformity and supporting Test Report.
8. Term	The Term shall commence on 26/05/2020

	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. The parties agree and acknowledge that it is a requirement of this Contract that the Supplier confirm to the Authority in writing and with evidence (and the Authority is satisfied) that the Supplier's manufacturer of the Goods has obtained the relevant export permissions from the Government of the country from which the Goods are exported ('The White List Condition'). If the Supplier has not sent such confirmation and evidence to the Authority within ten (10) days of the date on which this Contract is signed, this Contract (and any orders) shall immediately and automatically terminate, and the Supplier shall immediately send back to the Authority any sums paid by the Authority to the Supplier under this Contract, and any invoices issued under this Contract shall automatically be void. Without prejudice to any other rights or remedies available to the Authority, the Authority may terminate this Contract with immediate effect by giving written notice to the Supplier if (a) the Supplier's manufacturer of the Goods is unable to maintain any export permissions, or (b) where the Authority has good cause to believe that there has been a material deterioration in the financial circumstances of the Supplier's manufacturer of the Goods.
9. Charges	The Charges for the Deliverables shall be set out below**.** See table below

Item	NPC (internal DHSC use)	Qty	Unit price in £	Contract Value in £
Type IIR Face Masks [EN14683:2019] (non-sterile) manufactured by Henan Yubei Sanitary Materials Co Ltd - 3ply Type IIR Face Masks	[redacted]	[redacted]	[redacted]	£259,000.00
TOTAL		[redacted]		**£259,000.00**

10. Payment

All invoices must be send quoting a valid purchase order number.

Item	%	Payment Value	Payment Due Date
Delivery Payment	100%	£259,000.00	On-delivery

(a) The Supplier may issue an invoice for the pre-payment in the table above immediately on the signature of this Order Form. The parties agree and acknowledge that the Authority shall be under no obligation to pay any such invoice unless and until the White List Condition as per Section 8 - Term has been met to the Authority's reasonable satisfaction, such invoice shall be paid by the Authority within 2 Business days of the date of the Supplier's notification issued in accordance with Section 6 above;

(b) The Supplier may issue further invoices upon each delivery of the Goods at the Delivery Address set out in Section 6 above and in accordance with the Table in Section 10 above to represent the indicated instalment payment value representing a payment towards 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 be 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 Procurement.Operations@dhsc.gov.uk or, in their absence, [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 Attention: [redacted] Email: [redacted]	Supplier: **P1F LIMITED** (ON BEHALF OF "THE MASKS FOR NHS HEROES CHARITABLE TRUST") 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 Attention: [redacted] Email: [redacted]	Supplier: **P1F LIMITED** (ON BEHALF OF "THE MASKS FOR NHS HEROES CHARITABLE TRUST") Fieldfisher Riverbank House, 2 Swan Lane, London, EC4R 3TT, UK

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	18th May 2020

Signed by the authorised representative of THE SUPPLIER

Name:	[redacted]	Signature	[redacted]
Position:	[redacted]	Date	18th May 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 **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 following quality assurance standards shall apply, as appropriate, to the manufacture, supply, and/or installation of the Goods:

3.1.1 BS 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 and shall ensure that the any Purchase Order is clearly noted on each delivery. 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 **Error! Reference source not found.**.

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 **[*insert 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 Error! Reference source not found. **☐ (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 **Error! Reference source not found.** shall cease **[*insert period – e.g. 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) 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 **Error! Reference source not found.** of **Error! Reference source not found.** 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 **Error! Reference source not found.** 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 [***insert period***] of their delivery to the Authority and/or which have a remaining shelf life of less than [***insert 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 **Error! Reference source not found.**.

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 10.8 and 10.9 of this Schedule 1 shall then apply accordingly and this Clause, together with Clauses 10.8 and 10.9 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 Save in relation to any PPE Goods for which the Supplier has approval in accordance with the cross-Government Decision Making Committee and without prejudice to the generality of clause 12.2, the Supplier shall ensure for PPE 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.

12.7 The Supplier shall ensure that each delivery of PPE Goods shall be properly labelled in accordance with PPE Laws and such labelling and any user instructions relating to the use of the PPE Goods is clearly legible and in English.

Annex A – Technical Specification

This Annex sets out details of the technical specification of the Goods including photographs and certificates which provides information relating to the specification of the Goods supplied under this Contract.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ ZERTIFIKAT ◆ CERTIFICATE

CERTIFICATE OF NOTIFICATION

This is to certify that, according to the council directive 93/42/EEC, SUNGO performed all notification duties and responsibilities as the European authorized representative of:

Applicant: Henan Yuhci Sanitary Materials Co., Ltd

Address: Pudong Industrial Park, Changyuan County, Henan Province, China

The Manufacturer has provided SUNGO with all the appropriate declarations according to the 93/42/EEC Directive requirements including the EC Declaration of Conformity confirming that his medical device, as stipulated here below, is fulfilling the applicable requirements of the European Council Directive 93/42/EEC.

Product(s): Masks, Protective Clothing, Isolation gown

Type(s): Masks: Large Size, Small Size

Protective Clothing: Type I, Type II

Isolation gown: Type A, Type B, Type C

Product Classification: Class I

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

The notification of aforementioned device has been completed by the European Representative in Netherlands. The Netherlands Competent Authority is notified of the manufacturer's medical devices and has allocated registration. NOTIS number is CIBG-20200617.

[redacted]

Issued: Mar. 23 2020
Cert. No.: EU211518
Expiration Date: Mar. 22 2025

CE

This is not a CE mark and is only provided as a template for information purposes.

Produkte
Products

TÜVRheinland®

Prüfbericht-Nr.: *Test Report No.:*	60382818 001	**Auftrags-Nr.** *Order No.:*	188268384	Seite 1 von 12 *Page 1 of 12*
Kunden-Referenz-Nr.: *Client Reference No.:*	N/A	**Auftragsdatum:** *Order date:*	Mar. 30, 2020	
Auftraggeber: *Client:*	Henan Yubei Sanitary Material Co., Ltd. Pudong Industrial Park, Changyuan County, Changyuan, 453400, P.R.China			
Prüfgegenstand: *Test item:*	Face Mask			
Bezeichnung / Typ-Nr.: *Identification / Type No.:*	Rectangle, Type IIR			
Auftrags-Inhalt: *Order content:*	Type test			
Prüfgrundlage: *Test specification:*	EN 14683:2019+AC:2019 except for clause 5.2.6			

Wareneingangsdatum: *Date of receipt:*	Apr. 01, 2020	See Attachment: Photo documentation for details.
Prüfmuster-Nr.: *Test sample No.:*	04200208	
Prüfzeitraum: *Testing period:*	Apr. 02, 2020 to Apr. 24, 2020	
Ort der Prüfung: *Place of testing:*	See page 3	
Prüflaboratorium: *Testing laboratory:*	TÜV Rheinland (Shenzhen) Co., Ltd.	
Prüfergebnis*: *Test result*:*	Pass	

geprüft von / tested by: [redacted]

Apr. 24, 2020
Datum / Date

kontrolliert [redacted]

Apr. 26, 2020
Datum / Date

Sonstiges / Other:

- The test report consists of EN 14683 test report including this cover page (12 pages) and attachment: Photo documentation (2 pages).
- The Biocompatibility (clause 5.2.6) is not evaluated in this test report.

Zustand des Prüfgegenstandes bei Anlieferung: *Condition of the test item at delivery:*	Prüfmuster vollständig und unbeschädigt *Test item complete and undamaged*

*Legende:	1 = sehr gut	2 = gut	3 = befriedigend	4 = ausreichend	5 = mangelhaft
	P(ass) = entspricht o.g. Prüfgrundlage(n)		F(ail) = entspricht nicht o.g. Prüfgrundlage(n)	N/A = nicht anwendbar	N/T = nicht getestet
Legend:	1 = very good	2 = good	3 = satisfactory	4 = sufficient	5 = poor
	P(ass) = passed a. m. test specification(s)		F(ail) = failed a. m. test specification(s)	N/A = not applicable	N/T = not tested

Dieser Prüfbericht bezieht sich nur auf das o.g. Prüfmuster und darf ohne Genehmigung der Prüfstelle nicht auszugsweise vervielfältigt werden. Dieser Bericht berechtigt nicht zur Verwendung eines Prüfzeichens.
This test report only relates to the a. m. test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any test mark.

TÜV Rheinland (Shenzhen) Co., Ltd., East of F1, F2 - F4, Building 1, Cybio Technology Building, No. 6 Langshan No. 2 Road, North Hi-tech Industry Park, Nanshan District, Shenzhen, P.R. China
http://www.tuv.com

EN 14683:2019+AC: 2019 Medical face masks — Requirements and test methods	
Report Reference No. ..... :	50362818 001
Date of issue..... :	See cover page
Total number of pages..... :	See cover page
Testing Laboratory..... :	TÜV Rheinland (Shenzhen) Co., Ltd.
Address..... :	1F East & 2-4F, Cybio Technology Building No.1, No.16 Keji Bei 2nd Road, High-Tech Industrial Park North Nanshan District, 518057, Shenzhen, China
Applicant's name ..... :	Henan Yubei Sanitary Materials Co., Ltd.
Address..... :	Pudong Industrial Park, Changyuan County, Changyuan, 453400, P.R.China
Test specification:	
Standard..... :	EN 14683:2019+AC:2019
Test procedure..... :	Type test
Non-standard test method..... :	N/A
Test Report Form No. ..... :	EN 14683:2019+AC:2019_A
Test Report Form Originator..... :	TÜV Rh (SZ)
Master TRF..... :	2020-03
Test item description..... :	Face Mask
Trade Mark..... :	
Manufacturer..... :	Same as the applicant
Model/Type reference..... :	Rectangle, Type IIR
Classification..... :	Type IIR

List of Attachments (including a total number of pages in each attachment):	
Attachment – Photo Documentation (2 pages)	
Summary of testing:	
Tests performed (name of test and test clause): Construction check according to: Clause 5.1.1 Materials and construction Clause 5.1.2 Design	**Testing location:** TÜV Rheinland (Shenzhen) Co., Ltd, 1F East & 2-4F, Cybio Technology Building No.1, No.16 Keji'bei 2nd Road, High-Tech Industrial Park North Nanshan District, 518057, Shenzhen, China
Clause 5.2.2 Bacterial filtration efficiency (BFE) Clause 5.2.3 Breathability Clause 5.2.4 Splash resistance Clause 5.2.5 Microbial cleanliness (Bioburden)	**Sichuan Testing Center of Medical Devices** No. 4-28, Xinye Road, High tech west Area, Chengdu, Sichuan, 611731, P.R.China

Copy of marking plate

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

See attachment for other information.

Testing	
Date of receipt of test item(s)	See cover page
Dates of tests performed	See cover page

Possible test case verdicts:	
- test case does not apply to the test object	N/A
- test object does meet the requirement	P (Pass)
- test object was not evaluated for the requirement	N/E (collateral standards only)
- test object does not meet the requirement	F (Fail)

General remarks:

"(See Attachment #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.
The tests results presented in this report relate only to the object tested.
This report shall not be reproduced except in full without the written approval of the testing laboratory.
List of test equipment must be kept on file and available for review.
Additional test data and/or information provided in the attachments to this report.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

Name and address of factory (ies): Same as the applicant

General product information:

1, The tested medical mask classified as type IIR.
2, The Biocompatibility (clause 6.2.6) is not evaluated in this test report.
3, The test results are for reference only. Relevant certification may be needed if the mask is intended to be sold in Europe.

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
4	**Classification**		P
	Medical face masks specified in this European Standard are classified into two types (Type I and Type II) according to bacterial filtration efficiency whereby Type II is further divided according to whether or not the mask is splash resistant. The 'R' signifies splash resistance.	Type IIR	P
5	**Requirements**		P
5.1	**General**		P
5.1.1	**Materials and construction**		P
	The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric.	3 ply designed with two layers of polypropylene spunbond nonwoven and one layer of polypropylene melt-blown nonwoven.	P
	The medical face mask shall not disintegrate, split or tear during intended use.		P
	In the selection of the filter and layer materials, attention shall be paid to cleanliness.		P
5.1.2	**Design**		P
	The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides.		P
	Medical face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours).	With nose clip	P
5.2	**Performance requirements**		P
5.2.1	**General**		P
	All tests shall be carried out on finished products or samples cut from finished products.		P
5.2.2	**Bacterial filtration efficiency (BFE)**		P
	When tested in accordance with Annex B, the BFE of the medical face mask shall conform to the minimum value given for the relevant type in Table 1.	See appended table 5.2.2	P
	For thick and rigid masks such as rigid duckbill or cup masks the test method may not be suitable as a proper seal cannot be maintained in the cascade impactor. In these cases, another valid equivalent method shall be used to determine the BFE.	Not such mask.	N/A

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
	When a mask consists of two or more areas with different characteristics or different layer-composition, each panel or area shall be tested individually.	Same characteristics and same layer-composition declared by manufacturer.	N/A
	The lowest performing panel or area shall determine the BFE value of the complete mask.	See above.	N/A
5.2.3	**Breathability**		P
	When tested in accordance with Annex C, the differential pressure of the medical face mask shall conform to the value given for the relevant type in Table 1.	See appended table 5.2.3	P
	If the use of a respiratory protective device as face mask is required in an operating theatre and/or other medical settings, it might not fulfil the performance requirements with regard to differential pressure as defined in this European Standard. In such case, the device should fulfil the requirement as specified in the relevant Personal Protective Equipment (PPE) standard(s).		N/A
5.2.4	**Splash resistance**		P
	When tested in accordance with ISO 22609:2004 the resistance of the medical face mask to penetration of splashes of liquid shall conform to the minimum value given for Type IIR in Table 1.	See appended table 5.2.4	P
5.2.5	**Microbial cleanliness (Bioburden)**		P
	When tested according to EN ISO 11737-1:2018 the bioburden of the medical mask shall be ≤ 30 CFU/g tested (see Table 1).	See appended table 5.2.5	P
5.2.6	**Biocompatibility**		N/E
	According to the definition and classification in EN ISO 10993-1:2009, a medical face mask is a surface device with limited contact.	The biocompatibility is not evaluated in this test report.	N/E
	The manufacturer shall complete the evaluation of the medical face mask according to EN ISO 10993-1:2009 and determine the applicable toxicology testing regime.		N/E
	The results of testing should be documented according to the applicable parts of the EN ISO 10993 series.		N/E
	The test results shall be available upon request.		N/E
8	**Marking, labelling and packaging**		P
	Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the medical face mask is supplied.	See attachment.	P
	The following information shall be supplied:		P
	a) number of this European Standard;		P

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
	b) type of mask (as indicated in Table 1).		P
	EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered.		P

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict

6.2.2	TABLE: Bacterial filtration efficiency (BFE)							P
Batch/ lot no.:	Test Specimen no.:	Dimension of the test specimen L x W (mm x mm)	test area (cm^2)	Flow rate (l/min)	Mean of the total plate counts of the two positive controls	Mean plate count of the negative controls	BFE for each test specimen (%)	Remarks
04200208	1	158x164	63.6	28.3	1873	0	89.79	–
	2	157x162	63.6	28.3			89.67	–
	3	158x163	63.6	28.3			89.25	–
	4	158x164	63.6	28.3			89.73	–
	5	158x163	63.6	28.3			89.67	–

Supplementary information:
1, Each specimen was conditioned at 21 °C and 85 % relative humidity for 4 h to bring them into equilibrium with atmosphere prior to testing.
2, The side of the test specimen was facing towards the challenge aerosol: the outside of the test specimen.

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
6.2.3	TABLE: Breathability (Differential pressure)		P

Batch/ lot no.:	Test Specimen number-Test area number	Differential pressure for each test area (Pa/cm²)	The averaged differential pressure for each test specimen (Pa/cm²)	Flow rate (l/min)	Remarks
04200208	1-1	41.7	41.8	8.0	–
	1-2	40.8		8.0	–
	1-3	40.6		8.0	–
	1-4	46.6		8.0	–
	1-5	40.4		8.0	–
	2-1	37.2	41.5	8.0	–
	2-2	40.1		8.0	–
	2-3	37.9		8.0	–
	2-4	43.9		8.0	–
	2-5	48.6		8.0	–
	3-1	48.8	44.9	8.0	–
	3-2	44.5		8.0	–
	3-3	46.2		8.0	–
	3-4	47.9		8.0	–
	3-5	38.1		8.0	–
	4-1	30.7	37.3	8.0	–
	4-2	38.8		8.0	–
	4-3	43.9		8.0	–
	4-4	33.7		8.0	–
	4-5	38.4		8.0	–
	5-1	42.1	40.8	8.0	–
	5-2	41.3		8.0	–
	5-3	47.7		8.0	–
	5-4	38.3		8.0	–
	5-5	32.6		8.0	–

Supplementary Information:
Each specimen was conditioned at 21 °C and 85 % relative humidity for 4 h to bring them into equilibrium with

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
atmosphere prior to testing.			

5.2.4	TABLE: Splash resistance			P
Batch/ lot no.:	Test mask no.:	The material of tested mask	Test result (Pass/fail)	Remarks
04200208	1	See clause 5.1.1	Pass	–
	2		Pass	–
	3		Pass	–
	4		Pass	–
	5		Pass	–
	6		Pass	–
	7		Pass	–
	8		Pass	–
	9		Pass	–
	10		Pass	–
	11		Pass	–
	12		Pass	–
	13		Pass	–
	14		Pass	–
	15		Pass	–
	16		Pass	–
	17		Pass	–
	18		Pass	–
	19		Pass	–
	20		Pass	–
	21		Pass	–
	22		Pass	–
	23		Pass	–
	24		Pass	–
	25		Pass	–
	26		Pass	–
	27		Pass	–
	28		Pass	–

EN 14683:2019+AC:2019				
Clause	Requirement + Test		Result - Remark	Verdict
	29		Pass	–
	30		Pass	–
	31		Pass	–
	32		Pass	–

Supplementary information:
1, Each specimen was conditioned at 21 °C and 85 % relative humidity for 4 h to bring them into equilibrium with atmosphere prior to testing.
2, The description of target area tested: the centre of the specimen.
3, Any technique used to enhance visual detection of synthetic blood: cotton absorbent swab.
4, The temperature and relative humidity for testing: 21 °C and 80 %.
5, Description of any pre-treatment techniques used: N/A.

6.2.6	TABLE: Microbial cleanliness (Bioburden)			P
Batch/ lot no.:	Mask(under test) no.:	Weight of each mask (g)	Total bioburden per individual mask (CFU/g)	Remarks:
04200208	1	3.1	<1	–
	2	3.1	6	–
	3	3.0	0	–
	4	3.1	0	–
	5	3.0	0	–

Supplementary information:

End of EN 14683 test report

ATTACHMENT **Photo Documentation**

TÜVRheinland®

Report No.: 50362818 001

Product: Face Mask

Type Designation: Rectangle, Type IIR

Figure 1 General view of package

Figure 2 General view of package

Product: Face Mask

Type Designation: Rectangle, Type IIR

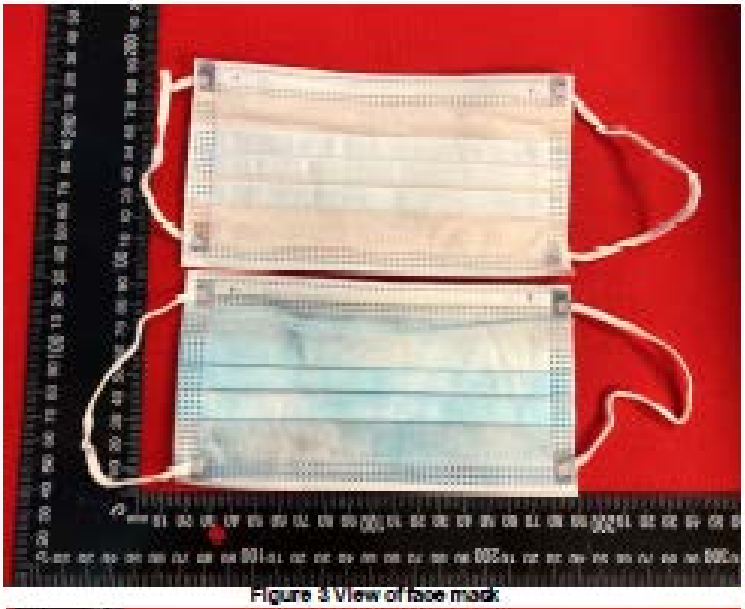

Figure 3 View of face mask

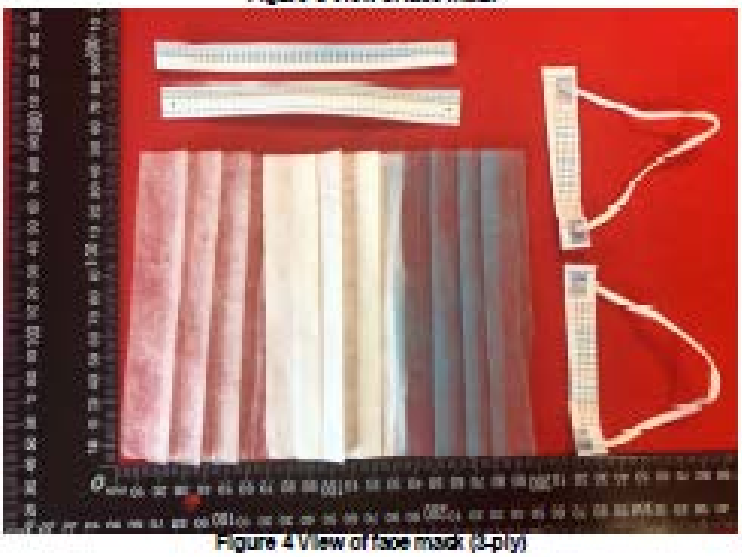

Figure 4 View of face mask (3-ply)

END OF THE PHOTO DOCUMENTATION

Made in China
Henan Yubei Sanitary Materials Co., Ltd.
Address: Puding Industrial Park, Changyuan County, Henan Province, China
Tel: +86 373-8816226 / 8816227 www.xxyubei.com
EC REP
SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Contact Person: SUNGO Secretary
E-mail: ec.rep@sungogroup.com
NOTIS Number:CBG-20200617
FACE MASK
Cert.No. EU211518
EC REP
Standard: EN 14683 TYPE IIR
Henan Yubei Sanitary Materials Co., Ltd.
Address: Puding Industrial Park, Changyuan County, Henan Province, China
Tel: +86 373-8816226 / 8816227 www.xxyubei.com

豫北 YU BEI

生产许可证编号：豫食药监械生产许20150112号
产品注册证编号：豫械注准20182140569
产品技术要求编号：豫械注准20182140569
符合YY0469-2011标准要求

20 PCS

Made in China CE
Cert.No.:EU211518
EN 14683:2019+AC:2019

FACE MASK NON-STERILE

OPEN

Type:Rectangle Type IIR Standard EN 14683 TYPE IIR

BFE:≥98%

NON STERILE

Discard after single use
Do not use it if the package is opened or damaged
Do not store at extreme temperatures

Product Instruction

1. Take the mask by the ear loops blue side facing outand nose clip on the upper side.
2. Fix the ear loops onto both of your ears covering completely nose and mouth.
3. Adjust the nose clip to the shape of your nose andpull the lower end of mask to the lower jaw.

Henan Yubei Sanitary Materials Co., Ltd.
Address: Pudong Industrial Park, Changyuan County, Henan Province, China
Tel: +86 373-8816226 / 8816227 **www.xxyubei.com**

EC REP

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Contact Person: SUNGO Secretary
E-mail: ec.rep@sungogroup.com
NOTIS Number:CIBG-20200617