DHSC Terms and Conditions for the Supply of Goods

The Authority	**Department of Health and Social Care** 39 Victoria Street, London, SW1H 0EU
The Supplier	**P14 Medical Limited** The Plaza, 100 Old Hill Street, Liverpool, L3 9QL **Registered Company Number: 10911187**
Date	
Type of Goods	**Personal Protective Equipment - Isolation Gowns**

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

<table>
<tr><td>1. Contract Reference</td><td>DHSE/1838B</td></tr>
<tr><td>2. Date</td><td></td></tr>
<tr><td>3. Buyer</td><td>Department of Health and Social Care, 39 Victoria Street, London, SW1H 0EU</td></tr>
<tr><td>4. Supplier</td><td>P14 Medical Limited, The Plaza, 100 Old Hill Street, Liverpool, L3 9QL

Registered Company Number: 10911187</td></tr>
<tr><td>5. The Contract</td><td>The Supplier shall supply the deliverable described below on the terms set out in this Order Form and the Schedules and Annex A.

Unless the Contract otherwise requires, capitalised expressed used in this Order Form have the same meanings as in Schedule 3.

In the event of any conflict between this Order Form and the Schedules, this Order Form shall prevail.

Please do not attach any supplier terms and conditions to this Order Form as they will not be accepted by the Buyer and may delay conclusion of the Contract.</td></tr>
<tr><td>6. Deliverables</td><td>The deliverables/delivery dates are as set out in the Purchase Order(s) at Annex A and as follows:

<table>
<tr><th colspan="2">SIZE</th></tr>
<tr><td>Small</td><td>20%</td></tr>
<tr><td>Medium</td><td>20%</td></tr>
<tr><td>Large</td><td>20%</td></tr>
<tr><td>XL</td><td>20%</td></tr>
<tr><td>XXL</td><td>20%</td></tr>
</table>

The NPC Codes are as follows:

<table>
<tr><th colspan="2">NPC</th></tr>
<tr><td>Small</td><td>GCIINS0100</td></tr>
<tr><td>Medium</td><td>GCIINS0101</td></tr>
<tr><td>Large</td><td>GCIINS0102</td></tr>
<tr><td>XL</td><td>GCIINS0103</td></tr>
<tr><td>XXL</td><td>GCIINS0104</td></tr>
</table>

Delivered in accordance with the following instructions:

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 address:</td></tr>
</table>

	Xinle Huabao Medical Products Co., Ltd. *Cheng'an Industrial Park, Xinle City, Henei Province,* *China 050701* The supplier will submit Advance Shipping Notices to the following email address: nhsppebookings@clippergroup.co.uk Please include the following detail within the notice: • Supplier Name (and code) • Purchase Order No. • Part No. / NPC Code (NHS specific code) • Product Description (as complete as possible, ideally as 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	The Term shall commence on on placement of Purchase Order 001 at Annex A. And the Expiry Date shall be 24 months after placement of Purchase Order 001 at Annex A, 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 the Purchase Order(s) in Annex A.
10. Payment	All invoices must be emailed quoting a valid purchase order number to the following email address COVID-19FinanceOperations@dhsc.gov.uk. Payments shall be as followed: 1. The Authority agrees to pay the Supplier the value of the Goods as set out in Line 01A of the Purchase Order Form 001 at Annex A (50% of Batch 01 order value) upon the commencement of this Contract and presentation of a valid invoice. 2. Upon presentation of a valid invoice and accompanying

	collection confirmation from the Authority's agent; the Authority agrees to pay Lines 01B, 01C, 01D, 01E and 01F as set out in Purchase Order 001 at Annex A. 3. The Authority agrees to pay the Supplier the value of the Goods as set out in Line 02A of the Purchase Order Form 001 at Annex A (50% of Batch 02 order value) on 10/06/2020 following delivery and acceptance of Batch 01B. 4. Upon presentation of a valid invoice and accompanying collection confirmation from the Authority's agent; the Authority agrees to pay Lines 02B, 02C, 02D and 02E as set out in Purchase Order 001 at Annex A. 5. The Authority agrees to pay the Supplier the value of the Goods as set out in Lines 03 of the Purchase Order Form 001 at Annex A (50% of Batch 03 order value) on 10/07/2020 following delivery and acceptance of Batch 02B. 6. Upon presentation of a valid invoice and accompanying collection confirmation from the Authority's agent; the Authority agrees to pay Lines 03B, 03C, 03D and 03E as set out in Purchase Order 001 at Annex A. 7. The Authority agrees to pay the Supplier the value of the Goods as set out in Lines 04 of the Purchase Order Form 001 at Annex A (50% of Batch 04 order value) on 10/08/2020 following delivery and acceptance of Batch 03B. 8. Upon presentation of a valid invoice and accompanying collection confirmation from the Authority's agent; the Authority agrees to pay Lines 04B and 04C as set out in Purchase Order 001 at Annex A. Within 10 Business Days of receipt of your countersigned copy of the Contract, we will send you a unique Purchase Order number (the **"PO Number"**). You must in receipt of a valid PO Number before submitting an invoice. To avoid delay in payment it is important that the invoice is compliant and that it includes a valid PO Number, PO item number (if applicable) and the details (name and telephone number) of your Buyer contact (i.e. Contract Manager). Non-compliant invoices will be sent back to you, which may lead to a delay in payment. If you have a query regarding an outstanding payment, please contact us by email, marking for the attention of our Accounts Payable section and send to the following email address COVID-19FinanceOperations@dhsc.gov.uk.
11. Buyer Authorised	For general liaison your contact will continue to be

Representative(s)	**Department of Health and Social Care** 39 Victoria Street, London, SW1H 0EU	
12. Seller's Authorised Representative(s)	For general liaison your contact will continue to be: [redacted]	
13. Address for notices	**Buyer:** **Department of Health and Social Care** 39 Victoria Street, London, SW1H 0EU	**Supplier:** **P14 Medical Limited** The Plaza, 100 Old Hill Street, Liverpool, L3 9QL [redacted]
14. Key personnel	**Buyer:** **Department of Health and Social Care** 39 Victoria Street, London, SW1H 0EU	**Supplier:** **P14 Medical Limited** The Plaza, 100 Old Hill Street, Liverpool, L3 9QL [redacted]
15. Procedures and Policies	The Buyer may require the Supplier to ensure that any person employed in the delivery of the Deliverables has undertaken a Disclose and Barring Service check. The supplier shall ensure that no person who discloses that he/she has a conviction that is relevant to the nature of the Contract, relevant to the work of the Buyer, or is of a type otherwise advised by the Buyer (each such conviction a "**Relevant conviction**"), or is found by the Supplier to have a Relevant Conviction (whether as a result of a police check, a Disclosure and Barring Service check or otherwise) is employed or engaged in the provision of any part of the Deliverables.	

Signed by the authorised representative of THE AUTHORITY

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

Signed by the authorised representative of THE SUPPLI[redacted]

Name:	[redacted]	Signature	[redacted]
Position:	Managing Director	Date	20th 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 1.10 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 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.Error! Reference source not found.**12.4 (i) of **Error! Reference source not found.Error! Reference source not found.**Schedule 2.

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

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

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

7.1 The Authority's rights and remedies under Clause **Error! Reference source not found.Error! Reference source not found.**4.6 of **Error! Reference source not found.Error! Reference source not found.**Schedule 2 shall cease [12 months] from the date of delivery of the relevant Goods.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10.7 Each [***week/month/quarter/other agreed period***] the Authority shall take into use and purchase at the Contract Price at least the minimum quantity of Consigned Goods specified in the Order Form for such period (if any) ("**Minimum Quantity**"). If the Supplier fails to supply the Authority with any Consigned Goods required by

the Authority (including, without limitation, where the Authority obtains substitute goods from a third party as a result), the Minimum Quantity for the period in question shall be reduced by the quantity of the Consigned Goods that the Supplier fails to supply. Except to the extent that the Authority's failure to purchase the Minimum Quantity during any given period is caused by the Supplier's default or a Force Majeure Event, if the Authority purchases less than the Minimum Quantity for a given period, the Supplier may charge the Authority for any shortfall between:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Regulatory Requirements

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

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

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

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

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

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

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

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

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

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

Goods bought to the market before 21 April 2019

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

Other Specific Requirements

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

SCHEDULE OF REQUIREMENTS FOR THE SUPPLY OF DHSE/1838A

Deliverables					
Item Number	Specification	Delivery Schedule	Total Qty	Firm Price (£) Ex VAT	
				Per Item	Total £
01A	Isolation Gowns – Batch 01A - 50% of Batch 01 order value to be paid on contract	N/A	[redacted]		
01B	Isolation Gowns – Batch 01B - Payment on shipping	06/06/2020			
01C	Isolation Gowns – Batch 01C - Payment on shipping	12/06/2020			
01D	Isolation Gowns – Batch 01D - Payment on shipping	19/06/2020			
01E	Isolation Gowns – Batch 01E - Payment on shipping	26/06/2020			
01F	Isolation Gowns – Batch 01F - Payment on shipping	03/07/2020			
02A	Isolation Gowns – Batch 02A - 50% of Batch 02 order value to be paid on 10/06/2020 following delivery and acceptance of Batch 01B	N/A			
02B	Isolation Gowns – Batch 02B - Payment on shipping	10/07/2020			
02C	Isolation Gowns – Batch 02C - Payment on shipping	17/07/2020			
02D	Isolation Gowns – Batch 02D - Payment on shipping	24/07/2020			
02E	Isolation Gowns – Batch 02E - Payment on shipping	31/07/2020			
03A	Isolation Gowns – Batch 03A - 50% of Batch 03 order value to be paid on 10/07/2020 following delivery and acceptance of Batch 02B	N/A	N/A	N/A	£24,724,000.00
03B	Isolation Gowns – Batch 03B - Payment on shipping	07/08/2020	[redacted]		£6,181,000.00

03C	Isolation Gowns – Batch 03C - Payment on shipping	12/08/2020	[redacted]	
03D	Isolation Gowns – Batch 03D - Payment on shipping	19/08/2020		
03E	Isolation Gowns – Batch 03E - Payment on shipping	25/08/2020		
04A	Isolation Gowns – Batch 04A - 50% of Batch 04 order value to be paid on 10/08/2020 following delivery and acceptance of Batch 03B	N/A		
04B	Isolation Gowns – Batch 04B - Payment on shipping	31/08/2020		
04C	Isolation Gowns – Batch 04C - Payment on shipping	06/09/2020		
		TOTALS	[redacted]	**£156,291,000.00**

CE

EC Declaration of Conformity

CE

according to the Medical Devices Directive 93/42/EEC

Class I Medical Device

(non-sterile, non-measuring function)

Manufacturer:	Xinle Huahao Medical Products Co.,Ltd
Address:	Dongguan, Cheng, an Town, Xinle City, Hebei Province, 050701,China
EC Representative:	Wellkang Ltd Suite B, 29 Harley Street, London W1G 9QR, UK

We, the manufacturer, declare under our sole responsibility that

the medical device(s)	Product Name	:	**Isolation Gowns**
	Type/model, identification of product allowing traceability (Where applicable)	:	**A-S、A-M、A-L、A-XL、A-XXL B-S、B-M、B-L、B-XL、B-XXL C-S、C-M、C-L、C-XL、C-XXL**
of class	according to annex IX of directive 93/42/EEC	:	**Class I**

is/are in conformity with the relevant provisions and requirements of directive 93/42/EEC, as amended by Directive 2007/47/EC.

Applied harmonised standards, national standards or other normative documents	EN 980:2008	EN 1041:2008
	EN ISO 14971:2012	EN ISO 10993-1:2009/AC:2010
	EN ISO 10993-5:2009	EN ISO 10993-10:2013
	EN 62366:2008	EN 13795-1:2002+A1:2009
	EN 13795-2:2004+A1:2009	EN 13795-3:2006+A1:2009
Conformity assessment procedure	**Module A (EC Declaration of Conformity (Annex VII) + Technical Files)**	
Notified Body (name & number) Certificate & number	**NOT applicable**	

Signed this Day/ 18 of Month/ Aug of Year/ 2016 , Place (Beijing), PR China

Signature (on behalf of the manufacturer) :

Name of authorized signatory:

Position held in the company:

General Manager

Official Seal

第一类医疗器械生产备案凭证

备案编号：冀石食药监械生产备20190021号

企业名称	新乐华宝医疗用品有限公司		
住　所	新乐市承安镇东关		
生产地址	新乐市承安镇东关		
法定代表人	刘敏奇	企业负责人	刘敏奇
生产范围	2002分类目录 I类:6864-1-防护用品 2017分类目录 I类:14-14-医护人员防护用品		

生产产品列表	产品名称	产品备案号	登载日期	备注
	一次性使用隔离衣	冀石械备20190072号	2019-11-08	

备案部门（公章）：河北省石家庄市行政审批局

备案日期：2019年11月8日

CE Technical Documentation Review Report

TÜVRheinland®

Applicant:	**XINLE HUABAO MEDICAL PRODUCTS CO.,LTD** Dongguan, Cheng'an Town, Xinle City, Hebei Province,050701,China
Report Number:	**16806072.001**
Examination intent:	Examination the completeness of the Technical Documentation according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII
Product(s):	Please see attachment
Type(s)/Model(s):	Please see attachment
Classification:	Class I (according to manufacturer's declaration)
Examination period:	Aug.18.2016
Date of expiry:	Aug.17.2021
Review result:	During the examination of the provided Technical Documentation (No.: Q/HBMP06.36-2015, Revision: A/1, dated 2015-04-20), no Non-compliance according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII was detected.

TÜV Rheinland (China) Ltd

Yuhong CHEN
Manager
Medical Services

Safety • Quality Assurance TÜV Rheinland Approved

Rev.01, 2002-10-10

Unit 707, AVIC Bldg., No. 10B, Central Road, East 3rd Ring Road, Chaoyang District, Beijing, 100022, P.R.China
Tel: (8610)6566 6660 Fax: (8610)6566 6667
e-mail: info@bj.chn.tuv.com Internet: http://www.chn.tuv.com

CE Technical Documentation Review Report

TÜVRheinland®

Attachment to

Report Number: **16806072.001**

Applicant: **XINLE HUABAO MEDICAL PRODUCTS CO.,LTD**
Dongguan, Cheng'an Town, Xinle City, Hebei Province, 050701,China

Product(s): **non-sterile non-woven products**
(Surgical Gowns, Surgical Drapes, Table Covers, Isolation Gowns, Coveralls, Patient Shorts, Dental Bibs, Mayo Covers, CSR Wraps, Caps, Bed Sheets, Bed Covers, Sleeve Covers, Pillow Covers, Face Masks, Examination Sheets, Shoe Covers)

non-sterile non-woven and PE composited products
(Surgical Gowns, Surgical Drapes, Table Covers, Isolation Gowns, Coveralls, Patient Shorts, Dental Bibs, Mayo Covers, CSR Wraps, Caps, Bed Sheets, Bed Covers, Sleeve Covers, Pillow Covers, Examination Sheets, Shoe Covers)

non-sterile PE products
(Surgical Gowns, Surgical Drapes, PE Gowns, Table Covers, Isolation Gowns, Coveralls, Patient Shorts, Dental Bibs, Mayo Covers, CSR Wraps, Caps, Bed Sheets, Bed Covers, Sleeve Covers, Pillow Covers, Examination Sheets, Shoe Covers)

non-sterile paper products
(Dental Bibs, Bed Sheets, Examination Sheets)

non-sterile PE and paper composited products
(Dental Bibs, Bed Sheets, Examination Sheets)

Type(s)/Model(s): Please see above

Examination period: Aug.18.2016

Date of expiry: Aug.17.2021

TÜV Rheinland (China) Ltd.

Yuhong CHEN
Manager
Medical Services

Product Safety • Quality Assurance TÜV Rheinland Approved

Rev 01, 2002-10-10

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Test Report No.: 721616476-1
Report Date: 4 September 2014

ORIGINAL

SUBJECT	**Resistance To Wet Microbial Penetration Test**
TEST LOCATION	**TÜV SÜD China** TÜV SÜD PSB Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	**Xinle Huabao Medical Products Co., Ltd.**
CLIENT ADDRESS	Cheng'an Industrial Park, Xinle City, Hebei Province, China 050701
TEST PERIOD	25-Aug-2014~29-Aug-2014

Prepared By

(Zhu Yichen)
Customer Service

Authorized By

(Spark Shi)
Technical Manager

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

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ORIGINAL

Resistance To Wet Microbial Penetration Test

1. **Purpose**

   For evaluation of resistance to wet bacterial penetration.

2. **Sample description was given by the client**

   PE COATED WITH NONWOVEN FABRIC TYPE: 55gsm (STERILE)

3. **Reference**

   EN 13795:2011+A1:2013
   EN ISO 22610:2006

4. **Apparatus and materials**

   4.1 *Staphylococcus aureus* ATCC 29213
   4.2 Peptone water
   4.3 Nurient agar plates (14cm diameter)
   4.4 Carrier material: PU film (30μm thickness)
   4.5 Covering material: HDPE film
   4.6 Cylindrical body
   4.7 RULLA 2 Wet-Penetration-Test
   4.8 Oven

5. **Test specimen**

   5.1 Sample had been sterilized. Cut 5 test specimens 25cm×25cm under aseptic conditions.

6. **Procedure**

   6.1 Preparation
   6.1.1 Six petri dishes, 14cm in diameter, were filled with nutrient agar to (3±0.2)mm from the brim.
   6.1.2 Preparation of donor: Evenly distribute 1.0mL of the *Staphylococcus aureus* suspension with a concentration of 1.5×10^4 CFU/mL over an area corresponding to the lid of the agar plate of the carrier. Dry the donor at 56°C for approximately 30min.
   6.2 Place the first agar plate on the turntable.
   6.3 Put a test specimen on the ring, and put the donor, contaminated side down, on the specimen. Cover the PU film with a piece of HDPE film, then push the outer ring down firmly so that the three materials were securely held between the two rings.
   6.4 With the materials slightly slack, place the ring on the first lidless agar plate, such that the steel ring hangs freely outside the turntable. Apply the finger to the HDPE film just inside the brim in such a way that the test specimen comes into contact with the agar surface. Run the test as described for 15min with a finger pressure of 3N.
   6.5 After 15min, remove the ring and the assemblage immediately and retain.
   6.6 Remove the first agar plate from the turntable and seal it with its lid. Immediately put the second agar plate on the turntable, together with the retained ring assemblage.
   6.7 Perform the above-mentioned procedure on the same test assemblage using the next four plates.

   6.8 When five plates have been tested, remove and discard the donor, turn the test specimen upside down and cover it with the HDPE film.

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6.9 Run the sixth plate for 15min on the first replicate to complete the test run.
6.10 Repeat the procedure 6.2 to 6.9 for each of the other four test specimen, using a freshly prepared donor with each test specimen.
6.11 If liquid had accumulated on the agar surface, dry the plate(s) on a clean beach and incubate the six agar plates with their lids on for 48h at 35°C.
6.12 Count the colonies of *Staphylococcus aureus* on each plate. Disregard the count in the area with a radius of 15mm around the centre of the plate.

7. Calculation

7.1 The estimated bacterial challenge, T, was calculated as follows:
$T = Z+X_1+X_2+X_3+X_4+X_5$
Where
Z is the number of colonies from the top side of the test specimen that are left over after the five agar plates have been run, measure on the sixth agar plate (plate 6);
$X_1,\cdots,X_5$ are the numbers of colonies on the 5 plates in one replicate test, using the same test specimen and donor.

7.2 The cumulative penetration ratio of plates 1 to 5, $R_{CUM1},\cdots,R_{CUM5}$, was calculated as follows:

$$R_{CUM1}=\frac{X1}{T}$$

$$R_{CUM2}=\frac{(X1+X2)}{T}$$

$$R_{CUM3}=\frac{(X1+X2+X3)}{T}$$

$$R_{CUM4}=\frac{(X1+X2+X3+X4)}{T}$$

$$R_{CUM5}=\frac{(X1+X2+X3+X4+X5)}{T}$$

7.3 Barrier index, I_B, was calculated as follows:
$I_B=6-(R_{CUM1}+R_{CUM2}+R_{CUM3}+R_{CUM4}+R_{CUM5})$

8. Test results

Test Items*			Test Results					Test Methods
			1	2	3	4	5	
Resistance to Microbial Penetration-Wet	Test time \(CFU)	15 min	0	0	0	0	0	EN ISO 22610:2006
		30 min	0	0	0	0	0	
		45 min	0	0	0	0	0	
		60 min	0	0	0	0	0	
		75 min	0	0	0	0	0	
		Donor	6	7	10	73	266	
	Barrier Index, I_B	Individual	6.000	6.000	6.000	6.000	6.000	
		Mean	6.000					

Note1: Suspension Conc.:1.5×10^4 CFU/ml.

Note2:* denotes this test was carried out by external laboratory assessed as competent.

-END OF THE TEST REPORT-

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Test Report No.: 721616476-2
Report Date: 4 September 2014

ORIGINAL

SUBJECT	**Bursting Strength Test in Dry and Wet State**
TEST LOCATION	**TÜV SÜD China** TÜV SÜD PSB Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	**Xinle Huabao Medical Products Co., Ltd.**
CLIENT ADDRESS	Cheng'an Industrial Park, Xinle City, Hebei Province, China 050701
TEST PERIOD	25-Aug-2014~29-Aug-2014

Prepared By

(Zhu Yichen)
Customer Service

Authorized By

(Spark Shi)
Technical Manager

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

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ORIGINAL

Bursting Strength Test in Dry and Wet State

1. Purpose

For evaluation of bursting strength in dry and wet state.

2. Sample description was given by the client

PE COATED WITH NONWOVEN FABRIC TYPE: 55gsm (STERILE)

3. Reference

EN 13795:2011+A1:2013
EN ISO 13938-1:1999
EN 29073-3:1992

4. Apparatus

Mullen Burst Tester: a test area of 8 cm^2 (32mm diameter), a constant rate of increase in volume of (95±5)cm^3/min.

5. Test specimen

5.1 Take test specimens from the critical area and non-critical area as requested by client.
5.2 Cut 10 critical area test specimens and 5 non critical area specimens which are at least 15cm×15cm.
5.3 Prior to testing the dry test specimens were conditioned at (20±2)℃ and (65±5)% relative humidity for at least 4 hours.
5.4 For wet test, soak the test specimens for 1h in a solution containing 1g of non-ionic wetting agent per liter of distilled water. Prior to testing the wet test specimens were not conditioned.

6. Procedure

6.1 For dry test
6.1.1 Ensure that the test machine was reset, with the diaphragm flat and the maximum pressure indicator was set to zero.
6.1.2 Place the test specimen face side up and over the diaphragm so that it lay in a flat tensionless condition, avoiding distortion in its own plane. Clamp it securely in the circular holder, avoiding jaw damage, to prevent slippage during the test. For sleeve seam, put the seam on the central line.
6.1.3 Apply pressure to the test specimen until the test specimen bursts. Immediately after burst, reverse the apparatus to starting position. Record the bursting pressure.
6.1.4 Examine the test specimen. If the test specimen bursts close to the edge of the clamping device or the test specimen slipped in the clamp then discard the results and repeat the test with another test position.
6.1.5 Repeat the procedure 6.1.1 to 6.1.4 for each of the other four test specimens.
6.2 For wet test
Remove a test sample from the water, placing it on blotting paper to remove excess water. Immediately perform the test according to 6.1.

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7. Calculation

Because the individual bursting pressure values of each specimen were not similar, the individual result of each specimen was used and the mean of the five bursting pressure values did not calculated.

8. Test results

Test Items*			Test Results	Test Methods
Bursting Strength (kPa)	Dry	1	137.9	EN ISO 13938-1:1999
		2	206.9	
		3	172.4	
		4	172.4	
		5	206.9	
	Wet	1	206.9	
		2	206.9	
		3	172.4	
		4	172.4	
		5	172.4	

Note1:* denotes this test was carried out by external laboratory assessed as competent.

-END OF THE TEST REPORT-

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Test Report No.: 721616476-3
Report Date: 4 September 2014

ORIGINAL

SUBJECT	**Cleanliness of Microbial Test**
TEST LOCATION	**TÜV SÜD China** TÜV SÜD PSB Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	**Xinle Huabao Medical Products Co., Ltd.**
CLIENT ADDRESS	Cheng'an Industrial Park, Xinle City, Hebei Province, China 050701
TEST PERIOD	25-Aug-2014~29-Aug-2014

Prepared By

(Zhu Yichen)
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Authorized By

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Technical Manager

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

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Cleanliness of Microbial Test

1. Purpose

For determination of a population of microorganisms (Facultative, non-fastidious, aerobic bacteria; Yeasts and moulds).

2. Sample description was given by the client

PE COATED WITH NONWOVEN FABRIC TYPE: 55gsm (NON-STERILE)

3. Reference

EN 13795:2011+A1:2013
EN ISO 11737-1:2006

4. Apparatus and materials

4.1 Stomacher (BagMixer400)
4.2 Stomacher bag
4.3 Eluent: Buffered peptone water
4.4 Tryptone soya agar (TSA)
4.5 Sabouraud dextrose agar (SDA)
4.6 Filtration equipment
4.7 Sterilized membrane (0.45μm)

5. Test specimen

5.1 Take a total of 6 test specimens.(Each sample was taken 2 test specimen. One test specimen for Facultative, non-fastidious, aerobic bacteria and one test specimen for Yeasts and moulds.)
5.2 Cut a test specimen 100mm×100mm under aseptic condition.

6. Procedure

6.1 Bioburden test
- 6.1.1 Cut a test specimen into small pieces, and enclose in a stomacher bag under aseptic conditions.
- 6.1.2 Pour into 100mL eluent (buffered peptone water) and process 3min in a stomacher individually by highest speed. Filtrate the eluent by membrane filter.
- 6.1.3 Individually, membrane filters were put on TSA and incubated 5d at 35°C for Facultative, non-fastidious, aerobic bacteria, and on SDA 7d at 25°C for Yeasts and moulds.
- 6.1.4 Test 3 test specimens for Facultative, non-fastidious, aerobic bacteria. And test 3 test specimens for Yeasts and moulds.

6.2 Recovery efficiency test
- 6.2.1 Take one test specimen from Facultative, non-fastidious, aerobic bacteria and one test specimen from for Yeasts and moulds.
- 6.2.2 Repetitive treatment as bioburden test four times.
- 6.2.3 Finally, coating the surface of test specimens with molten medium (TSA and SDA), allowing the media to solidify and exposing the test specimens to specified culture conditions.

6.3 The colonies formed on incubation were counted.

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7. Calculation

Treatment	TSA	SDA
1	1	2
2	0	0
3	0	0
4	0	0
Agar overlay	0	0
Total colony count	1	2

7.1 Recovery efficiency (%)= $\frac{\text{Number recovered by first treatment}}{\text{Total number recovered}} \times 100$

7.2 Correction factor= $\frac{100}{\text{Recovery efficiency (\%)}}$

Items	B	F
Recovery efficiency (%)	100.0	100.0
Correction factor	1.0	1.0

Note: B= Facultative, non-fastidious, aerobic bacteria
F= Yeasts and moulds

7.3 Bioburden=Number recovered by first treatment × Correction Factor

8. Test results

Test Items*	Test Results			Test Methods
	Specimen 1	Specimen 2	Specimen 3	
Facultative, non-fastidious, aerobic bacteria (CFU/100cm^2)	1	3	<1	EN ISO 11737-1:2006 B.2.2.1/B.4.2
Yeasts and moulds (CFU/100cm^2)	2	1	4	

Note1:* denotes this test was carried out by external laboratory assessed as competent.

-END OF THE TEST REPORT-

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