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 (ON BEHALF OF “THE MASKS FOR NHS HEROES CHARITABLE TRUST”) – FACTORY = Anhui MedPurest Medical Technology Co., Ltd
Date	**23 April 2020**
Type of Goods	Isolation Gowns [EN13795]

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/Hicare-P1F-003
2. Date	23/04/2020
3. Buyer	**Department of Health and Social Care** 39 Victoria Street, London, SW1H 0EU UK
4. Supplier	P1F LIMITED (ON BEHALF OF “THE MASKS FOR NHS HEROES CHARITABLE TRUST”) – FACTORY = Anhui MedPurest Medical Technology Co., Ltd

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	As set out in the Purchase Order(s) at Annex A. Delivered in accordance with the following instructions: Delivered in accordance with the following instructions: Suppliers to send ADVANCE SHIPPING NOTICES to the following email address: nhsppebookings@clippergroup.co.uk 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 Contact Name: [redacted] Contact Number: [redacted] Email: [redacted] Date(s) of Delivery: as set out in the Purchase Order Form in Annex A.
7. Specification	The specification of the Deliverables is as set out in Annex B.
8. Term	The Term shall commence on placement of the Purchase Order 001 at Annex A. 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. 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.
9. Charges	The Charges for the Deliverables shall be set out in Annex A.
10. Payment	All invoices must be sent quoting a valid purchase order number to the following email address COVID-19FinanceOperations@dhsc.gov.uk. 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

<table>
<tr><td></td><td colspan="2">Payable section and send to the following email address COVID-19FinanceOperations@dhsc.gov.uk.</td></tr>
<tr><td>11. Buyer Authorised Representative(s)</td><td colspan="2">For general liaison your contact will continue to be:

Procurement.Operations@dhsc.gov.uk
Department of Health and Social Care
39 Victoria Street,
London,
SW1H 0EU,
UK</td></tr>
<tr><td>12. Seller's Authorised Representative(s)</td><td colspan="2">For general liaison your contact will continue to be

[redacted]

or, in their absence,

[redacted]</td></tr>
<tr><td>13. Address for notices</td><td>Buyer:

[redacted]
Department of Health and Social Care
39 Victoria Street, London, SW1H 0EU, UK</td><td>Supplier:

P1F LIMITED
(ON BEHALF OF "THE MASKS FOR NHS HEROES CHARITABLE TRUST")

Fieldfisher Riverbank House,
2 Swan Lane, London,
EC4R 3TT, UK</td></tr>
<tr><td>14. Key personnel</td><td>Buyer:

[redacted]
Department of Health and Social Care
39 Victoria Street, London, SW1H 0EU, UK</td><td>Supplier:

[redacted]
(Director, P1F Limited), and Trustee of "The Masks for NHS Heroes Charitable Trust"</td></tr>
<tr><td>15. Procedures and Policies</td><td colspan="2">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.</td></tr>
</table>

Signed by the authorised representative of THE AUTHORITY

Name:	[redacted]	Signature:	[redacted]
Position:	Deputy Director	Date	23/04/2020

Signed by the authorised representative of THE SUPPLIER

Name:	[redacted]	Signature	[redacted]
Position:	DIRECTOR OF P1F LIMITED, AND TRUSTEE OF "THE MASKS FOR NHS HEROES CHARITABLE TRUST "	Date	21ST APRIL 2020

P1F LIMITED
P1F
DESIGN DEVELOPMENT & INVESTMENT

Schedule 1

Key Provisions

Standard Key Provisions

1 Application of the Key Provisions

1.1 The standard Key Provisions at Clauses 1 to 6 of this Schedule 1 shall apply to this Contract.

1.2 The optional Key Provisions at Clauses 7 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 1.10 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:

[EN 13795]

CE Certificate number G2S 005447 0002 Rev. 00

MDD 93/42/EEC Annex V

[ISO 13485 : 2016]

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 12.1 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.

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

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

9.1 Either Party may terminate this Contract by issuing a Termination Notice to the other Party if such other Party commits a material breach of this Contract in circumstances where it is served with a valid Breach Notice having already been served with at least [two (2)] previous valid Breach Notices within the last twelve (12) calendar month rolling period as a result of any previous material breaches of this Contract which are capable of remedy (whether or not the Party in breach has remedied the breach in accordance with a Remedial Proposal). The twelve (12) month rolling period is the twelve (12) months immediately preceding the date of the [third] Breach Notice.

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

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

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

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

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

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

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

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

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

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

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

10.7 Each [***week/month/quarter/other agreed period***] the Authority shall take into use and purchase at the Contract Price at least the minimum quantity of Consigned Goods specified in the Order Form for such period (if any) ("**Minimum Quantity**"). If the Supplier fails to supply the Authority with any Consigned Goods required by the Authority (including, without limitation, where the Authority obtains substitute goods from a third party as a result), the Minimum Quantity for the period in question shall be reduced by the quantity of the Consigned Goods that the Supplier fails to supply. Except to the extent that the Authority's failure to purchase the Minimum Quantity during any given period is caused by the Supplier's default or a Force Majeure Event, if the Authority purchases less than the Minimum Quantity for a given period, the Supplier may charge the Authority for any shortfall between:

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

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

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

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

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

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

10.12 On the termination or expiry of this Contract for whatever reason, all Consigned Goods not taken into use by Authority as at the point of such termination or expiry shall be deemed Returned Goods. Such Returned Goods shall be deemed the subject of a Returns Notice that shall be deemed to have been received by the Supplier with a notice date the same as the date of the expiry or earlier termination of this Contract. Clauses 12.8 and 12.9 of this Schedule 1 shall then apply accordingly and this Clause, together with Clauses 12.8 and 12.9 23.9 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.

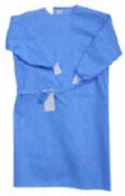
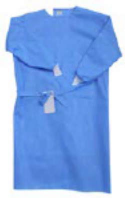
PURCHASE ORDER FORM No 001

Deliverables					
Item Number	**Item Specification**	**Delivery Schedule**	**Total Qty (units)**	**Firm Price (£) Ex VAT**	
				Per Item (GBP/unit) £	**Total £**
01	Gowns (Tranche 1)	14 days	[redacted]	£[redacted]	£[redacted]
02	Gowns (Tranche 2)	30 days	[redacted]	£[redacted] (subject to [20] % price tolerance revision)	£[redacted] (subject to [20] % price tolerance revision)
				Total	**£738,805.98**

Annex B – Technical Specification

Commodity, Quantity and Price:

RMB to GBP (21st April 2020) = 0.11

Item No	Trance	Description of Goods	Texture of material	Image	Size and Quantity pieces	Exw. Unit Price (RMB/GBP)	AMOUNT (RMB)
1.	Tranche 1 (weeks 1-2, delivery EXW every 7 days)	Isolation Gowns	Non-woven fabrics 45G		[redacted]	[redacted]	[redacted]
2.	Tranche 2 (weeks 3-4, delivery EXW every 7 days)	Isolation Gowns	Non-woven fabrics 45G		[redacted]	[redacted]	[redacted]
TOTAL : **SEVEN MILLION AND EIGHTY-FIVE THOUSAND CHINESE YUAN (SEVEN HUNDRED AND SEVENTY-NINE THOUSAND AND THREE HUNDRED AND FIFTY BRITISH POUNDS STERLING)* (** subject to [20]% price tolerance revision for Tranche 2)					[redacted]	[redacted]	[redacted] Tranche 2)

Remark on size: Isolation Gowns dimension (Unit: CM) Tolerance: ±3cm

Size	Length	Half bust width	Hem	Sleeve Length	Shoulder width	Waist ties	Half sleeve width	Collar	Knit cuff length	Knit cuff width
L	125	145	153	53	65.5	3.5*65	30	60	8	5.5

XL	130	150	158	55	68	3.5*65	31	61	8	5.5

Delivery Terms and Loading Schedule:

Tranche	Batch	Loading Date	Quantity	Delivery	Payment	Per unit price
1	1.1	29th April 2020*	[redacted]	EXW	50% (of total)	[redacted] [redacted]
	1.2	6th May 2020*	[redacted]	EXW		
2	2.1	13th May 2020*	[redacted]	EXW	50% (of total)	[redacted] [redacted] (+20% tolerance) – anything more new price negotiation
	2.2	20th May 2020*	[redacted]	EXW		
Total			[redacted]			
* subject to when contract executed and						

ZLG

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-BS-244.10.08

TÜV SÜD
Product Service

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

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 005447 0002 Rev. 00

Manufacturer	**Anhui MedPurest Medical Technology Co.,Ltd** Jia Bao Industrial Park 246000 Anqing, Anhui Province PEOPLE'S REPUBLIC OF CHINA
Facility(ies):	Anhui MedPurest Medical Technology Co.,Ltd Jia Bao Industrial Park, 246000 Anqing, Anhui Province, PEOPLE'S REPUBLIC OF CHINA
Product Category(ies):	**Sterile Surgical Gowns,** **Sterile Surgical Drapes,** **Sterile Surgical Packs**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.:	SH18131201
Valid from:	2018-10-30
Valid until:	2023-10-29

Date, 2018-10-30

[redacted]

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TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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

TÜV®

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

TÜV SÜD
Product Service

Certificate

No. Q6 005447 0001 Rev. 00

Holder of Certificate: **Anhui MedPurest Medical Technology Co.,Ltd**
Jia Bao Industrial Park
246000 Anqing, Anhui Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Anhui MedPurest Medical Technology Co.,Ltd
Jia Bao Industrial Park, 246000 Anqing, Anhui Province,
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
tuv-sud.com/ps-cert

Scope of Certificate: **Production and Distribution of**
Sterile Surgical Gowns,
Sterile Surgical Drapes,
Sterile Surgical Packs

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH18131201

Valid from: 2018-10-30
Valid until: 2021-10-29

Date, 2018-10-30

[redacted]

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

TÜV®

CQC

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate No. 00118Q3120[illegible]0S/3400

We hereby certify that

Anhui MedPurest Medical Technology Co., Ltd.

Unified Social Credit Code: [illegible]

D4-B-2 Building, Jiabao Industrial Park, Anqing City, Anhui Province, P.R.China

by reason of its

Quality Management System

has been awarded this certificate for compliance with the standard

GB/T 19001-2016 / ISO 9001:2015

The Quality Management System Applies in the following area:

Manufacturing Non-Woven Medical Supplies, Like Surgical Gown, Surgical Packs (Coverall, Drape and Spatula) and So On

Certified since: November 26, 2018 Valid from: November 26, 2018 Valid until: November 25, 2021

After a surveillance cycle, the certificate is valid only when used together with an Acceptance Notice of Surveillance Audit issued by CQC.
Please access www.cqc.com.cn for checking validity of the certificate.
This certificate and its relevant information can query in the website of Certification and Accreditation Administration of the People's Republic of China (www.cnca.gov.cn).

IAF CNAS

MANAGEMENT SYSTEM CNAS C001-M

Signed by: Wang Kejiao

IQNet

CHINA QUALITY CERTIFICATION CENTRE

Section 9, No.188, Nansihuanxilu South Fourth Ring Road West, Beijing 100070, China

Q 0133759 2015年版

Review Report –审查报告–검토 보고서– Rapport d'Evaluation

Form QAT_10-M04, version 00, effective since March 6th, 2020

CE Documentation Review

No. 4M200320.AHMP028

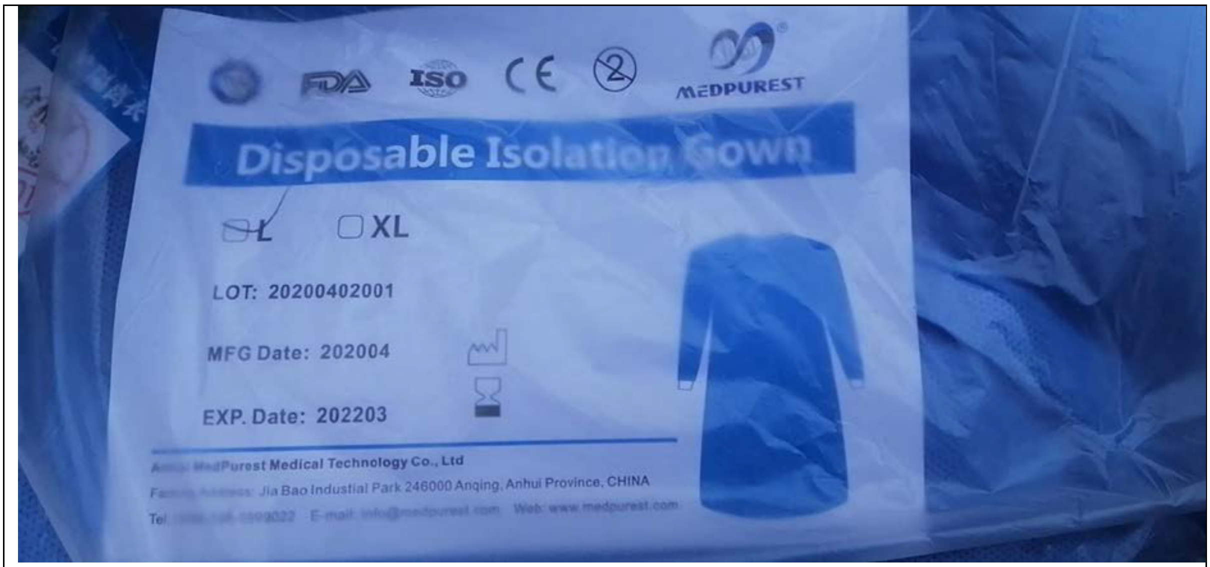
Holder:	Anhui Medpurest Medical Technology Co.,Ltd Jia Bao Industrial Park，Anqing，Anhui Province
Review goal:	Verification of the presence of the Technical File in regards of the Medical Devices Directive 93/42/EEC Annex VII
Product:	Class I medical protective isolation clothing **(no sterile)**
Model(s):	S、M、L、XL、XXL、XXXL
Classification:	Class I (no sterile) (accordingly to the Manufacturer's declaration)
Review output:	We attest that a Technical File in reference to the Directive 93/42/EEC is in place for the CE Marking process. Test Report identified with the no. BTS-20588M. This document has been issued on voluntary basis and not as NB. Whereas the Manufacturer is responsible and not exempted to carry out all the necessary activities, as required by the Directive, before placing the CE Mark on the product.

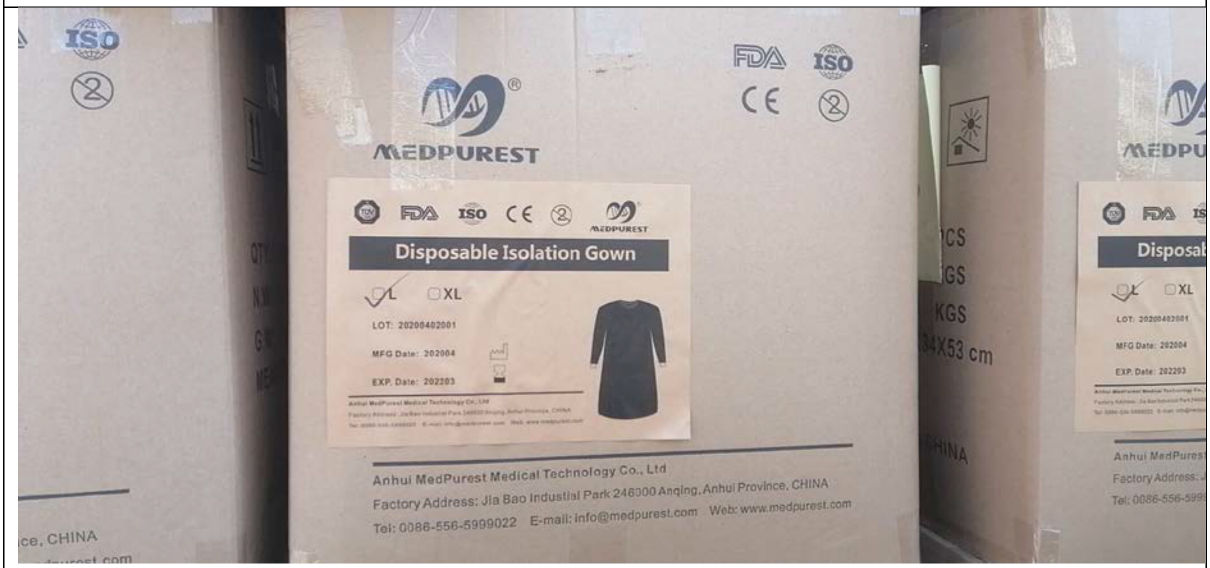
Issuance date: 20 March 2020
Expiry date:19 March 2025

Reviewer
Technical expert
Amanda Payne

Apporver
ECM Service Director
Luca Bedonni

Ente Certificazione Macchine
Via Cà Bella, 243 - 40053 Valsamoggia Loc. Castello di Serravalle (Bo) Italy
☎ +39.0516705141 🖶 +39.0516705156 ✉ info@entecerma.it www.entecerma.it


FDA ISO CE
MEDPUREST
Disposable Isolation Gown
L XL
LOT: 20200402001
MFG Date: 202004
EXP. Date: 202203
MedPurest Medical Technology Co., Ltd
Jia Bao Industial Park 246000 Anqing, Anhui Province, CHINA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Anhui MedPurest Medical Technology Co., Ltd
Factory Address: Jia Bao Industial Park 246000 Anqing, Anhui Province, CHINA
Tel: 0086-556-5999022 E-mail: info@medpurest.com Web: www.medpurest.com

TEST REPORT

No: 180201118

VERIFICATION WEBSITE: www.gtt.net.cn
VERIFICATION CODE: BYVJ-1453-34

DATE: 2018-07-05

APPLICANT: ANHUI MEDPUREST MEDICAL TECHNOLOGY CO., LTD
KMN COMPANY, LELING INDUSTRIAL PARK, YIXIU DISTRICT, ANQING CITY

TEN(10) REINFORCED GOWN
BRAND: 03
STYLE NO.: 2018060803
COLOR: BLUE
INGREDIENTS OF FIBRE: SMS NONWOVEN FABRIC
SIZE: 130X150cm
WEIGHT: 50g
MANUFACTURE'S NAME: ANHUI MEDPUREST MEDICAL TECHNOLOGY CO., LTD

DATE RECEIVED/DATE TEST STARTED: 2018-06-22 16:59

CONCLUSION:

CLEANLINESS-MICROORGNISM	M
THE RESISTANCE TO WET BACTERIAL PENETRATION	M
STATIC HYDROSTATIC RESISTANCE	M
BREAKING STRENGTH[DRY STATE]	M
BREAKING STRENGTH[WET STATE]	M
LINT AND OTHER PARTICLES GENERATION IN THE DRY STATE	M
CLEANLINESS-PARTICULATE MATTER	M
BURSTING STRENGTH[DRY STATE]	M
BURSTING STRENGTH[WET STATE]	M

NOTE: "M"-MEET CLIENT'S REQUIREMENT "F"-BELOW CLIENT'S REQUIREMENT
"—"-NO COMMENT "N"-HALF GRADE LOW "L"-ONE GRADE LOW

REMARK:
IN THIS REPORT, THE SAMPLES ARE TESTED UNDER PRESCRIBED ENVIRONMENTAL CONDITIONS IN THE CORRESPONDING STANDARDS UNLESS OTHERWISE NOTED.
COPIES OF THE REPORT ARE VALID ONLY RE-STAMPED.
THE EXPERIMENT WAS CARRIED OUT AT No. 1-2, ZHUJIANG ROAD, CHAOTIAN INDUSTRIAL ZONE, SHILOU TOWN, PANYU DISTRICT, GUANGZHOU

检验检测专用章

AUTHORIZED SIGNATORY:
冯文
Wen Feng SENIOR ENGINEER

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GTT

TEST REPORT

No: 180201118

CLEANLINESS-MICROORGNISM

(EN ISO 11737-1:2006/AC:2009, MEMBRANE FILTRATION METHOD)

		REQUIREMENT
	TOTAL 1 CFU/100cm²	TOTAL ≤300 CFU/100cm² (BS EN 13795:2011+A1:2013)

THE RESISTANCE TO WET BACTERIAL PENETRATION

(EN ISO 22610:2006, TEMP:21℃ RH:65%, THE DISTANCE OF AGAR TO PLATES BRIM:3mm, CARRIER MATERIAL:30mm POLYURETHANE (PU))

		REQUIREMENT
THE BARRIER INDEX 4.7		THE BARRIER INDEX ≥2.8 (BS EN 13795:2011+A1:2013)

STATIC HYDROSTATIC RESISTANCE

(BS EN 13795:2011+A1:2013 ANNEX B.5, PRESSURE RATE:10cmH₂O/min, TEMPERATURE OF THE WATER:20.0℃, FACE SIDE TESTED)

		REQUIREMENT
	33.8cmH₂O	≥20cmH₂O (BS EN 13795:2011+A1:2013)

BREAKING STRENGTH[DRY STATE]

(EN 29073-3:1992, STRIP METHOD, DRY STATE, THE DISTANCE BETWEEN THE CLAMPS:200mm, RATE:100mm/min)

		REQUIREMENT
LENGTH	89.0N	≥20N
WIDTH	53.9N	≥20N
		(BS EN 13795:2011+A1:2013)

BREAKING STRENGTH[WET STATE]

(EN 29073-3:1992, STRIP METHOD, WET STATE, THE DISTANCE BETWEEN THE CLAMPS:200mm, RATE:100mm/min)

		REQUIREMENT
LENGTH	86.7N	≥20N
WIDTH	54.3N	≥20N
		(BS EN 13795:2011+A1:2013)

LINT AND OTHER PARTICLES GENERATION IN THE DRY STATE

(BS EN 13795:2011+A1:2013 ANNEX B.1 SIZE OF PARTICLES COUNTED:3μm~25μm)

		REQUIREMENT
TOTAL LINTING:		
A: FACE	79	
B: FACE	81	
AVERAGE	82	
COEF OF LINTING:		COEF OF LINTING ≤4.0 (BS EN 13795:2011+A1:2013)
A: FACE	1.9	
B: FACE	1.9	
AVERAGE	1.9	

CLEANLINESS-PARTICULATE MATTER

(BS EN 13795:2011+A1:2013 ANNEX B.3, SIZE OF PARTICLES COUNTED:3μm~25μm)

		REQUIREMENT
IPM:		IPM ≤3.5 (BS EN 13795:2011+A1:2013)
A: FACE	1.8	
B: FACE	1.8	
AVERAGE	1.8	

检验检测专用章

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TEST REPORT

No:18020[illegible]1118

BURSTING STRENGTH[DRY STATE]

(ISO 13938-1:1999,HYDRAULIC METHOD,DRY STATE,TEST AREA:7.3cm²)

BURSTING STRENGTH 97.2kPa

REQUIREMENT
BURSTING STRENGTH ≥40kPa
(BS EN 13795:2011+A1:2013)

BURSTING STRENGTH[WET STATE]

(ISO 13938-1:1999,HYDRAULIC METHOD,WET STATE,TEST AREA:7.3cm²)

BURSTING STRENGTH 120.[illegible]kPa

REQUIREMENT
BURSTING STRENGTH ≥40kPa
(BS EN 13795:2011+A1:2013)

GTTC

检验检测专用章

——End of Report——

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