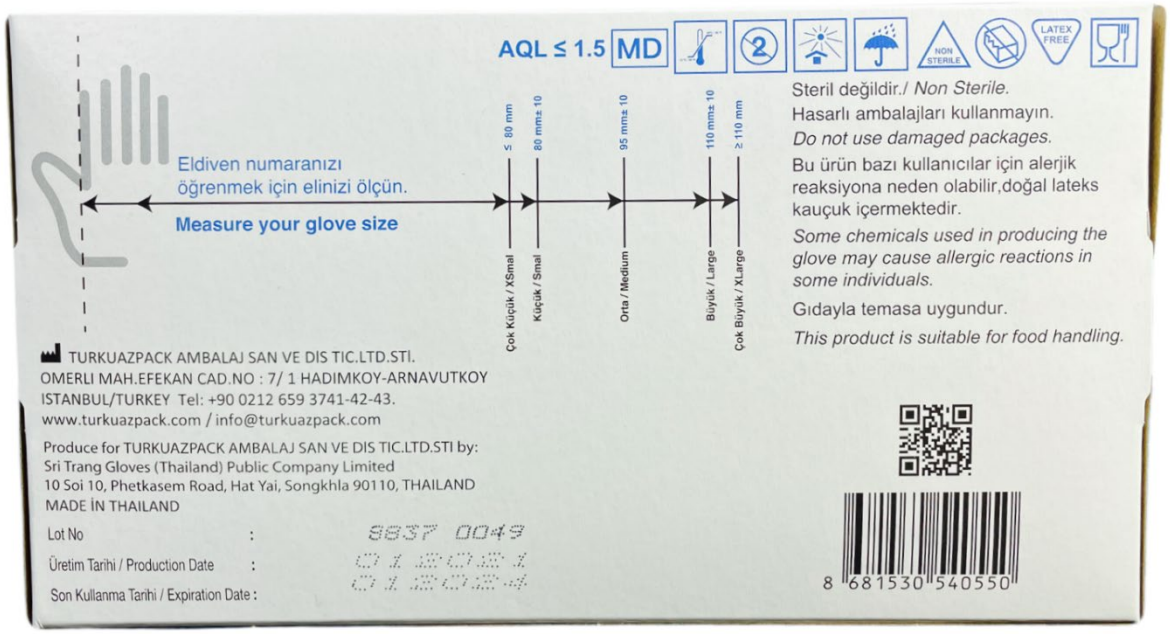

BPG Nitrile
Examination Gloves
Powder Free
100 Gloves By Weight
open here
FR Gants d'examen en nitrile non poudrés
IT Guanti da esplorazione in nitrile senza polvere
LT Nitrilo apžiūros pirštinės be miltelių
RO ănuşi de examinare cu nitril fără pulbere
DE Nitril-Untersuchungshandschuhe puderfrei
EE Nitriilieksamplari kindad on pulber vabad
IE Lámhainní scrúdaithe nitrile púdar saor in aisce
LU Nitrilexamen Handschueder ouni Puder
MT Ingwanti ta 'l-ezamijiet nitrile hielsa mit-trab
PT Luvas de exame de nitrilo sem pó
SK Nitrilové vyšetrovacie rukavice bez prášku
ES Guantes de examen de nitrilo sin polvo
FI Nitriilikokeilla ei saa pulveria
SE Nitrilundersökningshandskar pulverfri
BG Ръкавици за изпитване на нитрил без прах
HR Rukavice za ispitivanje nitrila bez praha
CZ Nitrilové vyšetřovací rukavice bez prášku
SK Nitrilni pregledni rokavice brez prahu
LT Latekso tyrimo pirštinės be miltelių
LV Lateksa pārbaudes cimdi bez pulvera
SL Latex testne rokavice brez prahu
EE Lateksivälijaannete kindad pole saadaval
SK Nitrilni pregledni rokavice brez prahu
HU Nitril vizsgálókesztyű pormentes
LV Nitrila pārbaudes cimdi bez pulvera
NO Nitrileksamenhansker pulverfri
RU Нитриловые смотровые перчатки без пудры
CN 丁腈检查手套无粉
AR قفازات فحص النتريل مسحوق الحرة


BPG Nitrile
Examination Gloves
Powder Free
BPG Nitrile
Examination Gloves
Powder Free
SIZE
Extra Small
Small
Medium
Large
Extra Large
Manufactured in Malaysia by:
Meditech Gloves Sdn Bhd,
PT 3345, Jalan Permata 1/3,
Arab Malaysian Industrial Park,
71800 Nilai, Negeri Sembilan
Darul Khusus, Malaysia.
Telephone: +606-799 7742, +606-799 7746
Fax: +606-799 7749
www.meditechgloves.com
EC REP
Authorised Representative in
The European Community
Best Putra Gloves (UK) Ltd.,
103 Carrickasticken Road, Forkhill,
Newry, County Down, BT35 9RL,
Northern Ireland, United Kingdom
Tel: +44 2830889232
Email: admin@bpgloves.co.uk


BPG Nitrile
Examination Gloves
Powder Free
100 Gloves By Weight
BPG Nitrile
Examination Gloves
Powder Free
CE 2797 (PPE Regulation (EU) 2016/425)
Single Use Only
LATEX FREE
Store in a Cool and Dry Place
Avoid Direct Sunlight
EN ISO 374-1/ Type C
Marking of Type C gloves
CAUTION :


AQL ≤ 1.5
MD
NON STERILE
LATEX FREE
Eldiven numaranızı öğrenmek için elinizi ölçün.
Measure your glove size
≤ 80 mm
80 mm± 10
95 mm± 10
110 mm± 10
≥ 110 mm
Çok Küçük / XSmall
Küçük / Small
Orta / Medium
Büyük / Large
Çok Büyük / XLarge
Steril değildir./ Non Sterile.
Hasarlı ambalajları kullanmayın.
Do not use damaged packages.
Bu ürün bazı kullanıcılar için alerjik reaksiyona neden olabilir,doğal lateks kauçuk içermektedir.
Some chemicals used in producing the glove may cause allergic reactions in some individuals.
Gıdayla temasa uygundur.
This product is suitable for food handling.
TURKUAZPACK AMBALAJ SAN VE DIS TIC.LTD.STI.
OMERLI MAH.EFEKAN CAD.NO : 7/ 1 HADIMKOY-ARNAVUTKOY
ISTANBUL/TURKEY Tel: +90 0212 659 3741-42-43.
www.turkuazpack.com / info@turkuazpack.com
Produce for TURKUAZPACK AMBALAJ SAN VE DIS TIC.LTD.STI by:
Sri Trang Gloves (Thailand) Public Company Limited
10 Soi 10, Phetkasem Road, Hat Yai, Songkhla 90110, THAILAND
MADE İN THAILAND
Lot No :
Üretim Tarihi / Production Date :
Son Kullanma Tarihi / Expiration Date :
8681530540550

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Meditech Gloves Sdn. Bhd.
Lot 3345, Jalan Permata 1/3
Arab Malaysian Industrial Park
71800 Nilai
Negeri Sembilan, Darul Khusus
Malaysia

Holds Certificate No: **MD 631470**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The manufacture of powdered and powder-free sterile latex surgical gloves, powder-free sterile latex surgical under gloves and examination gloves.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2015-03-09
Latest Revision Date: 2019-02-27

Effective Date: 2018-03-09
Expiry Date: 2021-03-08

...making excellence a habit.™

2. CE Marking

bsi.

By Royal Charter

EU Type Examination Certificate

This is to certify that:

Meditech Gloves Sdn. Bhd.
PT 3345, Jalan Permata 1/3
Arab Malaysian Industrial Park
Nilai
Negeri Sembilan, Darul Khusus
71800
Malaysia

Holds Certificate Number: CE 698568

In respect of:

Natural rubber gloves for personal protection- models MEPF3 & MSPF2
(NBR) Nitrile Butadiene Rubber Latex gloves for personal protection- model MNEPF1.
To EN 420:2003+A1:2009, EN ISO 374-1:2016 & EN ISO 374-5:2016.

on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 0086):

Chris Lewis - Certification Director, Product Certification

First Issued: 2019-05-02
Latest Issue: 2019-07-31

Effective Date: 2019-07-31
Expiry Date: 2024-05-02

...making excellence a habit.™

↑Top

EU Type Examination Certificate

No. CE 698568

Product Specification:

The PPE equipment Protective Gloves that are covered by the scope of this Module B Certificate and the Harmonized European Standards and technical specifications to which the products are approved are to the following specifications:

Model:	**MEPF3 Polycare Latex Examination Gloves**
Classification:	Protective gloves for use against microorganisms and general applications.
Description:	Natural rubber latex examination gloves, powder free and non-sterile. Ambidextrous gloves with beaded cuff, available in off-white to light yellow colours.
Size Range:	XS to XL
Product codes:	MEPF3-XS, MEPF3-S, MEPF3-M, MEPF3-L and MEPF3-XL.

Product Specification

Performance:

Resistance to penetration to EN 374-2:2014
Pass

Resistance to degradation to EN 374-4:2013
Tested for degradation against the chemical listed below.
Sodium Hydroxide 40% (CAS:1310-73-2)
Mean Degradation: -84.3%

Resistance to chemical permeation to EN ISO 374-1:2016 (Test method EN 16523-1:2015) **Type C**

Chemical	**Level**
Sodium Hydroxide 40% (K)	6

General requirements for gloves to EN 420:2003+A1:2009

Dexterity:	Level 5
pH:	7.5
Protein Content:	84.5 µg/g

First Issued: 2019-05-02
Latest Issue: 2019-07-31

Effective Date: 2019-07-31
Expiry Date: 2024-05-02

EU Type Examination Certificate

No. CE 698568

Product Specification continued:

Model: **MSPF2 - ExcellPC Sterile Latex Surgical Gloves Powder Free**

Classification: Protective gloves for use against microorganisms and general applications.

Description: Natural rubber latex sterile polymer coated Surgical Gloves, powder free, disposable single use, sterilized by Gamma Irradiation, beaded cuff and anatomical shape., available in off-white to light yellow colours.

Size Range: 5.5 to 9.0

Product codes: MSPF2-5.5, MSPF2-6.0, MSPF2-6.5, MSPF2-7.0, MSPF2-7.5, MSPF2-8.0, MSPF2-8.5 and MSPF2-9.0.

Product Specification

Performance:

Resistance to penetration to EN 374-2:2014
Pass

Resistance to degradation to EN 374-4:2013
Tested for degradation against the chemical listed below.
Sodium Hydroxide 40% (CAS:1310-73-2)
Mean Degradation: -78.9%

Resistance to chemical permeation to EN ISO 374-1:2016 (Test method EN 16523-1:2015) **Type C**

Chemical	Level
Sodium Hydroxide 40% (K)	6

General requirements for gloves to EN 420:2003+A1:2009

Dexterity: Level 5
pH: 7.2
Protein Content: 123.5 µg/g

First Issued: 2019-05-02
Latest Issue: 2019-07-31

Effective Date: 2019-07-31
Expiry Date: 2024-05-02

EU Type Examination Certificate

No. CE 698568

Product Specification continued:

Model:	**MNEPF1 – BPG Nitrile Examination Gloves Powder-free**
Classification:	Protective gloves for use against microorganisms and general applications.
Description:	NBR (Nitrile Butadiene Rubber Latex) examination gloves, powder free and non-sterile. Ambidextrous gloves with beaded cuff, available in blue colour.
Size Range:	XS to XL
Product codes:	MNEPF1-XS MNEPF1-S, MNEPF1-M, MNEPF1-L and MNEPF1-XL.

Product Specification

Performance:

Resistance to penetration to EN 374-2:2014
Pass

Resistance to degradation to EN 374-4:2013
Tested for degradation against the chemical listed below.
Sodium Hydroxide 40% (CAS:1310-73-2)
Mean Degradation: -21.6%

Resistance to chemical permeation to EN ISO 374-1:2016 (Test method EN 16523-1:2015) **Type C**

Chemical	**Level**
Sodium Hydroxide 40% (K)	6

General requirements for gloves to EN 420:2003+A1:2009

Dexterity:	Level 5
pH:	6.2
Protein Content:	N/A

First Issued: 2019-05-02
Latest Issue: 2019-07-31

Effective Date: 2019-07-31
Expiry Date: 2024-05-02

EU Type Examination Certificate

No. CE 698568

Applicable Standards:

The following Harmonized European Standards:

EN 420:2003+A1:2009 Protective gloves. General requirements.

EN ISO 374-1:2016. Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for chemical risks.

EN 374-2:2014. Protective gloves against dangerous chemicals and microorganisms. Determination of resistance to penetration.

EN 374-4:2013. Protective gloves against chemicals and micro-organisms. Determination of resistance to degradation by chemicals.

EN ISO 374-5:2016. Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for micro-organisms risks.

EN 16523-1:2015. Determination of material resistance to permeation by chemicals. Permeation by liquid chemical under conditions of continuous contact.

First Issued: 2019-05-02
Latest Issue: 2019-07-31

Effective Date: 2019-07-31
Expiry Date: 2024-05-02

EU Type Examination Certificate

No. CE 698568

Certificate Administration Details

Manufacturer's technical file reference: MEPF3 v1, MSPF2 v0 and MNEPF1 v0 Technical Files.

Certificate Amendment Record:

Issue Date	Comments	Internal BSI Project Number
April 2019	Transition of PPE Directive, Article 10 CE 684183. Model: MEPF3. Addition on new models MNEPF1 & MSPF2.	0086:19:9640615
July 2019	Addition of sizes XS & XL to MNEPF1	0086:19:3043355

Note: The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspect of the overall processes utilised in the manufacture of the product, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes.

Monitoring of manufactured PPE:
The validity of the Certificate is also dependent on the conformity to the type based on the internal production control plus supervised product checks at random intervals (Annex VII, Module C2), for the specific standards/product that are referenced in the BSI issued Module C2 Certificate Number CE 615886.

First Issued: 2019-05-02
Latest Issue: 2019-07-31

Effective Date: 2019-07-31
Expiry Date: 2024-05-02

10. ISO 13485: 2016 Certificate

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Meditech Gloves Sdn. Bhd.
Lot 3345, Jalan Permata 1/3
Arab Malaysian Industrial Park
71800 Nilai
Negeri Sembilan, Darul Khusus
Malaysia

Holds Certificate No: **MD 631470**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The manufacture of powdered and powder-free sterile latex surgical gloves, powder-free sterile latex surgical under gloves and examination gloves.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2015-03-09
Effective Date: 2018-03-09
Latest Revision Date: 2019-02-27
Expiry Date: 2021-03-08

...making excellence a habit.™

↑Top

11. Declaration of Conformity

MEDITECH GLOVES SDN BHD (580515-T)
Registration No. 200201012852

PT 3345, JALAN PERMATA 1/3,
ARAB MALAYSIAN INDUSTRIAL PARK,
71800 NILAI,
NEGERI SEMBILAN DARUL KHUSUS,
MALAYSIA
TEL: +6 06 799 7742
+6 06 799 7746
FAX: +6 06 799 7749
http: www.meditechgloves.com

MEDICAL DEVICE DIRECTIVE
EC DECLARATION OF CONFORMITY

Manufacturer/ Supplier :	**MEDITECH GLOVES SDN. BHD.** **PT 3345, Jalan Permata 1/3, Arab Malaysian Industrial Park,** **71800 Nilai, Negeri Sembilan, Malaysia**
Authorised Representative:	**Best Putra Gloves (UK) Ltd.,** **103 Carrickasticken Road, Forkhill,** **Newry, County Down, BT35 9RL,** **Northern Ireland, United Kingdom.**
Model :	**BPG Nitrile Examination Gloves, Powder-free (MNEPF1)**
Classification :	**Class I**
Description :	**Nitrile Butadiene Rubber latex examination gloves, powder-free & non-sterile. Ambidextrous gloves with beaded cuff, available in blue colour.**

Standards Applied:

EN 374-2:2014	**EN ISO 374-1:2016**	**EN 455-1**	**EN 455-3**
EN 374-4:2013	**EN 420:2003+A1:2009**	**EN 455-2**	**EN 455-4**

MEDITECH GLOVES SDN. BHD. declares that the device described above conforms to the relevant provision of **Directive 93/42/EEC,** and complies with the relevant Essential Requirements of the Annex V and is manufactured in accordance with the **ISO 13485: 2016** Medical Device Quality Management System (QMS).

Signed for and on behalf of the manufacturer, Meditech. Gloves. Sdn. Bhd.:

4/1/xx

MEDITECH GLOVES SDN. BHD. 580515-T

DR. MOHAMMED EFFENDI MOHAMMED TENANG
Managing Director
Meditech Gloves Sdn. Bhd.

↑Top

11. Declaration of Conformity

MEDITECH GLOVES SDN BHD (580515-T)
Registration No. 200201012852

PT 3345, JALAN PERMATA 1/3,
ARAB MALAYSIAN INDUSTRIAL PARK,
71800 NILAI,
NEGERI SEMBILAN DARUL KHUSUS,
MALAYSIA
TEL: +6 06 799 7742
+6 06 799 7746
FAX: +6 06 799 7749
http: www.meditechgloves.com

MEDICAL DEVICE DIRECTIVE
EC DECLARATION OF CONFORMITY

Manufacturer/ Supplier :	**MEDITECH GLOVES SDN. BHD.** **PT 3345, Jalan Permata 1/3, Arab Malaysian Industrial Park,** **71800 Nilai, Negeri Sembilan, Malaysia**
Authorised Representative:	**Best Putra Gloves (UK) Ltd.,** **103 Carrickasticken Road, Forkhill,** **Newry, County Down, BT35 9RL,** **Northern Ireland, United Kingdom.**
Model :	**BPG Nitrile Examination Gloves, Powder-free (MNEPF1)**
Classification :	**Class I**
Description :	**Nitrile Butadiene Rubber latex examination gloves, powder-free & non-sterile. Ambidextrous gloves with beaded cuff, available in blue colour.**

Standards Applied:

EN 374-2:2014	**EN ISO 374-1:2016**	**EN 455-1**	**EN 455-3**
EN 374-4:2013	**EN 420:2003+A1:2009**	**EN 455-2**	**EN 455-4**

MEDITECH GLOVES SDN. BHD. declares that the device described above conforms to the relevant provision of **Directive 93/42/EEC,** and complies with the relevant Essential Requirements of the Annex V and is manufactured in accordance with the **ISO 13485: 2016** Medical Device Quality Management System (QMS).

Signed for and on behalf of the manufacturer, Meditech. Gloves. Sdn. Bhd.:

4/1/xx

MEDITECH GLOVES SDN. BHD. 580515-T

DR. MOHAMMED EFFENDI MOHAMMED TENANG
Managing Director
Meditech Gloves Sdn. Bhd.

↑Top

Section 11:
DRAFT EU DECLARATION OF CONFORMITY

ANNEX VI
EU DECLARATION OF CONFORMITY

The manufacturer or his authorised representative established in the Meditech Gloves Sdn. Bhd, Jalan Permata 1/3, Arab Malaysian Industrial Park, 71800 Nilai Negeri Sembilan , Malaysia declares that the new PPE described hereafter BPG Nitrile Examination Gloves (MNEPF1) is in conformity with the provisions of PPE Regulation (EU) 2016/425 and, where such is the case, with the national standard transposing harmonized standard EN 16523-1:2016, EN 420:2003 + A1:2009, EN 374-2:2014, EN 374-1:2016 and EN 374-4:2013 is identical to the PPE which is the subject of EU Type Examination certificate of conformity No CE 698568 & CE 698569 and EU Quality Control system for final product No.CE 615886 issued by BSI Group, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom.

Meditech Gloves Sdn Bhd is subject to the procedure set out in Module C2 of PPE Regulation (EU) 2016/425 under the supervision of the approved body BSI Group.

Done at Meditech Gloves Sdn Bhd on 15th July 2019

Signed and behalf of the manufacturer,

(Dr. Mohamed Effendi Mohamed Tenang)
Managing Director,
Meditech Gloves Sdn. Bhd

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: BSI Group
Kitemark Court
Davy Avenue
Knowlhill
Milton Keynes
MK5 8PP

SATRA reference: CHM0294620 /2005 /2 /SPT

Your reference: SMO 9691148

Date of report: 6 February 2020

Samples received: 31 January 2020

Date(s) work carried out: 5 February 2020

TECHNICAL REPORT

Subject: Testing of gloves identified as MNEPF1 - BPG Nitrile Examination Gloves Powder-free in accordance with EN 374-2: 2019

Report signed by: Adam Mortiboys
Position: Team Leader
Department: Safety Product Testing

Adam Mortiboys

Work Requested

Samples of gloves, see Table 1, were received by SATRA, for testing in accordance with EN 374-2: 2019

Table 1 – Samples Received

Sample description as stated by the client	Sizes submitted for testing	Colour of samples submitted	Approximate weight of one glove
MNEPF1 - BPG Nitrile Examination Gloves Powder-free	6, 8 and 9	Blue	Size: 6 Weight: 3.0g

MNEPF1

Conclusion

Standard	Clause / Property		Result
EN 374-2: 2019	7.2	Air leak	See note ●
	7.3	Water leak	Pass

Note ● – The air leak procedure is not suitable for all gloves. For example, parts of some gloves may be overinflated while other parts of the same gloves can only be partially inflated. If the air leak test proves unsuitable, then only the water penetration test is carried out.

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: 2019

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 374-2:2019 Test Results of gloves identified as MNEPF1

Clause / Test	Test Results		UoM	Result
7.2 Air leak test	Total Air Pressure Used 2.42 kPa Sample size — Leaks 6 8 9 9		± 2.8 mmH_20	See note •
7.3 Water leak test	Sample size	Leaks	N/A	Pass
	6	No leaks detected		
	8	No leaks detected		
	9	No leaks detected		
	9	No leaks detected		

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

1. GENERAL

1.1 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.

1.2 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.

1.3 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.

1.4 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.

1.5 All references in these terms and conditions to:

(a) 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
(b) "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
(c) "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).

1.6 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.

1.7 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.

2. FEES AND PAYMENT

2.1 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 received.

2.2 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.

2.3 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.

2.4 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.

2.5 Quotations are valid from the date of issue for a period of 90 days unless otherwise specified or agreed in writing.

2.6 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.

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.

2.8 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.

2.9 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.

2.10 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 expenses.

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.

3.2 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.

3.3 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.

3.4 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.

3.5 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.

3.6 SATRA shall observe all statutory provisions with regard to data protection including but not limited to the provisions of the Data Protection Act 2018 and the EU General Data Protection Regulation (GDPR) Regulation (EU) 2016/679. 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 loss, destruction or damage to such data).

4. SUSPENSION OR TERMINATION OF SERVICES

4.1 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.

4.2 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 delivery 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 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 not yet supplied unless the cancellation is due to the Clients failure to comply with its obligations under the Contract.

5. LIABILITY AND INDEMNIFICATION

5.1 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.

5.2 Nothing in these terms and conditions shall limit or exclude SATRA's liability for:

(a) death or personal injury caused by its negligence or the negligence of its employees or agents;
(b) fraud or fraudulent misrepresentation;
(c) breach of the terms implied by Section 12 of the Sale of Goods Act 1979;
(d) defective products under the Consumer Protection Act 1987; or
(e) any other liability which cannot be limited or excluded by applicable law.

5.3 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.

5.4 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.

6. MISCELLANEOUS

6.1 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.

6.2 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.

6.4 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.

6.5 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.

6.6 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.

7. CONFIDENTIALITY

7.1 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.

7.2 Deliverables referred to in clause 7.1 shall not be disclosed to third parties or used in litigation without the consent of SATRA.

7.3 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.

7.4 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.

7.5 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.

8. 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. 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.

9.2 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.

9.3 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 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.

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

9.4 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

10.1 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.

10.2 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.

10.3 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.

10.4 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.

10.5 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.

10.6 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.

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.

10.7 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 Client from any or all obligations to SATRA.

10.8 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 complied with.

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 enable SATRA to carry out the Services in accordance with the methods, standards or other specifications as agreed.

11.2 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.

11.4 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.

12. DELIVERY AND NON-DELIVERY OF GOODS

12.1 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.

12.2 Should expedited delivery be requested and agreed, SATRA shall be entitled to make additional charges to cover overtime or any other additional costs.

12.3 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.

12.4 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.

12.5 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.

12.6 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).

13. RISK/TITLE OF GOODS

13.1 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:

a) 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

b) 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.

13.3 Title to the Goods shall not pass to the Client until the earlier of when: -

a) 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

b) 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.

13.4 Until ownership of Goods has passed to the Client, the Client shall:

a) hold the Goods as SATRA's bailee;

b) 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);

c) not destroy, deface or obscure any identifying mark or packaging on or relating to the Goods; and

d) 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.

13.5 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.

13.6 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:

a) the Client's right to resell the Goods or use them in the ordinary course of its business ceases immediately; and

b) 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

c) if the Client fails to do so promptly SATRA may exercise its rights under clause 13.7.

13.7 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.

13.8 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

14.1 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.

15. 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 and workmanship.

16. DEFECTIVE GOODS

16.1 Subject to clauses 16.6 and 16.7 if:

a) 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

b) SATRA is given a reasonable opportunity of examining such Goods; and

c) 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.

16.3 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.

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 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.

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:

a) 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; or

b) 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

c) the Client has breached any of the terms of the Contract under which the Goods were supplied; or

d) 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;

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:

a) 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;

b) 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.

16.8 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 – September 2019

Signed: Adam Matthews

SURGICAL MATERIAL TESTING LABORATORY

TEST REPORT

Examination Glove Report

Report No: 18/5747/1

Report Date: Tuesday 28th August, 2018

Authors:
Dr Pamela Ashman
Laura Price

Revision Information:
Template Version: 8cc317e
Revision: 1.8
Revision date: Tuesday 28th August, 2018
Revision Author: pamela

SMTL
Princess of Wales Hospital
Coity Road
Bridgend
CF31 1RQ

Web: www.smtl.co.uk
Email: info@smtl.co.uk
Tel: 01656 752820
Fax: 01656 752830

ilac-MRA UKAS TESTING 1492

Examination Glove Report
Report No: 18/5747/1

Dr Pamela Ashman
Laura Price

Tuesday 28th August, 2018

1 Name & Address of Client/Requesting Authority

Masnah Maklin
Sr QA Manager
Meditech Gloves Sdn. Bhb
Jalan Permata 1/3
Arab Malaysian Industrial Park
71800 Nilai, Negeri Sembilan Darul Khusus
Malaysia

Email: masnah@meditechgloves.com.my

2 Introduction

This document presents the results of BPG Nitrile Examination Gloves tested to BS EN 455 Parts 1[1], 2[2] and 3 Total Extractable Protein[3] and Residual Powder[4].

3 Test Products/Samples for this project

Table 1: Samples

Supplier	Product Name	Description	Catalogue Number	Batch/Lot Number	Quantity	Date received	SMTL Sample ID
Meditech	BPG Nitrile Examination Gloves	Examination Gloves, Powder-free, Size Medium, Manufacture date March 2018	MNEPF1	31812011 1	400	16/07/2018	56961

NOTE: The test results in this report relate only to the test sample(s) analysed.

3.1 Departures/Abnormalities of Sample Condition

None.

4 Date of Testing

19th July - 1st August 2018

5 Testing Details

5.1 Perforations - TM-22[5]

The number and location of perforations in a designated sample size was noted in accordance with *BS EN 455-1:2000 Medical gloves for single use. Requirements and testing for freedom from holes* using the SMTL test method TM-22.

Each glove batch was sampled in accordance with *ISO 2859-1* general inspection level 1, utilising a minimum sample size and corresponding acceptance/rejection numbers equivalent to sample size code letter L, and an acceptance quality level (AQL) of 1.5

Gloves were selected at random and attached to the base of a plastic tube of diameter 68mm. Cuffs were located at a point 3.8cm from the base of the tube and secured onto the tube.

Gloves were then filled with 1000 ± 50ml of water at a temperature of (15-35°C) and examined for evidence of leaks. Gloves were allowed to hang for 2-3 minutes, then again examined for evidence of leaks. The position and nature of any leaks was recorded. Any leaks identified within 40mm of the cuff were disregarded.

5.2 Force at break - TM-342[6]

The force at break of the gloves was measured in accordance with *BS EN 455-2:2015 Medical gloves for single use. Requirements and testing for physical properties* using SMTL test method TM-342.

The strength of the gloves was determined during shelf life and following ageing (7 days at 70 ± 2°C). Dumb-bell test pieces were cut from 13 individual (or from seven pairs) gloves from the same lot, following a conditioning period of at least 16hrs. Using a tensometer with a cross-head speed of 500mm/min the force at break in newtons (N) was recorded.

The single wall thickness of each dumb-bell and the double wall thickness of the middle finger tip of each glove was measured using a thickness gauge and a correction factor applied if applicable.

The median of the 13 samples (with correction factor applied if necessary) was calculated.

5.3 Dimensions - TM-343[7]

The length and width of the gloves was measured in accordance with *BS EN 455-2:2015 Medical gloves for single use. Requirements and testing for physical properties* using SMTL test method TM-343.

Length

The glove length was measured by freely suspending the glove by the middle finger on a vertical graduated rule with a rounded tip. Folds and wrinkles were removed without stretching the gloves and the minimum length recorded.

This was repeated so that a total of 13 gloves were measured and the median length was calculated.

Width

The width of the glove was measured using a calibrated rule to the nearest mm, when the glove was placed onto a flat surface.

This was repeated so that a total of 13 gloves were measured and the median width was calculated.

5.4 Extractable protein - TM-230[8]

The measurement of total extractable protein of the gloves was determined in accordance with Annex A of *BS EN 455-3:2015 Medical gloves for single use. Requirements and testing for biological evaluation* using TM-230.

A quantitative test method, based upon a Modified Lowry Assay, was used, which comprised three main parts. In the first part, residual soluble protein was aqueously extracted from a known weight of glove test sample using TES buffer as the extractant. The extraction procedure employed was such that both the inside and outside surfaces of the material were extracted simultaneously. Following this, the extracted protein was purified by a process which precipitates the proteins and removes interfering, water-soluble substances. In the final part, the optical density of a sample of the test extract was determined using a microplate plate reader at a wavelength of 650nm. A series of ovalbumin protein standard solutions were also prepared using extraction buffer as a diluent. The protein in each standard solution was precipitated and assayed in the same way as for the glove test samples. The optical density value of each well was recorded by an automated computer program linked to the microplate reader which performs regression analysis on the standard curve and calculates the protein concentration in µg per ml in each of the unknown glove extract samples. The total amount of protein extracted per glove was then calculated from which the total extractable protein in µg per gram of glove was determined.

Extraction buffer was used as a blank.

Four glove extracts were tested for each product.

The mean protein content of the four determinations was calculated and reported.

5.5 Removable Surface Powder - TM-391[9]

The measurement of readily removable powder on the surface of gloves for medical use was determined in accordance with *BS EN ISO 21171 : 2006* using TM-391.

The surfaces of 5 gloves are washed with water to remove the water-insoluble powder, the extract is filtered, and the filter dried then weighed. The weight of removed powder is then determined as the difference between the initial and final weight of the filter.

5.6 Standards relevant to the test method

- Perforation testing (TM-22) is performed in accordance with BS EN 455 Part 1: 2000[1]
- Force at break (TM-342) and dimension (TM-343) testing requirements are performed in accordance with BS EN 455 Part 2: 2015[2]
- Total extractable protein testing (TM-230) is in accordance with annex A of BS EN 455 Part 3: 2015[3]
- Determination of removable surface powder (TM-391) is performed in accordance with BS EN ISO 21171:2006[4]
- The limits of the test are read in conjunction with BS EN 455 Part 3: 2015[10]

5.7 Testing conditions

Force At Break

- Testing and conditioning was performed at 23 ±2°C, and at a relative humidity of 50 ±10%.

Total Extractable Protein

- The extraction was performed at 25 ±5°C with shaking for 120 ±5 minutes. The precipitation and concentration of protein was performed at 25 ±5°C.

Removeable Surface Powder

- The testing was performed at 25 ±5°C, the drying was performed at 100 ±5°C.

5.8 Deviations/exclusions from, and additions to standard methods

Force At Break

- The test pieces were conditioned and tested at a relative humidity of 50 ± 10% instead of 50 ± 5%.

Removeable Surface Powder

- The temperature was not monitored to confirm within 25 ±5°C during the testing, performed at ambient room conditions.

5.9 Uncertainty of Measurement

Uncertainty of measurement (UoM) has not been taken into account when interpreting the test results compliance with limits. However, the UoM budget for the relevant quantitative test methods are presented in Appendix A, and can be used to assess compliance of individual test results taking into account the UoM.

5.10 Sampling Details

All samples were selected and supplied by the client.

The batch size of the gloves supplied was not stated by the client. In accordance with BS EN 455 Part 1, a batch size between 35,001 to 150,000 was chosen, and therefore 50 gloves per stage were tested for perforations using General Inspection Level I at an AQL of 1.5%. With reference to Table 3, the sample size was tested up to the fifth sampling stage or until compliance or non compliance was determined.

5.11 Sample Preparation

Samples were prepared according to the relevant test method used.

6 Results

6.1 Perforation Testing

The results of perforation testing are presented in Table 2. Compliance has been determined with reference to Table 3.

Table 2: Perforation Testing results for Sample 56961

Stage No	Cumulative No Tested	Cumulative No Failed	Compliance
First	50	0	**Complies**
Second	100	-	
Third	150	-	
Fourth	200	-	
Fifth	250	-	

Table 3: Multiple sampling - Perforation compliance (BS EN 455-1)

	Cumulative No Gloves Tested	Accept	Reject
First stage	50	0	4
Second stage	100	1	6
Third stage	150	3	8
Fourth stage	200	5	9
Fifth stage	250	9	10

6.2 Force at Break

The results of testing are presented in Table 4. Compliance has been determined with reference to Table 5.

Table 4: Force at Break results for Sample 56961

Sample	Force at Break (N) Unchallenged	Force at Break (N) Challenged
1	7.0	6.6
2.	6.2	7.2
3	6.8	6.6
4	7.0	7.5
5	7.4	7.4
6	7.2	7.3
7	7.5	6.6
8	7.0	8.0
9	7.5	7.2
10	7.1	6.4
11	7.0	7.3
12	8.0	6.4
13	8.0	5.6
Median Result	7.1 **Complies**	7.2 **Complies**

Table 5: Median Force at Break Limits (BS EN 455-2)

	Limit
Force at break during shelf life (Unchallenged)	≥ 6.0N
Force at break after challenge testing (Within 12 months of manufacture)	≥ 6.0N

6.3 Dimensions

The results of dimension testing are presented in Table 6. Compliance has been determined with reference to Table 7.

Table 6: Dimension Testing results for Sample 56961

Sample	Length (mm)	Width (mm)
1	239	97
2	244	97
3	243	99
4	241	99
5	239	98
6	237	99
7	239	96
8	242	98
9	240	98
10	239	98
11	241	99
12	242	99
13	240	99
Median Result	240 **Complies**	98 **Complies**

Table 7: Dimension Limits (BS EN 455-2)

	Median Length	Median Width
Medium	≥ 240mm	95 ±10mm

6.4 Total Extractable Protein

The total amount of extractable protein per gram for each of the inner and outer surface test samples is presented in Table 8.

Table 8: Total Extractable Protein results for Sample 56961

Sample	Total Extractable Protein (µg/g) †
1	< 12.2
2	< 11.8
3	< 12.2
4	< 12.6
Mean	Cannot be calculated

† Ovalbumin Equivalent Protein

(Mean value not calculated as the measured concentration of protein in one or more of the samples was below the calculated concentration of the lowest standard in this test.)

6.5 Removable Surface Powder

The total amount of residual surface powder per glove is presented in Table 9.

Table 9: Removable Surface Powder results for Sample 56961

Mass (mg/glove)	Compliance †
0.6	**Complies**

† For compliance with BS EN 455 Part 3: 2015[10] powder-free gloves should contain no more than 2mg powder per glove.

7 Authorisation

Approved and signed electronically. Please see last page of this document.

Pete Phillips, Director, SMTL.

Appendix A

A.1 Medical Gloves - EN 455 Uncertainty of Measurement

A.1.1 TM-342 EN 455-2 Force at Break

UoM for TM-342 Force at Break of Medical Glove testing is 1.6%. The reported uncertainty is an expanded uncertainty using a coverage factor of k=2, which provides a level of confidence of approximately 95%.

A.1.2 TM-343 EN 455-2 Dimensions

UoM for TM-343 Dimensions of Medical Glove testing is 1.1mm for length and 1.5mm for width measurements. The reported uncertainty is an expanded uncertainty using a coverage factor of k=2, which provides a level of confidence of approximately 95%.

A.1.3 TM-391 EN 455-3 Powder

The UoM for TM-391 glove powder testing is 0.2mg. The reported uncertainty is an expanded uncertainty using a coverage factor of k=2, which provides a level of confidence of approximately 95%.

A.1.4 TM-254 EN 455-3 Endotoxin

The UoM for TM-254 endotoxin testing is 23%. The reported uncertainty is an expanded uncertainty using a coverage factor of k=2 which provides a level of confidence of approximately 95%.

References

(1) *Medical gloves for single use - part 1: Requirements and testing for freedom from holes. BS EN 455-1:2000.*

(2) *Medical gloves for single use - part 2: Requirements and testing for physical properties. BS EN 455-2:2015.*

(3) *Medical glove for single use - part 3: Requirements and testing for biological evaluation. annex A:Method for the determination of aqueous extractable proteins in natural rubber gloves using the modified lowry assay. BS EN 455-3:2015.*

(4) *Medical gloves - determination of removable surface powder. BS EN ISO 21171 2006.*

(5) SMTL. *Detection of perforations in medical gloves to BS EN 455 Part 1.* (TM-22).

(6) SMTL. *Force at break testing of medical gloves to BS EN 455 Part 2.* (TM-342).

(7) SMTL. *Determination of dimensions of medical gloves to BS EN 455 Part 2.* (TM-343).

(8) SMTL. *Determination of extractable protein in natural rubber gloves.* (TM-230).

(9) SMTL. *Medical Gloves - Determination of Removable Surface Powder.* (TM-391).

(10) *Medical glove for single use - part 3: Requirements and testing for biological evaluation. BS EN 455-3:2015.*

Digitally signed by:
Pete Phillips, Director SMTL
2018.08.29 12:23:44 BST
SMTL, Bridgend, UK.

This document can be verified in Adobe Acrobat.