# REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Denumire	Declaratia de conformitate
	te
	mita
	outo
	ge C
	ația (
	Declarația de conformi
	. De
Ë	G 52

AGENTIA MEDICAMENTULUI SI DISPOZITIVELOR MEDICALE

-	
-	
10.3	
	₹
10.0	
0.00	
2.0	
400	
H	
466	
100	
-	
100	
100	
1	
-	W.

Reprezentant 🚫 Ordin	e>	MEDEFERENT Rg04-000192 GRUP S.R.L.	MEDEFERENT Rg04-000192 GRUP S.R.L.	MEDEFERENT Rg04-000192 GRUP S.R.L.	MEDEFERENT Rg04-000192 GRUP S.R.L.	MEDEFERENT R004-000192
Producatorul 📀 Re	BLUE SAIL MEC 💎 mede	BLUE SAIL ME MEDICAL CO., GR LTD.	BLUE SAIL ME MEDICAL CO., GR LTD.	BLUE SAIL MEDICAL CO., GR	BLUE SAIL ME MEDICAL CO., GR LTD.	BLUE SAIL MEDICAL CO
Tara 🛇	€> €>	China	China	China	China	China
Nr. catalog 📎	0-					
	u pudră	měrimea M cu pudră	mărimea XS cu pudră	mărimea XL cu pudră	mărimea S cu pudră	mărimea L cu
Den.comerc. 🔝 Model	•					
Denumire 🖁	MÄNUŞI PENTR 🚏	MÄNUȘI PENTRU EXAMINARE DIN VINIL	MÄNUȘI PENTRU EXAMINARE DIN VINIL	MÄNUȘI PENTRU EXAMINARE DIN VINIL	MÄNUȘI PENTRU EXAMINARE DIN VINIL	MĂNUȘI PENTRU
Nr (S)	€-	DM000226083	DM000226081	DM000226085	DM000226082	DM000226084

🗸 💎 Содержит([Producatorul], 'BLUE SAIL MEDICAL CO., LTD.') И Содержит([Reprezentant], 'mede')...





SATRA Technology Centre Ltd Wyndham Way, Telford Way, Kettering, Northamptonshire, NN16 8SD United Kingdom Tel: +44 (0) 1536 410000

Fax +44 (0) 1536 410626 email: info@satra.com www.satra.com

Customer details:

Blue Sail Medical Co Ltd

Qilu Chemical Industrial Park.

No 21 Qingtian Road

Zibo Shandong China

SATRA reference: CHT0271193 /1821 V2

Your reference:

Long cuff and short

cuff

Date of report:

15<sup>th</sup> August 2018

Samples received: 22 May 2018

For the attention of: Xue Yan Li

Date(s) work carried out:

5 June 2018

## **TECHNICAL REPORT**

Subject:

Testing to EN420:2003+A1:2009 on vinyl gloves in three colours, both with powder and powder free, in five sizes XS-XL with both long cuff and short cuff.

#### Conditions of Issue:

This report may be forwarded to other parties provided that it is not changed in any way. It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.

Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for quidance only.

A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.

The uncertainty of the results (UoM) in this report is based on a standard uncertainty multiplied by a coverage factor k=2, which provides for a confidence level of approximately 95%.

Report signed by:

Aidan Bailey

Position:

Research Technologist

Department:

China Testing

(Page 1 of 9)

SATRA Technology Centre Ltd (a subsidiary of SATRA). Registered in



#### **Work Requested**

Samples of gloves, see Table 1, were received by SATRA, for testing in accordance with EN 420: 2003 + A1: 2009

Table 1 - Samples Received

Sample description as stated by the client	Sizes submitted for testing	Colour of samples submitted	Approximate weight of one glove
Disposable vinyl gloves Long cuff: clear colour, size (XS- XL) corresponds to (6-10).	6-10 ( XS-XL)	Clear	Size: 8 Weight: 6.9g
Disposable vinyl gloves: clear colour, yellow colour and white colour, size (XS- XL) corresponds to (6-10).	6-10 ( XS-XL)	Clear/yellow/white	Size: 8 Weight: 5.0g



Disposable vinyl gloves (Long Cuff)

BS0203716, BS0203717, BS0203718, BS0203719, BS0203720



Disposable vinyl gloves (Short Cuff)

#### White:

BS0100116, BS0100117, BS0100118, BS0100119, BS0100120, BS0100126, BS0100127, BS0100128, BS0100129, BS0100130

#### Yellow:

BS0100186, BS0100187, BS0100188, BS0100189, BS0100190, BS0100196, BS0100197, BS0100198, BS0100199, BS0100200

#### Clear:

BS0100546, BS0100547, BS0100548, BS0100549, BS0100550, BS0100106, BS0100107, BS0100108, BS0100109, BS0100110

Blue Sail Medical Co Ltd

SATRA Reference:

Date:

CHT0271193 /1821 15<sup>th</sup> August 2018 RUSENI, SO Sign

(Page 2 of 9)

Signed:



Section A: Testing in Section A was carried out at SATRA China Testing Lab in Dongguan, China

#### Conclusion

Standard		Claus	Level	
EN 420: 2003 + A1:	5.1	Length and fit		PASS
2009 ( Long cuff )	5.2	Dexterity		Level 5
EN 420: 2003 + A1:	5.1	Length and fit		See Note A
2009 ( Short cuff )	5.2	Dexterity		Level 5

## **Testing**

Testing was carried out in accordance with EN 420:2003 + A1:2009.

Samples for testing were conditioned for at least 24 hours in a conditioned environment maintained at (23±2) °C and (50±5) % relative humidity. Testing was carried out within the same environment.

#### Requirements

Table 2 - Requirements for EN 420:2003 + A1:2009 Clause 5 Size and Dexterity

Glove size	6	7	8	9	10	11
Minimum length / mm	220	230	240	250	260	270

Performance level	1	2	3	4	5
Diameter of dexterity pin /mm	11.0	9.5	8.0	6.5	5.0

Blue Sail Medical Co Ltd

SATRA Reference:

Date:

CHT0271193 /1821 15<sup>th</sup> August 2018

(Page 3 of 9)

Signed



#### **Test Results**

Table 3 - EN 420:2003 + A1:2009 Test Results reference as: Disposable vinyl gloves (Long cuff)

Clause / Test	Requirement Test Results			UoM⊕	Result	
		Cimo	Lengt	h /mm		
		Size	Left	Right		
		6	241	238		
		C	omfortable on	fit		
		7	285	290		
5.1 Glove	See table 2	Comfortable on fit			. 4.40	2400
length, comfort and fit		8	275	282	± 1.10	PASS
		C	omfortable on	fit		
		9	286	293		
		С	omfortable on	fit		
		10	283	284		
		C	omfortable on	fit		
		Size N	/linimum pin di	ameter / mm		
5.2 Dexterity	See table 2	6	5.0		N/A	Level 5
		7	5.0			

Blue Sail Medical Co Ltd

SATRA Reference:

Date:

CHT0271193 /1821 15<sup>th</sup> August 2018

(Page 4 of 9)



#### **Test Results**

Table 4 - EN 420:2003 + A1:2009 Test Results reference as: Disposable vinyl gloves (short cuff)

Clause / Test	Requirement		Test Results		UoM♣	Result
		Size	Lengt	th /mm		
		Size	Left	Right		
		6	238	236		
		C	omfortable on	fit		
		7	240	238		
5.1 Glove	See table 2	C	Comfortable on fit		. 4.40	See
length, comfort and fit		8	240	241	± 1.10	Note A
		Comfortable on fit				
		9	255	252		
		C	omfortable on	fit		
		10	256	260		
*		С	omfortable on	fit		
		Size M	/linimum pin di	ameter / mm		
5.2 Dexterity	See table 2	6	5.0	)	N/A	Level 5
		7	5.0			

**Note A** – Where gloves do not meet the minimum length requirements specified in Table 2 of EN 420:2003 + A1:2009, the standard therefore requires that the manufacturer shall clearly state in the user instructions the intended application of the gloves and the reason why the gloves do not conform to the minimum length requirements.

#### **Additional Information / Notes**

Note • – Estimated uncertainty of measurement applied at point of test (e.g. to applied force or to tolerance limits) to ensure product meets requirements of the standard.

Blue Sail Medical Co Ltd

SATRA Reference:

Date:

CHT0271193 /1821 15<sup>th</sup> August 2018 18 2 8

(Page 5 of 9)

Signed:

«MEDEFERENT GRUP»

S.R.L.



Section B: Tests identified in Section B of this technical report were subcontracted to a chemical test facility accredited to ISO/IEC 17025: 2005 by CNAS.

#### RESULTS:

Sample item	Sample Description	Location	Style
1001	Clear soft plastic	- 1	A&D
1002	Yellow soft plastic	-	В
1003	White soft plastic	-	С

#### pH Value

Test Method I:

With reference to ISO 3071:2005, by using potassium chloride (KCI) solution as extract solution...

Test Method II:

With reference to ISO 3071:2005, by using water as extract solution.

Client's	Requirement:	3.5-9.5
Chents	Requirement:	3.5

-	Unit		Result	
Test Item(s)	-	1001	1002	1003
Test Method	-	l l	I	1
Parameter	- 1	-	_	-
pH Value of Extracting Solution	-	-	-	-
Temp. of Aqueous Extract	deg. C	21.8	21.8	21.8
pH Value of Aqueous Extract	-	5.9	6.3	6.3
Conclusion	-	PASS	PASS	PASS

Note / Key:

eg. C = degree Celsius (°C)

Temp. = Temperature

Blue Sail Medical Co Ltd

SATRA Reference: Date:

CHT0271193 /1821

15<sup>th</sup> August 2018 (Page 6 of 9) Signed:

«MEDEFERENT



#### **RESULTS:**

Polycyclic Aromatic Hydrocarbons (PAHs) Content –European Parliament and Council Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Annex XVII with its Latest Amendment, Entry 50, point 5

Test Method: Solvent extraction and analysis by Gas Chromatograph Mass Spectrometer.

Maximum Allowable Limit:	Each of all listed PAHs: 1.0 mg/kg <sup>[a]</sup>	
-----------------------------	---	--

Tooted Home(a)	F	0 1		
Tested Item(s)	Detected Analyte(s)	Conc.	Unit	Conclusion
1001+1002+1003	ND	ND	mg/kg	PASS

Note / Key

ND = Not detected(<Detection Limit)

Detection Limit (mg/kg): Each: 0.2;

mg/kg = milligram per kilogram = ppm = part per million

Remark:

The list of polycyclic aromatic hyrdocarbons is summarized in table of Appendix.

Composite testing(s) was/were specified by client

[a] denotes as this maximum allowable limit applies to product(s) placed on the market for the first time on or

after December 27, 2015 only.

Rubber or plastic component(s) of articles that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity under normal or reasonably foreseeable conditions of use is (are) applicable to be tested. Such articles include amongst others:

- sport equipment such as bicycles, golf clubs, racquets
- household utensils, trolleys, walking frames
- tools for domestic use
- clothing, footwear, gloves and sportswear
- watch-straps, wrist-bands, masks, head-bands

APPENDIX List of Polynuclear Aromatic Hydrocarbons:						
No.	Name of Analytes	CAS-No.	No.	Name of Analytes	CAS-No.	
1	Chrysene	218-01-9	5	Dibenzo (a,h) anthracene	53-70-3	
2	Benzo (a) pyrene	50-32-8	6	Benzo (b) fluoranthene	205-99-2	
3	Benzo (e) pyrene	192-97-2	7	Benzo (j) fluoranthene	205-82-3	
4	Benzo (a) anthracene	56-55-3	8	Benzo (k) fluoranthene	207-08-9	

\*\*\* End of Report \*\*\*

(Page 7 of 9)

Blue Sail Medical Co Ltd

SATRA Reference:

CHT0271193 /1821

Date:

15<sup>th</sup> August 2018

Signed:



#### TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

- Work done, Services undertaken or the sale of Goods are subject to the terms and conditions detailed below and (subject to clause 5.2) all other conditions, warranties and representations, expressed or implied by statute relating thereto are hereby excluded. 1.1
- SATRA Technology Centre Limited, its subsidiaries and associated companies (hereinafter referred to as "SATRA") may parform Services for or supply Goods to persons or entities (public, private or governmental) issuing instructions (hereinafter termed the "Client"). Each also known individually as a Parly, or jointly as Parties.
- These terms and conditions will apply to the Contract between SATRA and the Client to the earny other terms which the Client may seek to impose or which may be implied by trade, custom, course of dealing 1.3
- Unless otherwise agreed in writing no party other than the Client is entitled to provide instructions or information relating to the Goods or Services required or to the delivery of goods, results, reports or certificates. 1.4
- 1.5 All references in these terms and conditions to:
- the 'Contract' is the contract between SATRA and the Client for the supply of Goods or Services which is made subject to these terms and conditions; and "Services" are the work or services to be supplied or performed under the Contract (including where relevant the supply of software, components and consumables); and 'Goods' are the equipment, consumables or other physical items sold under the Contract (including documents, drawings or other information required in order to operate the equipment). (a)
- (b)
- (c)
- All drawings, descriptive matter, specifications and advertising material (including brochures and catalogues) are issued or published with the sole purpose of giving an indication of the goods or services being described and shall not form part of the Contract.
- Where SATRA and the Client agree that the sale of Goods shall be governed by incoterms 2010 (or any subsequent revision thereto) then the sale shall be governed by the relevant incoterms mode of transport which is agreed by SATRA and the Client. 1.7
- 2.
- Where SATRA has agreed to perform the Services or supply the Goods on the basis of credit then payment terms are net 21 days from date of invoice, unless otherwise specified and may require part payment prior to delivery of the Services or Goods. In the event of the Client falling to make payment as agreed SATRA will be entitled to withhold delivery of the Goods or Services or cancel the Contract. SATRA reserves the right to charge interest on any overdue payments at a rate of 1.5% per month accruing on a daily basis from the date the invoice is due until the date payment is received.
- Where the provision of Services or the sale of Goods is subject to a proforma invoice then SATRA shall not be obliged to start working on the provision of the Goods or Services until after payment in full has been made as cleared funds to SATRA 22
- SATRA reserves the right to charge for any and all expenses incurred as a result of performing the Services required by the Client. Although SATRA will try and provide an estimate of such expenses these may change as a result of circumstances out of SATRA's control.
- Unless otherwise agreed in writing, the price for the Goods or Services shall be the price set in the order acknowledgement. SATRA shall not be bound by any price quoted which is not in writing. Prices for the sale of Goods include packing cases and materials but not carriage or installation which will be quoted separately and as agreed with the Client. 2.4
- 2.5 Quotations are valid from the date of issue for a period of 90 days unless otherwise specified or agreed in
- Should the Client become insolvent, bankrupt, subject to an administration order, enter into liquidation or receivership, or make arrangements with creditors SATRA reserves the right to cancel the Contract and terminate the supply of the Goods or Services. Where the Contract with SATRA is terminated all outstanding monies due from the Client to SATRA shall be immediately payable, and any materials supplied by SATRA to the Client returned. Termination of the Contract shall be without prejudice to any of SATRA's accrued rights. 26
- 2.7 All invoices issued by SATRA are payable in full. The Client is responsible for payment of withholding and any other taxes and all import duties. Payments made to SATRA shall not be reduced by such amounts.
- The Client shall not be entitled to withhold or defer payment due to SATRA as a result of any dispute or counter claim that it may allege against SATRA.
- SATRA reserves the right to bring action against the Client in order to collect unpaid fees, including court action. All fees associated with such actions shall be paid for by the Client including legal fees and related costs. 2.9
- Where unforeseen costs arise as a result of provision of the Goods or carrying out the Services SATRA shall inform the Client immediately but reserves the right to charge additional costs to cover said costs and
- All intellectual property rights belonging to a Party prior to entry into the Contract shall remain with that Party. Nothing in this Contract shall allow transfer of any intellectual property rights from one Party to the other. 31
- with the Client.
- All intellectual property rights in reports, drawings, graphs, charts, photographs or any other material (in whatever medium) produced by SATRA pursuant to this Contract shall belong to SATRA. The Client shall have the right to use said material in accordance with the terms of this Contract.
- The Client agrees and acknowledges that SATRA retains any and all propriety rights in concepts, ideas and inventions that may arise during the preparation or provision of any report (including any deliverables provided by SATRA to the Clerk) and the provision of the Services to the Clerk). 3.4
- All intellectual property rights in any software supplied to the Client shall belong to SATRA or SATRA's fecensors. With respect to the sale of SATRA Timeline, SATRASUMM and SATRA Visionstitch, provided that the Client is a member of SATRA and has paid its annual Smartcare fee then the Client will be entitled to use the software for its own internal use and will be entitled to receive minor software upgrades and fixes. SATRA may however terminate the supply of software upgrades and fixes for older versions of software which it no longer considers viable to support. The Client's rights to use the software and receive software upgrades and fixes will terminate if the Client has not paid its annual Smartcare fee. Major upgrades are not included within the entitlement to upgrades but may be offered by SATRA from time to time for an additional fee. 3.5
- SATRA shall observe all statutory provisions with regard to data protection including but not limited to the provisions of the Data Protection Act 1998. To the extent that SATRA processes or gets access to personal data in connection with the Services or otherwise in connection with this Contract, it shall take all reasonable technical and organisational measures to ensure the security of such data (and guard against unauthorised or unlawful processing, accidental lose, destruction or damage to such data).

- SUSPENSION OF TERMINATION OF SERVICES
- Cancellation by the Client of orders for Goods or Services will only be acceptable by prior agreement with SATRA and a charge will usually be made. 4.1
- SATRA shall not be liable for any delay or failure in providing the Goods or Services due to circumstances beyond its reasonable control (including any failure by the Client to comply with its obligations). If any such circumstances arise which prevent SATRA from delivering the Goods or completing the Services, then SATRA will be entitled to enacted or recentedule the defivery of Goods or Services at its discrection. In the event of cancellation SATRA will be entitled to retain all fees paid by the Client for Goods or Services arised yeupfeld but will return to the Client any fees paid by the Client for Goods or Services which have not yet been supplied. The Client will not be liable for any non-refundable expenses already incurred by SATRA in relation to Goods or Services on yet supplied unless the cancellation is due to the Clients failure to comply with its obligations under the Contract.

#### 5.

- Reports are issued on the basis of information, documents and or samples submitted to SATRA by the Client, or on behalf of the Client and are provided solely for the beneft of the Client who is responsible for acting as it sees fit on the basis of such reports and findings. Subject to clause 52, neither SATRA nor any of its employees, agents or subcontractors shall be liable to the Client or any third party for any actions taken or not taken on the basis of such findings and reports, nor for any morrect results arising as a result of unclear, erronsous, incomplete, misleading or false information provided to SATRA.
- 52 Nothing in these terms and conditions shall limit or exclude SATRA's liability for
- death or personal injury caused by its negligence or the negligence of its employees or agents; fraud or fraudulent misrepresentation; breach of the terms implied by Section 12 of the Sale of Goods Act 1979; defective products under the Consumer Protection Act 1987; or any other liability which cannot be limited or excluded by applicable law.

- Subject to clause 5.2 SATRA shall not be liable to the Client whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract for loss of profits, sales, contracts, articipated savings, lose or damage to goodwill or any indirect or consequential
- Subject to clause 5.2 SATRA's total aggregate liability to the Client, whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract shall be limited to the total amount of fees for the Services or the price of the Goods (excluding any value added tax or other sales tax or expenses) payable by the Client to SATRA under the Contract or £100,000 whichever

- If any one or more provisions of these conditions are found to be illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby. 61
- During the course of providing the Goods or Services and for a period of one year thereafter the Client shall not directly or indirectly entice, encourage or make any offer to SATRA's employees to leave their employment with SATRA.
- 6.3 The use of SATRAs corporate name or registered marks for advertising purposes is not permitted without SATRA's prior written authorisation.
- All reports and documentation which are supplied to the Client under the Contract remain the property of SATRA until paid in full. Under no circumstances will a Client's purchase order override SATRA's retention of title in accordance with this clause. 6.4
- The Client acknowledges that in entering into this Contract it has not relied on any representation, warranty, collateral contract or other assurance (except those set out or referred to in these terms and conditions) made by or on behalf of SATRA or any other partly before entering into the Contract. The Client waives all rights and remedies that, but for this clause, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance.
- All provisions of the Contract that limit or exclude the liability of SATRA are intended also to be for the benefit of SATRA's holding company (called SATRA) and being a company limited by guarantee and incorporated in England and Wales with company number 00153476), and shall accordingly be enforceable by such holding company as well as or instead of by SATRA, and on the basis that any limit on the liability of SATRA shall apply to it and to such holding company in the aggregate.

#### 7.

- Unless specifically excluded in the terms of an individual contract between SATRA and the Client, the following shall apply to all deliverables including, reports, advice, drawings, photographs, specifications, data or other forms of media. 7.1
- Deliverables referred to in clause 7.1 shall not be disclosed to third parties or used in litigation without the consent of SATRA. 72
- Where SATRA has given consent to disclosure of any service deliverables referred to in clause 7.1, the Client shall draw the attention of the third party to these terms of business and the basis on which SATRA undertakes testing, reporting and advising. The Client shall indemnify SATRA for any failure to do so.
- The service deliverables referred to in clause 7.1 are submitted to the Client as confidential documents. Confidentially shall continue to apply after completion of the business, but shall cease to apply to information or knowledge which has come into the public domain through no breach of this Contract by the Client. 7.4
- The Client shall not disassemble, remove parts or carry out any form of analysis on goods or materials sold by SATRA for the purposes of reverse engineering or obtaining information on the construction, content or composition of the item without the consent of SATRA. 7.5
- AMENDMENT
- 8.1 No amendment to this Contract shall be effective unless it is in writing, expressly stated to amend this Contract and signed by an authorised signatory of both Parties.

- 9.1 If there should be a dispute between the parties to this Agreement they undertake to act with goodwill and to use all reasonable endeavours to resolve that dispute.
- Failure to resolve any dispute by discussions between the parties shall, in the first instance, be referred to a medator for resolution. The parties shall attempt to agree upon the appointment of a medator, upon receipt, by either of them, of a written notice to concur in such appointment. Should the parties fail to agree within 21 days, either party, upon giving written notice, may apply to the President or the Vice President, for the time being, of the Chartered institute of Arbitrators, for the appointment of a medator.
- Should the mediation fail, in whole or in part, either party may, upon giving written notice, and within twenty-eight days thereof, apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a single arbitrator, for final resolution. The arbitrator shall have no conducted in writing. The arbitration shall be governed by both the Arbitration and the Controlled Cost Rules of Signed:

Blue Sail Medical Co Ltd

SATRA Reference: Date:

CHT0271193 /1821 15th August 2018

(Page 8 of 9E DEFERENT GRUP"

> S.R.L. TAZ REPU



#### TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

the Chartered Institute of Arbitrators (2000 Edition), or any amendments thereof, which Rules are deemed to be incorporated by reference into this clause. The seat of the arbitration shall be England and Welles. The laws of England shall govern the interpretation of this Contract. Subject to clauses 9.1, 9.2 and 9.3 any dispute arising out of or in connection with the Contract shall be subject to the exclusive jurisdiction of the courts of England. However, the Party obtaining a judgement in such courts shall be entitled to enforce it in any court it chooses.

#### 10 PROVISION OF SERVICES

- SATRA shall provide Services using reasonable care and skill and in accordance with the Clients specific instructions and as confirmed by SATRA as part of the Contract review process. 10.1
- Estimates for completion of the Services are made in good faith and date from receipt of a written order, payment of a proforma invoice if required, full information and samples to enable SATRA to proceed. While SATRA will make every effort to fulfil them, such estimates are subject to unforeseen events and if not achieved, cannot give rise to any claim. Time will not be of the essence in relation to the performance of the Services.
- Results given in test reports or certificates refer only to samples submitted for analysis to SATRA. A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. 10.3
- 10.4 SATRA may delegate all or part of the Services to a subcontractor and the Client authorises SATRA to disclose all information required to undertake the Services.
- Where the Client requests SATRA to witness testing of other services being undertaken by a third party the Client agrees that SATRAs sole responsibility is to be present at the time of the work and to forward the results or confirm that the service has been undertaken. The Client agrees that unless otherwise agreed SATRA is not responsible for the condition or calibration of any equipment unless provided by SATRA. 10.5
- Unless otherwise agreed in advance, test samples will be retained for 6 weeks from the date of the final report after which time they will be disposed of and SATRA shall cease to have any responsibility for such samples. 10.6

Where the nature of the samples or the Services undertaken results in specialist disposal then SATRA reserves the right to pass the cost of such disposal onto the Client. Storage for longer periods may be possible only if agreed in advance and may incur a storage charge payable by the Client.

Where practical and agreed in advance, samples may be returned at the Client's expense. However, samples are in most instances partially or fully destroyed as part of the work undertaken and SATRA cannot guarantee that samples will be returned in an 'as new' condition.

- Where SATRA receives documents reflecting engagements between the Client and third parties documents belonging to third parties, such documents shall be considered as being for information and shall not release the Client from any or all obligations to SATRA. 10.7
- SATRA reserves the right to make changes to the Services, provided that such changes do not materially affect the nature or quality of the provision of these Services or where they are necessary in order to ensure that any applicable laws or safety requirements are completed with. 10.8
- 10.9 The Client acknowledges that SATRA by providing the Services, neither takes the place of the Client or any third party or releases them from any of their obligations.
- 11. CLIENT RESPONSIBILITIES RELATING TO THE PROVISION OF SERVICES
- 11.1 The Client shall provide sufficient samples, information, instructions and documents as required to ens SATRA to carry out the Services in accordance with the methods, standards or other specifications
- Where applicable the Client shall allow access by members of SATRA staff to such premises where the Services are to be performed and provide any specialist equipment and personnel.
- 11.3 The Client shall inform SATRA in advance of any known hazards, dangers or other safety matters relating to samples submitted to SATRA or on site visits made by SATRA.
- Where the Client fails to comply with any of its responsibilities SATRA reserves the right to suspend any Services until such time as the Client has compled and may require the Client to reimburse SATRA the amount of any additional costs arising from the suspension.
- DELIVERY AND NON-DELIVERY OF GOODS 12.
- Delivery dates for the supply of the Goods are approximate only and not guaranteed. Time of delivery is not of the essence of the Contract and SATRA shall not be liable for any delay in delivery of Goods.
- 122 Should expedited delivery be requested and agreed, SATRA shall be entitled to make additional charges to cover overtime or any other additional costs.
- Delivery of the Goods shall take place at such location as SATRA and the Client agree. If the Client agrees to collect the Goods from SATRA's premises, then delivery will take place at those premises in which case the consignment of Goods as recorded by SATRA upon dispatch shall be evidence of the Goods received by the Client unless the Client can provide conclusive evidence to the contrary. 12.3
- SATRA shall not be liable for the non-delivery of Goods (even if caused by SATRA) unless the Client provides written notice of non-delivery in accordance with clause 13.2. Liability for non-delivery of Goods shall in any event be limited to replacing the Goods within a reasonable time frame or the issue of a credit note to the value of the Goods not delivered. 124
- Should delivery of the Goods be suspended or delayed by the Client for any reason SATRA reserves the right to charge for storage and for all expenses incurred, including loss of or westage of resources that cannot otherwise be used. If the delay extends beyond 30 days SATRA shall be entitled to immediate payment for any Goods that are ready for delivery, and any other additional costs.
- If for any reason the Client fails to accept delivery of any of the Goods when they are ready for delivery, or SATRA is unable to deliver the Goods on time because the Client has not provided appropriate instructions, documents, licenses or authorisations then risk in the Goods shall pass to the Client, the Goods and/or Services shall be deemed to have been delivered, and SATRA may store the Goods until delivery, whereupon the Client shall be lable for all related costs and expenses (including, without limitation, storage and insurance).
- 13. RISK/TITLE OF GOODS
- Subject to clause 12.6 the risk in the Goods will transfer to the Client on delivery of the Goods unless SATRA and the Client have agreed that the sale of the Goods will be governed by Incoterms 2010 (or any subsequent revision thereto) in which case risk will transfer to the Client in accordance with the Incoterms mode of transport which is agreed by SATRA and the Client.
- 13.2 The Company shall not accept responsibility for loss or damage in transit unless
- In the case of sales where delivery of Goods is made in the United Kingdom SATRA is notified by the Client within 10 days of the invoice date of non-arrival of Goods and within 3 days of the invoice date of receipt of Goods damaged in transit; or In all other cases the Client notifies SATRA on the non-arrival or damage in transit within a reasonable period of time as determined by SATRA.

- Title to the Goods shall not pass to the Client until the earlier of when:
- SATRA receives payment in full (in cash or cleared funds) for the Goods and any other Goods that SATRA has supplied to the Client in which case title to the Goods shall pass at the time of payment of all such
- sums; and the Client resells the Goods in accordance with clause 13.5 in which case title shall pass to the Client immediately before the time at which the resale by the Client occurs.
- Until ownership of Goods has passed to the Client, the Client shall: 13.4

- hold the Goods as SATRA's ballee; store the Goods (at no cost to SATRA) separately from all other goods belonging to the Cient or any third party in such a way that they remain readily identifiable as SATRA's property (including where the Goods have been sold to a 3rd party); not destroy, deface or obscure any identifying mark or packaging on or relating to the Goods; and maintain the Goods in satisfactory condition and keep them insured on SATRA's behalf for their full price against all risks to the reasonable satisfaction of SATRA. The Client shall obtain an endorsement of SATRA's interest in the goods on its insurance policy. On request the Client shall allow SATRA to inspect such Goods and shall produce the policy of insurance.
- The Client may resell the Goods before ownership has passed to it solely on condition that sale shall be effected in the ordinary course of the Client's business at full market value. 13.5
- If before title to the Goods passes to the Client, the Client becomes subject to any of the events referred to in clause 2.6 then without limiting any other right or remedy SATRA may have:
- the Client's right to resell the Goods or use them in the ordinary course of its business ceases immediately;
- and
  SATRA may at any time require the Client to deliver up all Goods in its possession that have not been resold or irrevocably incorporated into another product; and if the Client fails to do so promptly SATRA may exercise its rights under clause 13.7. b)
- c)
- The Client grants SATRA, its agents and employees an irrevocable licence at any time to enter any premises where the Goods are or may be stored in order to inspect them, or, where the Client's right to possession has terminated, to recover them.
- On termination of the Contract, howsoever caused, SATRA's (but not the Client's) rights contained in this clause 13 shall remain in effect. 13.8
- 14 PATENTS
- SATRA gives no indemnity against any claim of infringement of Letters Patent, Registered Design, Trade Mark or Copyright by the use of or sale of any article or material supplied to the Client. If its use is impossible without infringement of Letters Patent, Registered Design, Trade Mark or Copyright published at the date of the cortract, SATRA will refund to the Client the purchase price of the said article or material provided that it is returned to SATRA free of charge. The Client warrants that any design or instruction furnished or given by the Client shall not be such as will cause SATRA to Infringe any Letters Patent, Registered Design, Trade Mark or Copyright in the execution of the Client's order. 14.1
- WARRANTY OF GOODS
- 15.1 SATRA warrants that on delivery and for a period of 12 months from the date of delivery or within the shelf life of the Goods (whichever is the shorter period) the Goods shall be free from defects in design, material
- 16 DEFECTIVE GOODS
- 16.1 Subject to clauses 16.6 and 16.7 if:

- the Client gives notice in writing to SATRA in accordance with clause 16.3 and during the period referred to in clause 15.1 that the Goods do not comply with the warranty in that clause; and SATRA is given a reasonable to opportunity of examining such Goods; and the Client (if asked to do so by SATRA) returns such Goods to SATRA's place of business then SATRA will, at its option, repair or replace the defective Goods or refund the price of the defective Goods in full. SATRA reserves the right to repair the Goods at the Client's premises.
- 16.2 The Client must inspect all Goods upon delivery. Failure to do so may result in further charges being applied in the event of a return
- If Goods are found to be faulty, defective or damaged the Client must inform SATRA in writing as soon as reasonably possible and in any event within 10 working days of the fault, damage or defect being discovered.
- 16.4 Without prejudice to clause 16.1 if no notice of rejection has been received by SATRA within 3 months of delivery, the Client shall be deemed to have accepted the Goods.
- SATRA will pay the reasonable costs of carriage, packaging and insurance for any defective Goods which are returned by the Client provided that SATRA is liable under clause 16.1 to repair or replace the defective Goods. If SATRA determines that the Goods are not defective or if SATRA is not liable to repair or replace the Goods due to the circumstances under clauses 16.6 or 16.7 then the Client will be responsible for the payment of such costs.
- the defect is caused or substantially caused by wear and tear, overloading, misuse, neglect, modification or attempted modification carried out by any organisation other than by SATRA or their approved agents, or use with ancillary equipment not approved in writing by SATRA, or default in proper maintenance or a)
- b)
- clearing; or clearing supplies the apparent is may be defined, to design any open intermediate the clearing; or the Clear authorises or carries out any repair or replacement of any Goods without first affording SATRA a reasonable opportunity to replace or repair them; or the Clear has breached any of the terms of the Contract under which the Goods have been manifectured to a design or specification or in compliance with other information provided by the Client and the defect has arisen as a result of that design, specification or information;
- 167 Where Goods or parts of Goods are not manufactured by SATRA then SATRA shall be liable for defects only to the extent that SATRA obtains redress from the manufacturer or supplier thereof provided that:
- SATRA shall not be obliged to take any step to attempt to obtain such redress except at the request and expense of the Client and upon provision by the Client of a full indemnity as to costs for which SATRA may thereby become liable; nothing in this condition 16.7 shall have effect as to impose upon SATRA any additional liability or obligations other than those referred to in condition 16.1.
- b)
- Except as provided in clause 16.1 SATRA shall have no liability to the Client arising from any failure of the Goods to comply with the warranty in clause 15.1.

Terms and conditions - December 2016

Blue Sail Medical Co Ltd

SATRA Reference:

CHT0271193 /1821 15th August 2018

0 100260004 (Page 9 dry) «MEDEFERENT GRUP"

SENI, SOCIE

(ATA ? REDE



# **TEST CERTIFICATE**

This Certificate is issued to

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

#### **FOR**

Product:

1) Disposable Vinyl Powdered Examination Gloves

2) Disposable Vinyl Powder-Free Examination Gloves

Brand/Model:

1) BS 015-01

2) BS 015-02

Details:

1) Powdered Vinyl Examination Gloves, non-sterile,

sizes XS, S, M, L & XL

2) Powder-Free Vinyl Examination Gloves, non-sterile,

sizes XS, S, M, L & XL

Specification:

EN 455-1:2000

EN 455-2:2015 EN 455-3:2015

Test Reports:

1) 7191122236-EEC15/01-CSL and 7191176061-EEC17/01-CSL

2) 7191122236-EEC15/02-CSL and 7191176061-EEC17/02-CSL

Date of Test Reports:

13 Oct 2015 and 28 Dec 2017

## Summary

A sample of product has been tested and is found to meet with the requirements of the above specification.

TÜV SÜD PSB Pte Ltd

Certificate No:

Date of Original Issue:

Date of Last Revision:

Date of Expiry:

03831

04 January 2018

18 June 2018

03 January 2020

This Certificate is part of a full report and should be read in conjunction with it. This Certificate remains the property of TÜV SÜD PSB Pte Ltd and shall be returned upon request. The use of this Certificate is subjected to the terms and conditions of the Test Certification Scheme.

Note: This Certificate is issued pursuant to the terms set out overleaf.

«MEDEFEREN GRUP,

#### Please note that this Certificate is issued under the following terms:

- 1. This certificate applies to the sample of the specific product/equipment given at the time of its testing/calibration. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that TÜV SÜD PSB approves, recommends or endorses the manufacturer, supplier or user of such product/equipment, or that TÜV SÜD PSB in any way "guarantees" the later performance of the product/equipment. Unless otherwise stated in this report, no tests were conducted to determine long term effects of using the specific product/equipment.
- The sample/s mentioned in this certificate is/are submitted/supplied/manufactured by the Client. TÜV SÜD PSB therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, consignment or any information supplied.
- Nothing in this certificate shall be interpreted to mean that TÜV SÜD PSB has verified or ascertained
  any endorsement or marks from any other testing authority or bodies that may be found on that sample.
- 4. This certificate shall not be reproduced wholly or in parts and no reference shall be made by the Client to TÜV SÜD PSB or to the report or results furnished by TÜV SÜD PSB in any advertisements or sales promotion unless with the prior written consent of TÜV SÜD PSB.
- Unless otherwise stated, this certificate was issued pursuant to the test as reflected in the test report.
   This certificate shall be read in conjuction with the full test report carried out in TÜV SÜD PSB Pte Ltd, No.1 Science Park Drive Singapore 118221.



# Test Report No. 7191181524-EEC18/01-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.

Choose certainty. Add value.

#### SUBJECT:

Testing of Powdered Vinyl Examination Gloves submitted by Blue Sail Medical Co., Ltd. on 09 Mar 2018.

#### **TESTED FOR:**

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

#### **TEST DATE:**

13 Mar 2018 and 22 Mar 2018

#### **DESCRIPTION OF SAMPLES:**

S/N	Product Description	Colour	Reference No.	Lot No.	Size	Sample received (pieces)	Manufacturer						
	\			10156011	XS	-							
	Disposable Vinyl Powdered Examination Gloves	Clear	100			10156012	S	-	Blue Sail				
1			BS 015-01	BS 015-01 10165811 N	M	-	Medical Co.,						
											10166211	L	-
		<b>V</b>		10174811	XL	400							

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



Laboratory: TÜV SÜD PSB Pte. Ltd. No.1 Science Park Drive Singapore 118221 Phone: +65-6885 1333 Fax: +65-6776 8670 E-mail: enquiries@tuv-sud-psb.sg

www.tuv-sud-psb.sg Co. Reg: 199002667R Regional Head Office:
TÜV SÜD Asia Pacific Pte. Ltd.
1 Science Park Drive, #02-01
Singapore 118221
TUV®

# Test Report No. 7191181524-EEC18/01-CSL dated 23 Mar 2018



#### **RESULTS:**

Sample: Disposable Vinyl Powdered Examination Gloves, BS 015-01

Table: Results for EN 455-1:2000

Clause	Tests	Size	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
		XS		10	315	5	Passed
	Freedom from holes    S	S		10	315	3	Passed
4 5		M	Shall not leak	10	315	1	Passed
5			10	315	1	Passed	
		XL		10	315	5	Passed

#### **REMARKS:**

1. Freedom from holes test for XS, S, M and L sizes were tested in manufacturer's site, witnessed by TÜV SÜD Certification and Testing (China) Co., Ltd. Beijing Branch on 22 Mar 2018.

Shareen Chan Engineer Wong Bee Hui Product Manager Medical Health Services (NAM)

#### **APPENDIX:**



Photo: Disposable Vinyl Powdered Examination Gloves, BS 015-01

GRUP»

# Test Report No. 7191181524-EEC18/01-CSL dated 23 Mar 2018



#### Please note that this Report is issued under the following terms:

- 1. This report applies to the sample of the specific product/equipment given at the time of its testing/calibration. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that TÜV SÜD PSB approves, recommends or endorses the manufacturer, supplier or user of such product/equipment, or that TÜV SÜD PSB in any way "guarantees" the later performance of the product/equipment. Unless otherwise stated in this report, no tests were conducted to determine long term effects of using the specific product/equipment.
- The sample/s mentioned in this report is/are submitted/supplied/manufactured by the Client. TÜV SÜD PSB therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, consignment or any information supplied.
- 3. Nothing in this report shall be interpreted to mean that TÜV SÜD PSB has verified or ascertained any endorsement or marks from any other testing authority or bodies that may be found on that sample.
- 4. This report shall not be reproduced wholly or in parts and no reference shall be made by the Client to TÜV SÜD PSB or to the report or results furnished by TÜV SÜD PSB in any advertisements or sales promotion.
- 5. Unless otherwise stated, the tests were carried out in TÜV SÜD PSB Pte Ltd, No.1 Science Park Drive Singapore 118221.

July 2011





**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.

Choose certainty.
Add value.

#### SUBJECT:

Testing of Vinyl Powdered Examination Gloves submitted by Blue Sail Medical Co., Ltd. on 06 Dec 2017.

#### **TESTED FOR:**

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

#### **TEST DATE:**

07 Dec 2017 to 28 Dec 2017

#### **DESCRIPTION OF SAMPLES:**

S/N	Product Description	Colour	Reference No.	Lot No.	Size	Sample received (pieces)	Manufacturer							
			The State of	10156011	1 XS 82	82								
	Disposable Vinyl Powdered Examination Gloves	wdered Examination Clear					10156012	S	87	Blue Sail				
1			BS 015-01	10165811	M	89	Medical Co.,							
											10166211	L	92	Ltd.
				10175911	XL	80								

Lot size as specified by client: 200,000 pieces

#### **METHOD OF TEST:**

- 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: +65-6885 1333
Fax: +65-6776 8670
E-mail: enquiries@tuv-sud-psb.sg

www.tuv-sud-psb.sg Co. Reg: 199002667R Regional Head Office:
TÜV SÜD Asia Pacific Pte. Ltd.

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



#### **RESULTS:**

Sample: Disposable Vinyl Powdered Examination Gloves, BS 015-01

Table 1: Results for EN 455-2:2015 Clauses 4-5

Clause	Tests	Size	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
		XS		13	244	Passed
		S		13	245	Passed
	Dimension a) Length (mm)	M	≥ 240	13	246	Passed
	a) Length (min)	L		13	255	Passed
4		XL		13	254	Passed
4		XS	≤ 80	13	78	Passed
		S	80 ± 10	13	86	Passed
b) Width (mm)	b) Width (mm)	M	95 ± 10	13	96	Passed
		L	110 ± 10	13	108	Passed
		XL	≥ 110	13	114	Passed
		XS F	For	13	4.2	Passed
	Strength	S	For polyvinylchloride	13	4.5	Passed
	a) Force at break	M	examination	13	4.7	Passed
	(N)	L	gloves:	13	4.5	Passed
5		XL	≥ 3.6	13	4.6	Passed
5		XS	For	13	4.4	Passed
	b) Force at break	S	polyvinylchloride	13	4.7	Passed
	after challenge	M	examination	13	4.5	Passed
	testing (N)	L	gloves:	13	4.4	Passed
		XL	≥ 3.6	13	4.5	Passed

Table 2: Results for EN 455-2:2015 Clause 7

Clause	Tests	Requirements	Results	Inferred results
7	Labelling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2008+A1:2013. Date of manufacture is defined as the packaging date.	Observed	Passed





## RESULTS (cont'd):

Sample: Disposable Vinyl Powdered Examination Gloves, BS 015-01

Table 3: Results for EN 455-3:2015 Clauses 4.2-4.5

Clause	Tests	Requirements	Results / Remarks	Inferred results
		Gloves shall not be dressed with talcum powder (magnesium silicate).	Talcum powder not detected <sup>a</sup>	Passed
4.2	Chemicals	Other chemicals	Manufacturer shall disclose upon request a list of chemical ingredients	NA
4.3 5.1	Endotoxins	< 20 EU/pair for gloves labelled with 'low endotoxin content'.	Not labelled with 'low endotoxin content'	NA
4.4 5.2	Powder-free gloves	For powder-free gloves: The total quantity of powder residues shall not exceed 2 mg per glove.	Powdered glove	NA
4.5 5.3	Proteins, leachable	The manufacturer shall strive to minimize the leachable protein level for gloves containing natural rubber latex.	Non-natural rubber latex glove	NA

<sup>&</sup>lt;sup>a</sup> Detection limit for AAS (magnesium silicate) is 0.1 %.

#### Table 4: Results for EN 455-3:2015 Clause 4.6

Clause	Tests	Requirements	Results
		In addition to the labelling specified in EN 1041:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply:	
		<ul> <li>a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1:2012 symbol for latex;</li> </ul>	NA
		The labelling shall include the following or equivalent warning statement together with the symbol: '(Product) contains natural rubber latex which may cause allergic reactions, including anaphylactic responses';	NA
4.6	Labelling	<ul> <li>b) the labelling shall include a prominent indication of whether the glove is powdered or powder-free;</li> </ul>	Comply
		c) sterile powdered gloves shall be labelled with the following or equivalent: 'CAUTION: Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions';	NA
		<ul> <li>d) for any medical glove containing natural rubber latex the product labelling shall not include:</li> <li>- any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein;</li> <li>- any unjustified indication of the presence of allergens;</li> </ul>	NA
		e) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 5.3 shall be given.	NA
		Inferred results	Passed

«MEDEFERENT GRUP»



## **REMARKS:**

1. NA: Not applicable for the submitted sample.

Shareen Chan Engineer

Wong Bee Hui Product Manager Medical Health Services (NAM)

## **APPENDIX:**



Photo: Disposable Vinyl Powdered Examination Gloves, BS 015-01





#### Please note that this Report is issued under the following terms:

- 1. This report applies to the sample of the specific product/equipment given at the time of its testing/calibration. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that TÜV SÜD PSB approves, recommends or endorses the manufacturer, supplier or user of such product/equipment, or that TÜV SÜD PSB in any way "guarantees" the later performance of the product/equipment. Unless otherwise stated in this report, no tests were conducted to determine long term effects of using the specific product/equipment.
- The sample/s mentioned in this report is/are submitted/supplied/manufactured by the Client. TÜV SÜD PSB therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, consignment or any information supplied.
- Nothing in this report shall be interpreted to mean that TÜV SÜD PSB has verified or ascertained any endorsement or marks from any other testing authority or bodies that may be found on that sample.
- 4. This report shall not be reproduced wholly or in parts and no reference shall be made by the Client to TÜV SÜD PSB or to the report or results furnished by TÜV SÜD PSB in any advertisements or sales promotion.
- 5. Unless otherwise stated, the tests were carried out in TÜV SÜD PSB Pte Ltd, No.1 Science Park Drive Singapore 118221.

July 2011





SATRA Technology Centre Ltd Wyndham Way, Telford Way, Kettering, Northamptonshire, NN16 8SD United Kingdom Tel: +44 (0) 1536 410000 Fax +44 (0) 1536 410626 email: info@satra.com

www.satra.com



Customer details:

Blue Sail Medical Co Ltd

Qilu Chemical Industrial Park.

No 21 Qingtian Road

Zibo Shandong China

SATRA reference: CHT0271193 /1821

/SPT Issue 3

Your reference:

AWB 9060747920

Date of report:

22 August 2018

Samples received: 22 May 2018

For the attention of: Xue Yan Li

Date(s) work

8 June 2018

carried out:

## TECHNICAL REPORT

Subject:

Testing of gloves identified as,

Disposable vinyl powdered examination gloves BS0100546 to BS0100550 Disposable vinyl powder-free examination gloves BS0100106 to BS0100110 Disposable vinyl powdered examination gloves BS0100186 to BS0100190 Disposable vinyl powder-free examination gloves BS0100196 to BS0100200 Disposable vinyl powdered examination gloves BS0100116 to BS0100120 Disposable vinyl powder-free examination gloves BS0100126 to BS0100130

Long cuff exam vinyl gloves BS0203716 to BS0203720

in accordance with EN 374-2: 2014

This replaces SATRA report CHT0271193 /1821 /SPT Issue 2 dated the 17 August 2018

#### Conditions of Issue:

This report may be forwarded to other parties provided that it is not changed in any way. It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.

Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.

Tests marked ≠ fall outside the UKAS Accreditation Schedule for SATRA. All interpretations of results of such tests and the comments based upon them are outside the scope of UKAS accreditation and are based on current SATRA knowledge.

A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.

The uncertainty of the results (UoM) in this report is based on a standard uncertainty multiplied by a coverage factor k=2, which provides for a confidence level of approximately 95%.

Report signed by:

Position:

Department:

**Adam Mortiboys PPE Technologist** Safety Product Testing

(Page 1 of 6)

martisays

SATRA Technology Centre Ltd (a subsidiary of SATRA). Registered in England No. 3856296 at the above address.





## **Work Requested**

Samples of gloves, see Table 1, were received by SATRA, for testing in accordance with EN 374-2:2014. Protective gloves against dangerous chemicals and microorganisms. Determination of resistance to penetration.

As stated by the client the gloves identified in Table 1 and the picture below are the identical with the difference relating to the colour of the glove, the length of the cuff and the glove being powder free or powdered. Therefore the testing was performed using a combination of the different gloves

Table 1 - Samples Received

Sample description as stated by the client	Sizes submitted for testing	Colour of samples submitted	Approximate weight of one glove
Disposable vinyl powdered examination gloves BS0100546 to BS0100550			Size: 7 Weight: 4.6g
Disposable vinyl powder-free examination gloves BS0100106 to BS0100110		Translucent	Size: 7 Weight: 5.2g
Disposable vinyl powdered examination gloves BS0100186 to BS0100190			Size: 6 Weight: 4.6g
Disposable vinyl powder-free examination gloves BS0100196 to BS0100200	6 – 10	Yellow	Size: 6 Weight: 5.1g
Disposable vinyl powdered examination gloves BS0100116 to BS0100120			Size: 6 Weight: 4.4g
Disposable vinyl powder-free examination gloves BS0100126 to BS0100130		White	Size: 6 Weight: 5.2g
Long cuff exam vinyl gloves BS0203716 to BS0203720		Translucent	Size: 7 Weight: 6.5g

Signed:

Adam marthays



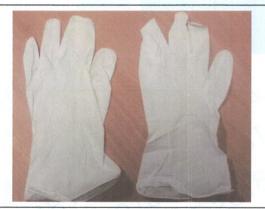




Disposable vinyl powdered examination gloves
BS0100546 to BS0100550
Disposable vinyl powder-free examination gloves
BS0100106 to BS0100110



Disposable vinyl powdered examination gloves
BS0100186 to BS0100190
Disposable vinyl powder-free examination gloves
BS0100196 to BS0100200



Disposable vinyl powdered examination gloves
BS0100116 to BS0100120
Disposable vinyl powder-free examination gloves
BS0100126 to BS0100130



Long cuff exam vinyl gloves BS0203716 to BS0203720

### Conclusion

Standard	Standard Clause / Property		Result
EN 274 2, 2014	7.2 Air leak		Pass
EN 374-2: 2014	7.3 Water leak		Pass

Blue Sail Medical Co Ltd CHT0271193 /1821 /SPT Issue 3 22 August 2018

(Page 3 of 6)

Adam martibays





## **Testing**

Samples for testing were conditioned for at least 24 hours in a conditioned environment maintained at (23±2) °C and (50±5) % relative humidity. Testing was carried out within the same environment.

## Requirements

Table 2 - Requirements for EN 374-2: 2014

7.2 Air leak test	No leak to be detected	
7.3 Water leak test	No leak to be detected	

#### **Test Results**

Table 3 - EN 374-2:2014 Test Results of gloves identified as Disposable vinyl powdered or powder-free examination gloves and Long cuff exam vinyl gloves

Clause / Test	Test Results		UoM	Result
7.2 Air leak test	Total Air Pressure	Air Pressure Used 2.87 kPa		
	Sample size	Leaks	± 2.8 mmH₂0	Pass
	6	No leaks detected		
	7	No leaks detected		
	8	No leaks detected		
	9	No leaks detected		
	10	No leaks detected		
7.3 Water leak test	Sample size	Leaks	N/A	
	6	No leaks detected		
	7	No leaks detected		Pass
	8	No leaks detected		
	9	No leaks detected		
	10	No leaks detected		



Signed:

Blue Sail Medical Co Ltd CHT0271193 /1821 /SPT Issue 3 22 August 2018

(Page 4 of 6)

Adam martibays





#### TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

#### GENERAL

- Work done, Services undertaken or the sale of Goods are subject to the terms and conditions detailed below and (subject to clause 5.2) all other conditions, warranties and representations, expressed or implied by statute relating thereto are hereby excluded.
- SATRA Technology Centre Limited, its subsidiaries and associated companies (hereinafter referred to as "SATRA") may perform Services for or supply Goods to persons or entities (public, private or governmental) issuing instructions (hereinafter termed the "Client"). Each also known individually as a Party, or jointly as Parties.
- These terms and conditions will apply to the Contract between SATRA and the Client to the exclusion of any other terms which the Client may seek to impose or which may be implied by trade, custom, practice or course of dealing
- Unless otherwise agreed in writing no party other than the Client is entitled to provide instructions or information relating to the Goods or Services required or to the delivery of goods, results, reports or certificates
- All references in these terms and conditions to:
- (b)
- the "Contract" is the contract between SATRA and the Client for the supply of Goods or Services which is made subject to these terms and conditions; and "Services" are the work or services to be supplied or performed under the Contract (including where relevant the supply of software, components and consumables); and "Goods" are the equipment, consumables or other physical items sold under the Contract (including documents, drawings or other information required in order to operate the equipment). (c)
- All drawings, descriptive matter, specifications and advertising material (including brochures and catalogues) are issued or published with the sole purpose of giving an indication of the goods or services being described and shall not form part of the Contract. 1.6
- Where SATRA and the Client agree that the sale of Goods shall be governed by Incoterms 2010 (or any subsequent revision thereto) then the sale shall be governed by the relevant Incoterms mode of transport which is agreed by SATRA and the Client. 1.7

#### 2

- Where SATRA has agreed to perform the Services or supply the Goods on the basis of credit then payment terms are net 21 days from date of invoice, unless otherwise specified and may require part payment prior to delivery of the Services or Goods. In the event of the Client failing to make payment as agreed SATRA will be entitled to withhold delivery of the Goods or Services or cancel the Contract. SATRA reserves the right to charge interest on any overdue payments at a rate of 1.5% per month accruing on a daily basis from the date the invoice is due until the date payment is a rate of 1.5% per month accruing on a daily basis from 2.1
- Where the provision of Services or the sale of Goods is subject to a proforma invoice then SATRA shall not be obliged to start working on the provision of the Goods or Services until after payment in full has been made as cleared funds to SATRA. 2.2
- SATRA reserves the right to charge for any and all expenses incurred as a result of performing the Services required by the Client. Although SATRA will try and provide an estimate of such expenses these may change as a result of circumstances out of SATRA's control.
- Unless otherwise agreed in writing, the price for the Goods or Services shall be the price set in the order acknowledgement. SATRA shall not be bound by any price quoted which is not in writing. Prices for the sale of Goods include packing cases and materials but not carriage or installation which will be quoted separately and as agreed with the Client. 2.4
- 25 Quotations are valid from the date of issue for a period of 90 days unless otherwise specified or agre-
- Should the Client become insolvent, bankrupt, subject to an administration order, enter into liquidation or receivership, or make arrangements with creditors SATRA reserves the right to cancel the Contract and terminate the supply of the Goods or Services. Where the Contract with SATRA is terminated all outstanding monies due from the Client to SATRA hall be immediately payable, and any materials supplied by SATRA to the Client returned. Termination of the Contract shall be without prejudice to any of SATRA's accrued 26
- All invoices issued by SATRA are payable in full. The Client is responsible for payment of withholding and any other taxes and all import duties. Payments made to SATRA shall not be reduced by such amounts. 27
- The Client shall not be entitled to withhold or defer payment due to SATRA as a result of any dispute or counter claim that it may allege against SATRA. 2.8
- SATRA reserves the right to bring action against the Client in order to collect unpaid fees, including court action. All fees associated with such actions shall be paid for by the Client including legal fees and related 2.9
- 2.10 Where unforeseen costs arise as a result of provision of the Goods or carrying out the Services SATRA shall inform the Client immediately but reserves the right to charge additional costs to cover said costs and

#### 3 INTELLECTUAL PROPERTY RIGHTS

- 3.1 All intellectual property rights belonging to a Party prior to entry into the Contract shall remain with that Party. Nothing in this Contract shall allow transfer of any intellectual property rights from one Party to the other.
- In the event of certification services the use of certification marks by the Client may be subject to national and international laws and regulations. The responsibility for the use of these certification marks lies solely with the Client. 3.2
- All intellectual property rights in reports, drawings, graphs, charts, photographs or any other material (in whatever medium) produced by SATRA pursuant to this Contract shall belong to SATRA. The Client shall have the right to use said material in accordance with the terms of this Contract. 3.3
- The Client agrees and acknowledges that SATRA retains any and all propriety rights in concepts, ideas and inventions that may arise during the preparation or provision of any report (including any deliverables provided by SATRA to the Client) and the provision of the Services to the Client.
- All intellectual property rights in any software supplied to the Client shall belong to SATRA or SATRA's licensors. With respect to the sale of SATRA Timeline, SATRASUMM and SATRA Visionstitch, provided that the Client is a member of SATRA and has paid its annual Smartcare fee then the Client will be entitled to use the software for its own internal use and will be entitled to receive minor software upgrades and fixes. SATRA may however terminate the supply of software upgrades and fixes for older versions of software which it no longer considers viable to support. The Client's rights to use the software and receive software upgrades and fixes will terminate if the Client has not paid its annual Smartcare fee. Major upgrades are not included within the entitlement to upgrades but may be offered by SATRA from time to time for an additional fee.
  - SATRA shall observe all statutory provisions with regard to data protection including but not limited to the provisions of the Data Protection Act 1998. To the extent that SATRA processes or gets access to personal data in connection with the Services or otherwise in connection with this Contract, it shall take all reasonable technical and organisational measures to ensure the security of such data (and guard against unauftholised or unlawful processing, accidental loss, destruction or damage to such data).

- SUSPENSION OR TERMINATION OF SERVICES
- Cancellation by the Client of orders for Goods or Services will only be acceptable by prior agreement with SATRA and a charge will usually be made.
- SATRA shall not be liable for any delay or failure in providing the Goods or Services due to circumstances beyond its reasonable control (including any failure by the Client to comply with its obligations). If any such circumstances arise which prevent SATRA from delivering the Goods or completing the Services, then SATRA will be entitled to cancel or reschedule the delevery of Goods or Services at its discretion. In the event of cancellation SATRA will be entitled to retain all fees paid by the Client for Goods or Services already supplied but will refund to the Client and the Client for Goods or Services which have not yet been supplied. The Client five limit for Goods or Services which have not yet been supplied. The Client will not be liable for any non-refundable expenses already incurred by SATRA in relation to Goods or Services not yet supplied unless the cancellation is due to the Clients failure to comply with its obligations under the Contract.

#### LIABILITY AND INDEMNIFICATION

- Reports are issued on the basis of information, documents and or samples submitted to SATRA by the Client, or on behalf of the Client and are provided solely for the benefit of the Client who is responsible for acting as it sees fit on the basis of such reports and findings. Subject to clause 5.2, neither SATRA nor any of its employees, agents or subcontractors shall be liable to the Client or any third party for any actions taken or not taken on the basis of such findings and reports, nor for any incorrect results arising as a result of unclear, erroneous, incomplete, misleading or false information provided to SATRA.
- Nothing in these terms and conditions shall limit or exclude SATRA's liability for 5.2
- death or personal injury caused by its negligence or the negligence of its employees or agents; fraud or fraudulent misrepresentation; breach of the terms implied by Section 12 of the Sale of Goods Act 1979; defective products under the Consumer Protection Act 1987; or any other liability which cannot be limited or excluded by applicable law. (a) (b) (c) (d) (e)

- Subject to clause 5.2 SATRA shall not be liable to the Client whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract for loss of profits, sales, contracts, anticipated savings, loss or damage to goodwill or any indirect or consequential loss. 5.3
- Subject to clause 5.2 SATRA's total aggregate liability to the Client, whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract shall be limited to the total amount of fees for the Services or the price of the Goods (excluding any value added tax or other sales tax or expenses) payable by the Client to SATRA under the Contract or £100,000 whichever is the lower figure. 54

#### MISCELL ANEOUS 6.

- If any one or more provisions of these conditions are found to be illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired 6.1
- During the course of providing the Goods or Services and for a period of one year thereafter the Client shall not directly or indirectly entice, encourage or make any offer to SATRA's employees to leave their employment with SATRA. 6.2
- The use of SATRAs corporate name or registered marks for advertising purposes is not permitted without SATRA's prior written authorisation. 6.3
- All reports and documentation which are supplied to the Client under the Contract remain the property of SATRA until paid in full. Under no circumstances will a Client's purchase order override SATRA's retention of title in accordance with this clause.
- The Client acknowledges that in entering into this Contract it has not relied on any representation, warranty, collateral contract or other assurance (except those set out or referred to in these terms and conditions) made by or on behalf of SATRA or any other party before entering into the Contract. The Client waives all rights and remedies that, but for this clause, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance.
- All provisions of the Contract that limit or exclude the liability of SATRA are intended also to be for the benefit of SATRA's holding company (called SATRA, and being a company limited by guarantee and incorporated in England and Wales with company number 00153475), and shall accordingly be enforceable by such holding company as well as or instead of by SATRA, and on the basis that any limit on the liability of SATRA shall apply to it and to such holding company in the aggregate.

#### CONFIDENTIALITY 7.

- Unless specifically excluded in the terms of an individual contract between SATRA and the Client, the following shall apply to all deliverables including, reports, advice, drawings, photographs, specifications, data or other forms of media. 7.1
- 7.2 Deliverables referred to in clause 7.1 shall not be disclosed to third parties or used in litigation without the consent of SATRA.
- Where SATRA has given consent to disclosure of any service deliverables referred to in clause 7.1, the Client shall draw the attention of the third party to these terms of business and the basis on which SATRA undertakes testing, reporting and advising. The Client shall indemnify SATRA for any failure to do so. 73
- The service deliverables referred to in clause 7.1 are submitted to the Client as confidential documents Confidentiality shall continue to apply after completion of the business, but shall cease to apply to information or knowledge which has come into the public domain through no breach of this Contract by the Client. 7.4
- The Client shall not disassemble, remove parts or carry out any form of analysis on goods or materials sold by SATRA for the purposes of reverse engineering or obtaining information on the construction, content or composition of the item without the conserve of SATRA. 7.5

#### 8.

8.1 No amendment to this Contract shall be effective unless it is in writing, expressly stated to amend this Contract and signed by an authorised signatory of both Parties.

#### 9. DISPUTE RESOLUTION

- 9.1 If there should be a dispute between the parties to this Agreement they undertake to act with goodwill and to use all reasonable endeavours to resolve that dispute.
- Failure to resolve any dispute by discussions between the parties shall, in the first instance, be referred to a mediator for resolution. The parties shall attempt to agree upon the appointment of a mediator, upon receipt, by either of them, of a written notice to concur in such appointment. Should the parties fail to agree within 21 days, either party, upon giving written notice, may apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a mediator.

Should the mediation fail, in whole or in part, either party may, upon giving written notice, and within twentyeight days thereof, apply to the President or the Vice President, for the time being, of the Chartered Institute
of Arbitrators, for the appointment of a single arbitrator, for final resolution. The arbitrator shall have no
connection with the mediator or the mediation proceedings, unless both parties have consented in writing.
The arbitration shall be governed by both the Arbitration Act 1996 and the Controlled Cost Rules of the
Chartered, Institute of Arbitrators (2000 Edition), or any amendments thereof, which Rules are deemed to be
incorporated by reference into this clause. The seat of the arbitration shall be England and Wales.

Blue Sail Medical Co Ltd CHT0271193 /1821 /SPT Issue 3 22 August 2018

"MEDEFERENT NS (Page p of 6)

Signed:

Adam martibays





#### TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

- The laws of England shall govern the interpretation of this Contract. Subject to clauses 9.1, 9.2 and 9.3 any dispute arising out of or in connection with the Contract shall be subject to the exclusive jurisdiction of the courts of England. However, the Party obtaining a judgement in such courts shall be entitled to enforce it in any court it chooses.
- PROVISION OF SERVICES 10
- SATRA shall provide Services using reasonable care and skill and in accordance with the Clients specific instructions and as confirmed by SATRA as part of the Contract review process. 10.1
- Estimates for completion of the Services are made in good faith and date from receipt of a written order, payment of a proforma invoice if required, full information and samples to enable SATRA to proceed. While SATRA will make every effort to fulfil them, such estimates are subject to unforeseen events and if not achieved, cannot give rise to any claim. Time will not be of the essence in relation to the performance of the Services.
- Results given in test reports or certificates refer only to samples submitted for analysis to SATRA. satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty given as to the performance of the product tested.
- SATRA may delegate all or part of the Services to a subcontractor and the Client authorises SATRA to disclose all information required to undertake the Services.
- Where the Client requests SATRA to witness testing of other services being undertaken by a third party the Client agrees that SATRAs sole responsibility is to be present at the time of the work and to forward the results or confirm that the service has been undertaken. The Client agrees that unless otherwise agreed SATRA is not responsible for the condition or calibration of any equipment unless provided by SATRA. 10.5
- Unless otherwise agreed in advance, test samples will be retained for 6 weeks from the date of the final report after which time they will be disposed of and SATRA shall cease to have any responsibility for such samples. 10.6

Where the nature of the samples or the Services undertaken results in specialist disposal then SATRA reserves the right to pass the cost of such disposal onto the Client. Storage for longer periods may be possible only if agreed in advance and may incur a storage charge payable by the Client.

Where practical and agreed in advance, samples may be returned at the Client's expense. However, samples are in most instances partially or fully destroyed as part of the work undertaken and SATRA cannot guarantee that samples will be returned in an "as new" condition.

- Where SATRA receives documents reflecting engagements between the Client and third parties or documents belonging to third parties, such documents shall be considered as being for information only and shall not release the Clernt from any or all obligations to SATRA. 10.7
- SATRA reserves the right to make changes to the Services, provided that such changes do not materially affect the nature or quality of the provision of these Services or where they are necessary in order to ensure that any applicable laws or safety requirements are compiled with. 10.8
- The Client acknowledges that SATRA by providing the Services, neither takes the place of the Client or any third party or releases them from any of their obligations.
- CLIENT RESPONSIBILITIES RELATING TO THE PROVISION OF SERVICES 11.
- The Client shall provide sufficient samples, information, instructions and documents as required to enable SATRA to carry out the Services in accordance with the methods, standards or other specifications as agreed.
- Where applicable the Client shall allow access by members of SATRA staff to such premises where the Services are to be performed and provide any specialist equipment and personnel. 11.2
- The Client shall inform SATRA in advance of any known hazards, dangers or other safety matters relating to samples submitted to SATRA or on site visits made by SATRA. 113
- Where the Client fails to comply with any of its responsibilities SATRA reserves the right to suspend any Services until such time as the Client has complied and may require the Client to reimburse SATRA the amount of any additional costs arising from the suspension. 11.4
- 12. DELIVERY AND NON-DELIVERY OF GOODS
- Delivery dates for the supply of the Goods are approximate only and not guaranteed. Time of delivery is not of the essence of the Contract and SATRA shall not be liable for any delay in delivery of Goods. 12.1
- 12.2 Should expedited delivery be requested and agreed, SATRA shall be entitled to make additional charges to cover overtime or any other additional costs.
- Delivery of the Goods shall take place at such location as SATRA and the Client agree. If the Client agrees to collect the Goods from SATRA's premises, then delivery will take place at those premises in which case the consignment of Goods as recorded by SATRA upon dispatch shall be evidence of the Goods received by the Client unless the Client can provide conclusive evidence to the contrary. 12.3
- SATRA shall not be liable for the non-delivery of Goods (even if caused by SATRA) unless the Client provides written notice of non-delivery in accordance with clause 13.2. Liability for non-delivery of Goods shall in any event be limited to replacing the Goods within a reasonable time frame or the issue of a credit note to the value of the Goods not delivered. 12.4
- Should delivery of the Goods be suspended or delayed by the Client for any reason SATRA reserves the right to charge for storage and for all expenses incurred, including loss of or wastage of resources that cannot otherwise be used. If the delay extends beyond 30 days SATRA shall be entitled to immediate payment for any Goods that are ready for delivery, and any other additional costs. 125
- If for any reason the Client fails to accept delivery of any of the Goods when they are ready for delivery, or SATRA is unable to deliver the Goods on time because the Client has not provided appropriate instructions, documents, licenses or authorisations then risk in the Goods shall pass to the Client, the Goods and/or Services shall be deemed to have been delivered; and SATRA may store the Goods until delivery, whereupon the Client shall be liable for all related costs and expenses (including, without limitation, storage and insurance). 12.6
- 13 RISK/TITLE OF GOODS
- Subject to clause 12.6 the risk in the Goods will transfer to the Client on delivery of the Goods unless SATRA and the Client have agreed that the sale of the Goods will be governed by Incoterms 2010 (or any subsequent revision thereto) in which case risk will transfer to the Client in accordance with the Incoterms mode of transport which is agreed by SATRA and the Client. 13.1
- 13.2 The Company shall not accept responsibility for loss or damage in transit unless
- In the case of sales where delivery of Goods is made in the United Kingdom SATRA is notified by the Client within 10 days of the invoice date of non-arrival of Goods and within 3 days of the invoice date of receipt of Goods damaged in transit; or In all other cases the Client notifies SATRA on the non-arrival or damage in transit within a reasonable period of time as determined by SATRA.
- b)
- Title to the Goods shall not pass to the Client until the earlier of when: -133

- SATRA receives payment in full (in cash or cleared funds) for the Goods and any other Goods that SATRA has supplied to the Client in which case title to the Goods shall pass at the time of payment of all such sums;
- and ...

  The Client resells the Goods in accordance with clause 13.5 in which case title shall pass to the Client immediately before the time at which the resale by the Client occurs. b)
- Until ownership of Goods has passed to the Client, the Client shall

- hold the Goods as SATRA's bailee; store the Goods (at no cost to SATRA) separately from all other goods belonging to the Client or any third party in such a way that they remain readily identifiable as SATRA's property (including where the Goods have been sold to a 3rd party); not destroy, deface or obscure any identifying mark or packaging on or relating to the Goods; and maintain the Goods in satisfactory condition and keep them insured on SATRA's behalf for their full price against all risks to the reasonable satisfaction of SATRA. The Client shall obtain an endorsement of SATRA's interest in the goods on its insurance policy. On request the Client shall allow SATRA to inspect such Goods and shall produce the policy of insurance.
- The Client may resell the Goods before ownership has passed to it solely on condition that sale shall be effected in the ordinary course of the Client's business at full market value.
- If before title to the Goods passes to the Client, the Client becomes subject to any of the events referred to in clause 2.6 then without limiting any other right or remedy SATRA may have:
- the Client's right to resell the Goods or use them in the ordinary course of its business ceases immediately;
- and

  SATRA may at any time require the Client to deliver up all Goods in its possession that have not been resold or irrevocably incorporated into another product; and if the Client feils to do so promptly SATRA may exercise its rights under clause 13.7. b)
- c)
- The Client grants SATRA, its agents and employees an irrevocable licence at any time to enter any premises where the Goods are or may be stored in order to inspect them, or, where the Client's right to possession has terminated, to recover them. 13.7
- 13.8 On termination of the Contract, howsoever caused, SATRA's (but not the Client's) rights contained in this clause 13 shall remain in effect.
- 14 PATENTS
- SATRA gives no indemnity against any claim of infringement of Letters Patent, Registered Design, Trade Mark or Copyright by the use of or sale of any article or material supplied to the Client. If its use is impossible without infringement of Letters Patent, Registered Design, Trade Mark or Copyright published at the date of the contract, SATRA will refund to the Client the purchase price of the said article or material provided that it is returned to SATRA free of charge. The Client warrants that any design or instruction furnished or given by the Client shall not be such as will cause SATRA to infringe any Letters Patent, Registered Design, Trade Mark or Copyright in the execution of the Client's order. 14.1
- 15.
- SATRA warrants that on delivery and for a period of 12 months from the date of delivery or within the shelf life of the Goods (whichever is the shorter period) the Goods shall be free from defects in design, material
- 16.
- Subject to clauses 16.6 and 16.7 if:
- a)
- he Client gives notice in writing to SATRA in accordance with clause 16.3 and during the period referred to n clause 15.1 that the Goods do not comply with the warranty in that clause; and SATRA is given a reasonable popprunity of examining such Goods; and he Client (if asked to do so by SATRA) returns such Goods to SATRA's place of business then SATRA will, it its option, repair or replace the defective Goods or refund the price of the defective Goods in full. SATRA serves the right to repair the Goods at the Client's premises.
- 16.2 The Client must inspect all Goods upon delivery. Failure to do so may result in further charges being applied in the event of a return.
- If Goods are found to be faulty, defective or damaged the Client must inform SATRA in writing as soon as reasonably possible and in any event within 10 working days of the fault, damage or defect being discovered. 16.3
- Without prejudice to clause 16.1 if no notice of rejection has been received by SATRA within 3 months of delivery, the Client shall be deemed to have accepted the Goods. 16.4
- 16.5 SATRA will pay the reasonable costs of carriage, packaging and insurance for any defective Goods which are returned by the Client provided that SATRA is liable under clause 16.1 to repair or replace the defective Goods. If SATRA determines that the Goods are not defective or if SATRA is not faible to repair or replace the Goods due to the circumstances under clauses 16.6 or 16.7 then the Client will be responsible for the
- 16.6 SATRA shall not be under any liability to repair or at its option replace or pay for the repair or replacement of any Goods which are found to be defective if:
- the defect is caused or substantially caused by wear and tear, overloading, misuse, neglect, modification or attempted modification carried out by any organisation other than by SATRA or their approved agents, or use with ancillary equipment not approved in writing by SATRA, or default in proper maintenance or cleaning; a)
- or the Client authorises or carries out any repair or replacement of any Goods without first affording SATRA a reasonable opportunity to replace or repair them; or the Client has breached any of the terms of the Contract under which the Goods were supplied; or the Goods have been manufactured to a design or specification or in compliance with other information provided by the Client and the defect has arisen as a result of that design, specification or information; b)
- c) d)
- 16.7 Where Goods or parts of Goods are not manufactured by SATRA then SATRA shall be liable for defects only to the extent that SATRA obtains redress from the manufacturer or supplier thereof provided that:
- SATRA shall not be obliged to take any step to attempt to obtain such redress except at the request and expense of the Client and upon provision by the Client of a full indemnity as to costs for which SATRA may thereby become liable; a)
- thereby become alone; nothing in this condition 16.7 shall have effect as to impose upon SATRA any additional liability or obligations other than those referred to in condition 16.1. b)
- Except as provided in clause 16.1 SATRA shall have no liability to the Client arising from any failure of the Goods to comply with the warranty in clause 15.1.

Terms and conditions - December 2016

NOI. RUSEN IDNO 10026000 "MEDEFERENT

S ATATIMITATA

Signed:

Adam martibays

Blue Sail Medical Co Ltd CHT0271193 /1821 /SPT Issue 3 22 August 2018

(Page 6 of 6)