

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	MGP Advisory Ltd 8 LEWISTON MILL, TOADSMOOR RD GLOUCESTERSHIRE GL5 2TE Registered Company Number: 10599501
Date	01/05/20
Type of Goods	1. Goggles 2. Cat III Isolation Gown 3. Gloves

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
Error! Reference source not found.	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/5538
2. Date	01/05/20
3. Buyer	Department of Health and Social Care

	39 Victoria Street, London, SW1H 0EU, UK
4. Supplier	MGP ADVISORY LTD 8 LEWISTON MILL, TOADSMOOR RD, GLOUCESTERSHIRE GL5 2TE
5. The Contract	<p>The Supplier shall supply the deliverable described below on the terms set out in this Order Form and the Schedules and Annex A.</p> <p>Unless the Contract otherwise requires, capitalised expressed used in this Order Form have the same meanings as in Schedule 3.</p> <p>In the event of any conflict between this Order Form and the Schedules, this Order Form shall prevail.</p> <p>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.</p>
6. Deliverables	<p>The deliverables/delivery dates are as set out in the Purchase Order(s) at Annex A.</p> <p>Delivered in accordance with the following instructions:</p> <p>The supplier will contact the Authority's agent as set out in Annex C to arrange for collection the goods in accordance with Annex A from the following addresses:</p> <p>GOGGLES: GUANGZHOU J & Y SAFETY PRODUCTS MANF. CO. LTD. NO. 5 YONGLE RD, HUASHAN TOWN, HUADU DISTRICT, GUANGZHOU, P.R. CHINA</p> <p>ISOLATION GOWNS: HUBEI HUANFU PLASTIC PRODUCTS CO. LTD. NO. 188 WANFU ST, CHENKU TOWN, HANCHUAN CITY, HUBEI PROVINCE, 431608, P.R. CHINA</p> <p>GLOVES: BLUE SAIL MEDICAL CO. LTD. QILU CHEMICAL IND. PARK, NO.21, QINGTIAN RD, 255414, ZIBO, SHANDONG, P.R. CHINA.</p> <p>The Supplier will submit Advance Shipping Notices to the following email address: nhsppbookings@clippergroup.co.uk</p> <p>Please include the following detail within the notice:</p> <ul style="list-style-type: none"> • Supplier Name (and code)

	<ul style="list-style-type: none"> • Purchase Order No. • Part No. / NPC Code (NHS specific code) • Product Description (as complete as possible, ideally as per 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
7. Specification	The specification of the Deliverables is as set out in Annex B.
8. Term	<p>The Term shall commence on placement of the Purchase Order 001 at Annex A.</p> <p>And the Expiry Date shall be upon delivery of Purchase Orders, unless it is otherwise extended or terminated in accordance with the terms and conditions of the contract.</p> <p>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.</p>
9. Charges	The Charges for the Deliverables shall be set out in Annex A.
10. Payment	<p>All invoices must be emailed quoting a valid purchase order number to the following email address COVID-19FinanceOperations@dhsc.gov.uk.</p> <p>The Authority agrees to pay the Supplier the value of the Goods as set out in Line 01, 03, & 05 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.</p> <p>Upon presentation of a valid invoice and accompanying collection confirmation from the Authority's agent; the Authority agrees to pay the remaining unit costs as specified at Lines 02, 04, & 06 of Purchase Order 001 at Annex A in increments based on the confirmed actual quantity collected by Uniserve</p> <p>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.</p>

15. Procedures and Policies	<p>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.</p> <p>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.</p>	

Signed by the authorised representative of THE AUTHORITY

Name:		Signature:	
Position:	Deputy Director	Date	1 st May 2020

Signed by the authorised representative of THE SUPPLIER

Name:		Signature	
Position:	CEO	Date	29/04/2020

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 **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 **Error! Reference source not found.** 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 60 days of the date of delivery of the relevant Goods.
- 7 Specific time periods for rights and remedies under Clause **Error! Reference source not found.** 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 **Error! Reference source not found.** of **Error! Reference source not found.** 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.
- 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 **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 **Error! Reference source not found.** 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 [**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 **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 12.8 and 12.9 of this Schedule 1 shall then apply accordingly and this Clause, together with Clauses 12.8 and 12.9 **Error! Reference source not found.** 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.

PURCHASE ORDER FORM No 001

Deliverables					
Item Number	Item Specification	Delivery Schedule	Total Qty (units)	Firm Price (£) Ex VAT	
				Per Item (£)	Total
01	PVC Medical Resistant Goggles 50% Payment of [REDACTED] Items on Contract Award	Contract Award			
02	PVC Medical Resistant Goggles Remaining 50% payment to be paid on shipment via Uniserve in accordance with Order Form Section 10.	Uniserve Collection from Manufacturer by 25th May 2020 *If CA is missed, schedule will slip to 25 days after receipt of deposit			
03	Coverall Category III – Isolation Gown 50% Payment of [REDACTED] Items on Contract Award	Contract Award			
04	Coverall Category III – Isolation Gown Remaining 50% payment to be paid on shipment via Uniserve in accordance with Order Form Section 10.	Uniserve Collection from Manufacturer by 10th May 2020 *If CA is missed, schedule will slip to 10 days after receipt of deposit			
05	Medical Gloves [REDACTED]	Contract Award			

	50% Payment of [REDACTED] Items on Contract Award		[REDACTED]	
06	<p>Medical Gloves</p> <p>[REDACTED]</p> <p>Remaining 50% payment to be paid on shipment via Uniserve in accordance with Order Form Section 10.</p>	<p>Uniserve Collection from Manufacturer by 4th May 2020</p> <p>*If CA is missed, schedule will slip to 3 days after receipt of deposit</p>		
			Total	<u>£825,000.00</u>

Annex B – Technical Specification – Goggles
(2777/13809-02/E00-00)

	Issued to:	Guangzhou J&Y Safety Products Manufacturer Co., Ltd No. 5 Yongle Road, Huashan Town Huadu District Guangzhou China
Notified Body: 2777	SATRA customer number: P19048	
EU Type-Examination Certificate		
Certificate number: 2777/13809-02/E00-00		
This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation: Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category II product.		
Product reference:	Description:	
SG-60001 SG-60074 SG-60002	Eye-protector, polycarbonate and polyvinyl chloride safety goggles for occupational use	
Classification:	Ocular marking	
Product	BDS 1 F – 166 3 F CE	
SG-60001	BDS 1 F – 166 3 F CE	
SG-60074	BDS 1 F – 166 3 F CE	
SG-60002		
		
Standards/Technical specifications applied: EN 166: 2001		
Technical reports/Approval documents: 1192-ECS-17/ MR 11924-ECS-17, 11925-ECS-1711926-ECS-17 QIMA: 20E-000625(A1)		
Signed on behalf of SATRA:		Kayleigh Aylward
Date first issued: 11/12/2019		Jacques Glasspool
Date of issue: 09/04/2020	Expiry date: 11/12/2024	
Page 1 of 2		

SATRA Technology Europe Limited, Bracetown Business Park, Clonoe, D15YN2P, Republic of Ireland.

Annex B – Technical Specification – Cat III Isolation Gowns
(GB04/61312)



Compliance Report

Applicant: Hubei Huanfu Plastic Products Co., Ltd.
Address: No.188, Wanfu Street, Chenhu Town, Hanchuan City, Hubei, China.

Product: Cap, Hood, Face Mask, Beard Cover, Coverall, Lab Coat, Isolation Gown, Surgical Gown, Patient Shirt, Pyjama, Apron, CPE Gown, Sleeve Cover, Shoe Cover, Bed Sheet, Pillow Case, Sleeping Bag, Blanket

Type: See annex for details

Product Classification: Class I

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

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.

This report is not a certificate of conformity.

No. 02414
Initial Issue Date: 20 Oct 2015

Tony Chen

General Manager (Signature)

This report is the property of NQA and should be returned to NQA upon request.



Certificate GB04/61312

The management system of

Hubei Huanfu Plastic Products Co., Ltd.

No. 188 Wanfu Street, Chenhu Town, Hanchuan City, Hubei Province, 431608, P.R. China

has been assessed and certified as meeting the requirements of

Regulation (EU) 2016/425 Module D

For the following activities

Manufacture of PPE Category III clothing Type 5/6 protective coveralls and gowns.
(Note: All products marked CE0120 must have a valid
EU type-examination certificate issued under Module B
or a valid EC type-examination certificate issued
under Article 10 of Directive 89/686/EEC)

This certificate is valid from 13 March 2019 until 12 March 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 2 March 2022
Issue 6. Certified since 12 March 2004

Authorised by



SGS United Kingdom Limited, Notified Body 0120

Unit 202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

HC SGS 2016/425 D 0118

Page 1 of 1



This document is issued by the Company subject to its General Conditions of Certification Services accessible at www.sgs.com/terms_and_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at <http://www.sgs.com/en/certified-clients-and-products/certified-client-directory>. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.



Fiscal Year 2020 CERTIFICATION OF REGISTRATION

This certifies that:

HUBEI HUANFU PLASTIC PRODUCTS CO., LTD
No. 188 WANFU STREET, CHENHU TOWN, HANCHUAN CITY,
Hubei, 431608, CHINA

has completed the FDA Establishment Registration (as manufacturer) and Device Listing with the US Food & Drug Administration, through

U.S. Agent for FDA Communications:	SUNGO TECHNICAL SERVICE INC. 6050 W EASTWOOD AVE APT 201, CHICAGO, ILLINOIS 60630, USA Telephone: +1-855-957-7779 / E-mail: sungogroup@yahoo.com
---------------------------------------	---

Registration Number:3004105221

Device Listing#: See annex

SUNGO Technical Service Inc. will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. SUNGO Technical Service Inc. makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. SUNGO Technical Service Inc. assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, SUNGO Technical Service Inc. is not affiliated with the U.S. Food and Drug Administration.



Executive Director
Issued: Nov. 25 2019
Cert. No.: 2006US783518
Expiration Date: Dec. 31 2020

Product Name and Brand: CPE Isolation Gown
Product Photo: [please see attchement.](#)
Product Type: HF-CPE001
Product Material: Majority of material is polyethylene(Including polyvinyl chloride additive CPE
Product Color: Light Blue
Product Size:
115*136CM
136*137CM
Product Structure:
Liquid Proofing
Longsleeve 35-36g,40g
Instrument Classification:
EU 2016/425
Annex IV of 93/42/EEC Medical Device Directive(including 2007/47/EC)
Listing No.E146217 for CODE FME
Listing No.D086153 for CODE OEA
Certification: CE, FDA Registration

Scope of Application:
Protection for personal
Protection for medical usage

Annex B – Technical Specification – Gloves
(2777/13809-02/E00-00)

Test Report No. 7191179419-EEC18-CSL
dated 23 Mar 2018

Note: This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.



PSB Singapore

Choose certainty.
Add value.

SUBJECT:

Testing of Powder Free Nitrile Examination Gloves submitted by Blue Sail Medical Co., Ltd. on 25 Jan 2018 and 09 Mar 2018.

TESTED FOR:

Blue Sail Medical Co., Ltd.
Qilu Chemical Industrial Park,
No. 21 Qingtian Rd.,
255414, Zibo, Shandong,
China.

TEST DATE:

26 Jan 2018 to 06 Feb 2018 and 22 Mar 2018

DESCRIPTION OF SAMPLES:

S/N	Product Description	Colour	Reference No.	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Powder Free Nitrile Examination Gloves	Blue	BS0002	12150511	XS	100	Blue Sail Medical Co., Ltd.
				03080511		69	
				12150521	S	100	
				12080311	M	100	
				12090411	L	100	
				12070611	XL	407	

Lot size as specified by client: 200,000 pieces

METHOD OF TEST:

- EN 455-1:2000 Medical gloves for single use
Part 1: Requirements and testing for freedom from holes
- EN 455-2:2015 Medical gloves for single use
Part 2: Requirements and testing for physical properties
- EN 455-3:2015 Medical glove for single use
Part 3: Requirements and testing for biological evaluation



Laboratory:
TÜV SÜD PSB Pte. Ltd.
No.1 Science Park Drive
Singapore 118221

Phone : +65-6895 1333
Fax : +65-6778 8670
E-mail: enquiries@tuv-sud-psb.sg
www.tuv-sud-psb.sg
Co. Reg : 19602967R

Regional Head Office:
TÜV SÜD Asia Pacific Pte. Ltd.
1 Science Park Drive, #02-01
Singapore 118221


Page 1 of 5

Annex C – The Authority’s Delivery Agent

On-Time Shanghai DHSC Contacts

	NAME	TEL	mail add
PPE	LOUIS SHI	13918282826	louis.shi@sha.ontime-express.com
	EASON ZHU	13482405212	eason.zhu@sha.ontime-express.com
VENT	EASY LI	13916939170	easy.li@sha.ontime-express.com
	STANLEY GUI	17821430308	stanley.gui@sha.ontime-express.com
DONATE	DAISY SHI	13816796039	daisy.shi@sha.ontime-express.com
	ANGELA TIAN	13764915323	angela.tian@sha.ontime-express.com

cc-

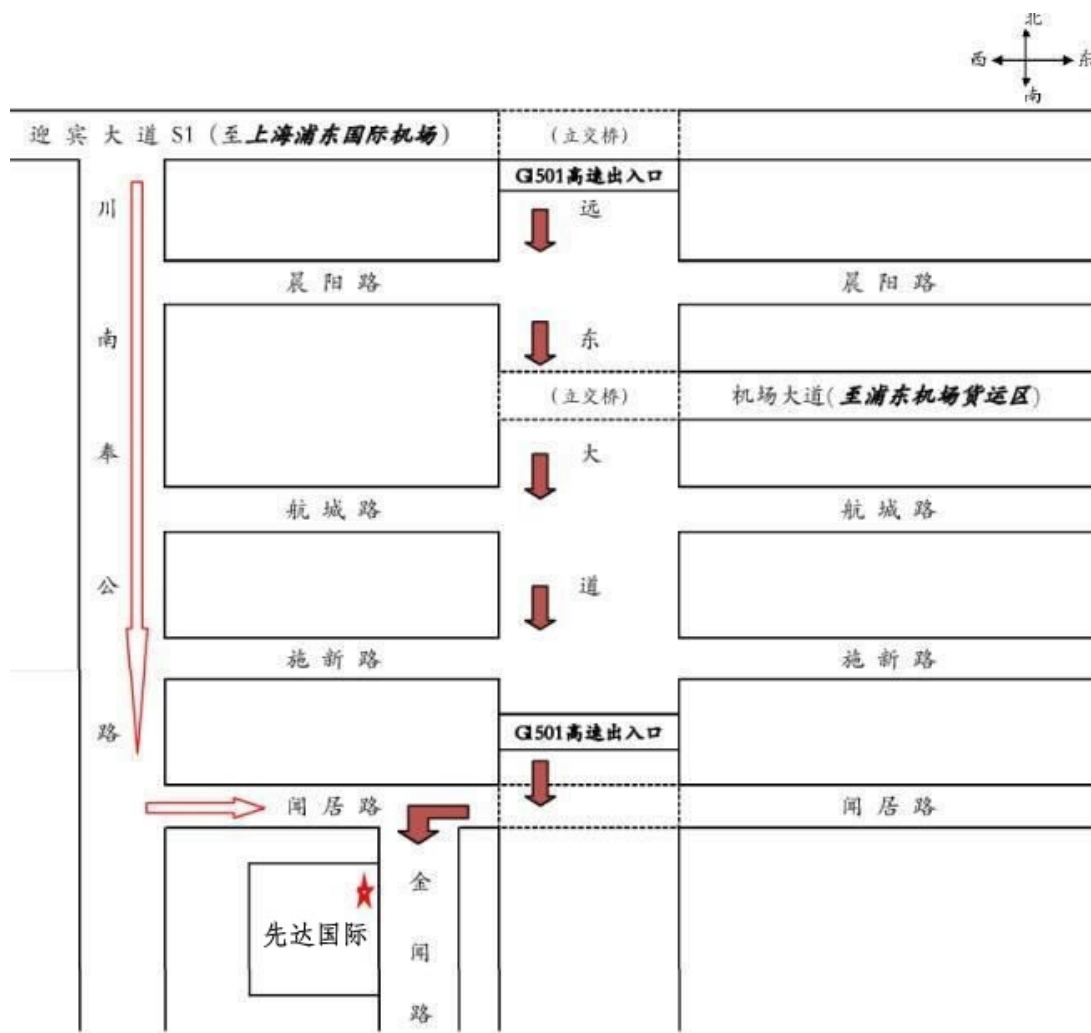
Maggie Ma - OTEL Shanghai maggie.ma@sha.ontime-express.com

Tony Wang tony.wang@bjs.ontime-express.com

Linda Lv linda.lv@bjs.ontime-express.com

Shanghai Warehouse Address

先达国际货运(上海)有限公司 空运普货进仓地图



仓库地址：上海浦东新区祝桥镇金闻路8号4幢仓库