NUNDINAE GROUP D.O.O.

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6000 KOPER-CAPODISTRIA, SLOVENIA-EU

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NITRILE GLOVES
MUMU PLUS EXTRA



TOP GLOVE SDN. BHD.

The World's Largest Manufacturer of Gloves GOOD HEALTH, SAFETY FIRST & BE HONEST

199101010171 (220483-T) 88T ID: B16-1808-22000008

A member of Top Glove Corporation Bhd, a Public Listed Company on Bursa Malaysia & Singapore Exchange.

FACTORY 9 : Lot 4969, Jalen Teratai, Betu 6, Off Jalan Meru, 41050 Kleng, Selengor D.E., Melaysia.

📞 +603 3392 1992 📸 +603 3392 1291/8410 🔲 +6012 2896 270 📾 sales@topglove.com.my @ www.topglove.com

EUSINESS DIRECTION : To Produce Consistently High Quality Gloves At Efficient Low Cost.

: 47 Factories (Malaysia, Thailand, Vietnam & China), 750 Production Lines, 90 Billion Gloves Per Annum, 21,000 Employees.

MARKET : Exports to 195 countries worldwide with Marketing Offices in the USA, Germany and Brazil.

EU DECLARATION OF CONFORMITY (EU DoC)

Manufacturing Site

TOP GLOVE SDN. BHD

: Lot 4969, Jalan Teratai, Batu 6. Off Jalan Meru, 41050 Klang, Selangor D.E., Malaysia.

Single Registration Number (SRN)

: MY-MF-000009690

European Authorized Representative

: Top Glove Europe GmbH Bliersheimer Str. 80A. 47229 Duisburg

Germany

Tel.: +49-(0)2065-76421-0, Fax: +49-(0)2065-76421-19

Single Registration Number (SRN)

: DE-AR-000004968

Name of Device

: Nitrile Examination Gloves

Type

: Powder Free : 955100430960BG

Basic UDI - Di **Brand Name**

: Mumu Plus Extra : XS, S, M, L, XL

Size

: Class I, Non Sterile

Classification (MDR)

: Category III

Classification (PPER)

: Annex I, Annex II and Annex IV (Self declared)

Conformity Assessment Procedure (MDR) Conformity Assessment Procedure (PPER)

: Annex VII (Module C2)

Rule (MDR)

: Rule 5

Product Group Reference

: EB201 (ENW40)

EU Type Examination Certificate Number (PPER)

: 2777/10648-04/E00-00

EU Type Examination Certificate Issued by (PPER): SATRA Technology Europe Limited,

Bracetown Business Park,

Clonee, D15YN2P,

Ireland.

Notified Body Number (PPER)

: 2777

"TO PREVENT CORRUPTION & BRIBERY. CORRUPTION & BRIBERY IS A CRIME. BE HONEST AND NO CHEATING"

DP 03/11/20/TGT

A TU

DOC OP2:R3 RA/DOC/MDRPPE/TG/NPFN/OP2/MPE/01/008/08/21/R2

We Top Glove Sdn Bhd herewith declare with our own responsibility that above mentioned product;

- is fully compliance with the General Safety Performance Requirement of the Medical Device Regulation (MDR) 2017/745. All supporting documentations are retained under the premise of manufacturer
- ii. is following to the EU Type Examination and conformity with the provisions of the new PPE Regulations (EU) 2016/425 Category III and, where such is the case, with the national standard transposing harmonized standard no. EN ISO 374-1:2016, EN 420:2003+A1:2009, EN 374-2:2014, EN 374-4:2013, EN 374-5:2016 and EN 16523-1:2015.
- iii. is subject to the procedures set out in Annex VII (Module C2) of the new PPE Regulations (EU) 2016/425 under the supervision of the notified body SATRA Technology Europe Limited, Bracetown Business Park, Clonee, D15YN2P, Ireland.

Applicable Standards (MDR):

No	Standard	Descriptions	Date Published	
1	EN 455-1:2020	Medical gloves for single use. Part 1: Requirement and testing for freedom from holes.	May 2020	
2	EN 455-2:2015	Medical gloves for single use. Part 2: Requirement and testing for physical properties.	April 2015	
3	EN 455-3:2015	Medical gloves for single use. Part 3: Requirement and testing for biological evaluation.	April 2015	
4	EN 455-4:2009	Medical gloves for single use. Part 4: Requirements and testing for shelf life determination.	October 2009	
5	EN ISO 14971:2019	Medical device - Application of risk management to medical device.	December 2019	
6	EN 62366-1:2015	Medical Devices-Part 1: Application of usability engineering to medical devices	April 2015	
7	ISO 2859-1:2011	Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection	June 2011	
8	ISO 10993-1:2018	Biological evaluation for medical device — Part 1: Evaluation and testing within a risk management process	August 2018	
9	ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	June 2009	
10	EN ISO 10993-10:2013	Biological evaluation of medical devices - Tests for irritation and skin sensitization.	August 2013	
11	EN ISO 10993-11:2018	Biological evaluation of medical devices. Tests for systemic toxicity	June 2018	
12	ISO 10993-12:2012	Biological evaluation for medical devices - Sample preparation and reference materials	June 2012	
13	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied: General requirements.		July 2021	





No	Standard	Descriptions	Date Published	
14	MDR 2017/745 {Annex I: Chapter 2)	Requirements Regarding Design and Manufacture	April 2017	
15	MDR 2017/745 (Chapter I: Article 2)	Scope and Definitions	April 2017	
16	MDR 2017/745 (Annex VIII)	Classification rules	April 2017	
17	MDR 2017/745 (Annex II)	Technical Documentation	April 2017	
18	MDR 2017/745 (Chapter II: Article 11&12)	Guideline for Authorized Representative	April 2017	
19	MDR 2017/745 (Annex XIV: Part A)	Clinical Evaluation	April 2017	
20	MEDDEV 2.7/1	2.7/1 Clinical Evaluation	Revision 4, June 2016	
21	MEDDEV 2.12-1 rev 8	Medical Device Vigilance System	January 2013	
22	MEDDEV 2.12/1	2.12/1 Medical Device Vigilance System	Revision 8, January 2013	
23	MDR 2017/745 (Chapter VII: Section 2: Article 87- 92)	Vigilance	April 2017	
24	MDR 2017/745 (Annex XIV: Part B)	Post Market Clinical Follow-up Studies	April 2017	
25	MEDDEV 2.12/2	2.12/2 Post Market Clinical Follow-up Studies	Revision 2, January 2012	
26	MDR 2017/745 (Chapter VII: Section 1: Article 83-86) Annex III	Post Marketing Surveillance (PMS)	April 2017	
27	MEDDEV 2.12/Rec 1	2.12 Post - Marketing Surveillance (PMS) post market / production	Revision 11, February 2000	
28	MDR 2017/745	Medical Device Regulation	April 2017	
29	EN 1041:2008 + A1 2013	Information supplied by the manufacturer of medical devices	December 2019	

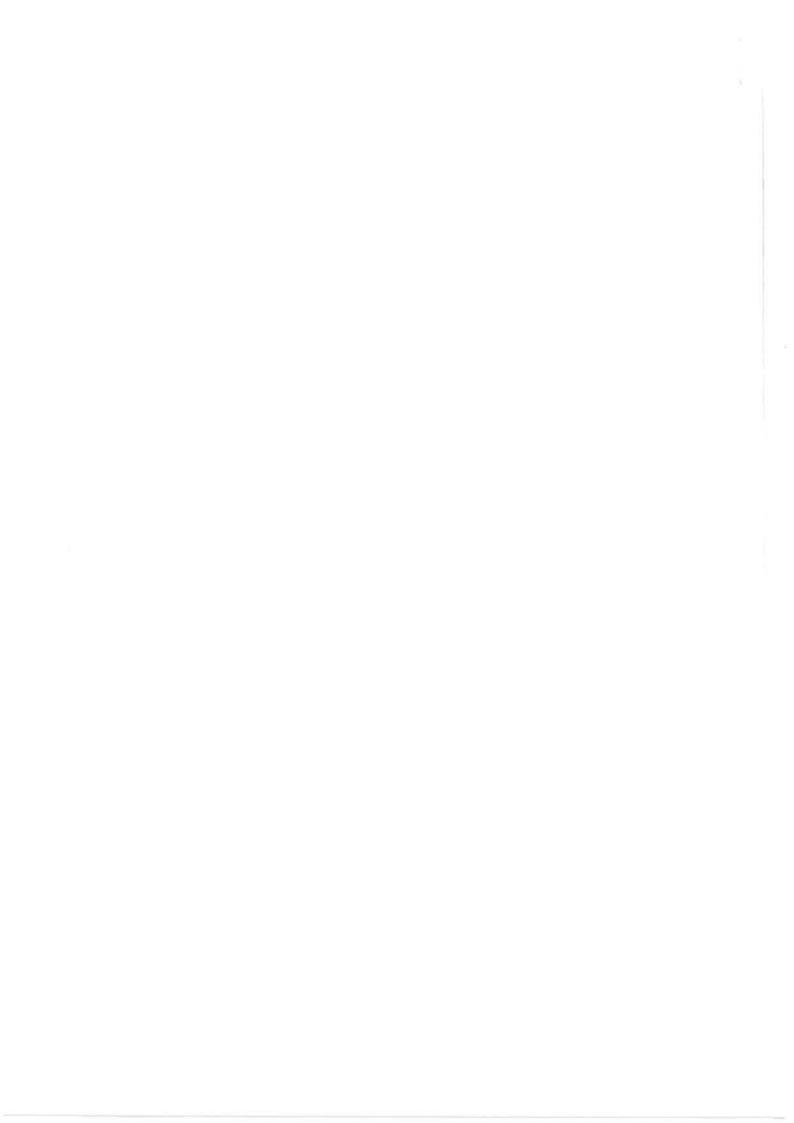
EU DoC Issuance Date

25th August 2021 to 24th August 2022

Name: Pn Noor Akilah Saidin Designation: RA General Manager







TOP GLOVE SDN. BHD.

INSTRUCTION FOR USE



Rev: 1, October 2020

Nitrile Examination Powder Free Gloves

(a) Manufacturer's Name:

Top Glove Sdn. Bhd.

(b) Manufacturer's Address

Lot 4969, Jalan Teratai, Batu 6, Off Jalan Meru, 41050 Klang, Selangor, Malaysia.

(c) Storage

Store in cool, dry place. Opened box should be shielded from exposure to direct sun or fluorescent lighting.

(d) Shelf life

5 years upon manufacturing date.

(e) Intended use:

The glove is intended to be worn on the hand of healthcare personal during medical examination as procedure to help protect cross contamination between healthcare and patient.

- (f) This is a single use device.
- (g) Caution

After use, wearers should visually check the gloves and remove any contamination from the outer surface before removing the gloves from the hand. Alternatively, carefully peel the gloves off the hand so that the contaminated glove outer does not touch your skin.

(h) **Indication**

This product can be worn on the hand of healthcare personal during medical examination as procedure to help protect cross contamination between healthcare and patient.

Contraindication:

- i) Re-use of this product is not recommended.
- ii) Do not use this product if the expiry date printed on the packaging materials has exceeded or the packaging seal has been opened before use.

Patient target group:

The targeted patient population is similar to a normal population.

Intended User profile:

Nitrile Examination Powder Free Gloves intended to be worn by healthcare personnel.

(i) Performance characteristic of the device

i. Freedom from holes : Acceptable Quality Limit (AQL): 1.5

ii. Physical properties : Median ≥ 6.0 Niii. Powder Residue : Max. 2mg/glove

TOP GLOVE SDN. BHD.

Rev: 1, October 2020

INSTRUCTION FOR USE

iv. Dimensions		
Description	Size	Standard
Length, mm	All Sizes	Min 240
Palm Width, mm	XS S M L XL	76 +/- 3 84 +/- 3 94 +/- 3 105 +/- 3 113 +/- 3

(j) Disposal procedure of device:

Incineration: Put appropriate amount of the gloves into the incinerator or furnace to destroy them following the requirements shown below.

Requirements:

- 1) Burning temperature exceeds 850°C
- 2) Combustion retention time is not less than 2 seconds

Note: Gloves should not be destroyed by open burning at low temperature or dispose at normal disposal area.

Other Disposal Considerations:

Check with state and local authorities before discarding. The information offered here is for product as shipped. Use and/or alterations to the product such as mixing with other materials may significantly change the characteristics of the material and alter the proper disposal method.

Disposal of the examination gloves according to the local clinical disposal requirements as this product are considered bio-hazard and non-degradable.

Prepared by: Reviewed by: Approved by:

RA Unit

Fatimawati/ Dr. Kiwi

Noor Akilah Bt Saidin

1st October 2020 Manager, RA/DGM, R&D DGM, RA





PPE REGULATION (EU) 2016/425 **MODULE C2 CERTIFICATE**

Issued to:

Top Glove Sdn Bhd Lot 4969 Jalan Teratai Batu 6 Off Jalan Meru 41050 KLANG Selangor D E Malaysia

This is to certify that the following products tested under SATRA reports referenced: STE0322555 & CHM0322579/2146/JL have been found to satisfy the requirement of PPE Regulation (EU) 2016/425 Module C2 EU quality control system for the final product for and on behalf of SATRA Technology Europe Limited

EU TYPE EXAMINATIO	N
CERTIFICATE NUMBER	₹

PRODUCT GROUP **REFERENCE**

PRODUCT TYPE

CLASSIFICATION

2777/10648-05/E00-00

EB201

Nitrile examination powder free glove available in various colours

EN ISO 374-1:2016 Type B

EN ISO 374-5:2016

Dated:

6th December 2021

This certificate is valid until:

December 2022

Signed By G Graham

For and on behalf of SATRA Technology **Europe Limited**

The issuance of this certificate is subject to the company maintaining its manufacturing and quality system to the required standard.

SATRA Technology Europe Limited. Bracetown Business Park Clonee Dublin 15 D15 YN2P. Republic of Ireland. (Notified Body number 2777)
Tel: +353 (0) 1 437 2484 Web: www.satraeurope.com



Issued to:

MY TICARET VE MEDIKAL A.S. Ömerli Mah General Sükrü Koralti Cad. No:33 34555 Amavutköy/Istanbul Turkey

Notified Body: 2777

SATRA customer number: P0130

EU Type-Examination Certificate

Certificate number: 2777/10648-04/E42-01

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:

Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference:

XS -MPE00, MPE11, MPEB00 S- MPE01, MPE12, MPEB01 M- MPE02, MPE13, MPEB02 L- MPE03, MPE14, MPEB03 XL- MPE04, MPE15, MPEB04

Sizes:

6 (XS) - 10 (XL)

Description:

Nitrile examination powder free gloves available in:

Black and Blue

Classification:

EN ISO 374-1:2016/Type B	Level	EN374-4:201
37% Formaldehyde	6	3.1%
40% Sodium Hydroxide	6	-25.6%
30% Hydrogen Peroxide	2	17.0%

EN ISO 374-5:2016

Resistance to Bacteria and Fungi	Pass
Resistance to Virus	Pass

Standards/Technical specifications applied:

EN 420: 2003+A1: 2009; EN ISO 374-1:2016; EN ISO 374-5:2016

Technical reports/Approval documents:

SATRA: CHM0265112/1749/EN/A, CHM0265112/1749/EN/B, CHM0265112/1749/SPT, CHM0272621/1826/JS, CHM0275215/1836/LH, CHM0275215/1836/LH/E, CHM0275215/1836/LH/D, CHM0275215/1836/LH/A/Final TUV: 7191143339-CHM16-01-RC

Signed on behalf of SATRA:

alahan

Geoff Graham

Date of issue: Expiry date: 03/11/2021 25/06/2023

TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement. This certificate has been issued in accordance with Annex V (Module B) of the applicable legislation (see note 11).

Please note:

- Where the product is classified as category III then CE or UKCA Marking of production is reliant on current compliance with module C2 or Module D of the applicable legislation (See note 11). (Except that specifically produced to fit an individual user).
- 2. Full details of the scope of the certification and product(s) certified are contained within the manufacturer's technical documentation.
- 3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
- 4. Certification is limited to production undertaken at the sites listed in the manufacturer's technical documentation.
- Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate and an EU declaration of product conformity shall be made available in accordance with the applicable legislation (See note 11)
- 6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
- 7. Where results obtained during type testing are within the budget of uncertainty when compared to the pass requirement, classification or performance level, then it is the responsibility of the manufacturer to ensure that the factory production control and manufacturing tolerances are such that the product placed on the market meets with the stated requirements, classifications or performance levels.
- 8. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state, or UK government.
- 9. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
- SATRA reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of the applicable legislation (See note 11).
- 11. These terms and conditions shall apply to the requirements set out in Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment or to UK legislation relating to UKCA Marking as defined within the issued certificate.



Issued to:

Top Glove Sdn Bhd Lot 4969 Jalan Teratai Batu 6 Off Jalan Meru 41050 KLANG Selangor D E Malaysia

Notified Body: 2777

SATRA customer number: P0130

EU Type-Examination Certificate

Certificate number: 2777/10648-04/E00-00

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:

Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference:

Description:

EB201

Nitrile examination powder free gloves available in:

Black, White, Red, Pink, Blue, Light Purple, Green, Forest Green, Cool Blue, Cornflower Blue, Violet Blue, Marlin Blue, Sky Blue, Dodger Blue, Pearlescent Pink, Harmony Blue,

Avocado.

Sizes:

Classification:

6(XS) - 10(XL)

 EN ISO 374-1:2016/Type B
 Level
 EN374-4:2013

 37% Formaldehyde
 6
 3.1%

 40% Sodium Hydroxide
 6
 -25.6%

 30% Hydrogen Peroxide
 2
 17.0%

EN ISO 374-5:2016

Resistance to Bacteria and Fungi Pass Resistance to Virus Pass

Standards/Technical specifications applied:

EN 420: 2003+A1: 2009; EN ISO 374-1:2016; EN ISO 374-5:2016

Technical reports/Approval documents:

SATRA: CHM0265112/1749/EN/A, CHM0265112/1749/EN/B, CHM0265112/1749/SPT, CHM0272621/1826/JS, CHM0275215/1836/LH, CHM0275215/1836/LH/E, CHM0275215/1836/LH/D, CHM0275215/1836/LH/A/Final TUV: 7191143339-CHM16-01-RC

Signed on behalf of SATRA:

Date first issued: 25/06/2018
Date of issue: 14/03/2019

(too)

Hannah Coe

alahan

Geoff Graham

Expiry date: 25/06/2023

Page 1 of 2

TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement.

The certificate holder is licensed to mark the products detailed within this certificate in accordance with Annex V (Module B) of the Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment once you have drawn up an EU declaration of product conformity. Please note:

- Where the product is classified as category III then CE Marking of production is reliant on current compliance with Regulation 2016/425 module C2 or Module D. (Except that specifically produced to fit an individual user).
- Full details of the certification and product are contained within the manufacturer's technical documentation.
- Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
- 4. Certification is limited to production undertaken at the sites listed in the manufacturers technical documentation.
- 5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate.
- The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
- 7. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state government.
- 8. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
- 9. SATRA Technology reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of Regulation 2016/425.



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:

Top Glove Sdn Bhd

Lot 4969 Jalan Teratai

Batu 6

Off Jalan Meru 41050 KLANG Selangor D E Malaysia

Your reference:

Date of report:

13th February 2018

Samples received: 29th August 2017

SATRA reference: CHM0265112/1749/EN

/A/Issue 2

For the attention of: Norahimah Bt Abd Rahim

Date(s) work

15th December 2017 to

carried out:

13th February 2018

TECHNICAL REPORT

Subject:

Chemical innocuousness testing in accordance with EN 420: 2003 + A1: 2009 and EN 16523-1: 2015 resistance to permeation by chemicals on gloves described as Nitrile Examination Powder Free Glove RA/080/008/2017/C.

This report replaces CHM0265112/1749/EN/A issued on the 13th February 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

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:

Emma Norris

Position:

Chemical Technologist

Department:

Chemical & Analytical Technology

(Page 1 of 12)

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

SATRA

TECHNICAL REPORT



WORK REQUESTED:

Samples of gloves described as Nitrile Examination Powder Free Glove RA/080/008/2017/C were received on the 29th August 2017 for testing in accordance with the innocuousness requirements of EN 420:2003 + A1:2009 and EN 16523-1:2015 and assessment in accordance with the requirements of EN ISO 374-1:2016.

CONCLUSION:

The samples of gloves described as Nitrile Examination Powder Free Glove were assessed in accordance with the innocuousness requirements of EN 420:2003 + A1:2009 and were found to meet with the requirement for pH value and the REACH annex XVII requirement for PAHs. When assessed in accordance with the requirements of EN ISO 374-1:2016 the samples of gloves described as Nitrile Examination Powder Free Glove achieved the following performance levels:

Chemical	Performance level
40% Sodium hydroxide (CAS: 1310-73-2)	6
65% Nitric acid (CAS: 7697-37-2)	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
37% Formaldehyde (CAS: 50-00-0)	1 22 1 22
30% Hydrogen peroxide (CAS: 7722-84-1)	2
40% Hydrofluoric acid (CAS: 7664-39-3)*	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved

^{*}Testing carried out at a subcontract laboratory and results reported under their reference CP151217C/VL.

Full results are given in the following tables.

TESTING REQUIRED:

- EN 420:2003 + A1: 2009 Clause 4.3.2 pH Value (ISO 3071 for textiles & other materials & ISO 4045 for leathers)
- #SATRA SOP CAT-018 Determination of PAHs (based on ZEK 01.4-08)
- EN 16523-1:2015 Determination of material resistance to permeation by chemicals. Part 1: Permeation by liquid chemical under conditions of continuous contact

Top Glove Sdn Bhd SATRA Reference: Date:

CHM0265112/1749/EN/A/Issue 2 28th March 2018 (Page 2 of 12)





RESULTS AND REQUIREMENTS:

EN 420:2003 + A1:2009 Clause 4.3.2 pH value

Date of determination: 10th January 2018

Sample	Method	pH Value	UoM	Pass/Fail
Nitrile Examination Powder Free Glove RA/080/008/2017/C	ISO 3071: 2005 (water extraction)	6.8	± 0.1	Pass
Requirement	pH value greater than 3.5 and less than 9.5			

The extraction solution temperature was 17°C and at pH 7.0

≠SATRA SOP CAT-018 - Determination of PAHs

Analysed by Gas Chromatography with Mass Spectrometry (GC-MS)

Sample	PAHs detected (mg/kg)	Pass/Fail	
Nitrile Examination Powder Free Glove RA/080/008/2017/C	<0.2 (of each PAH listed in the appendices)	Pass	
Requirements: REACH 1907/2006 annex XVII entry number 50	<1mg/kg of each PAH listed in the appendices	"DIE 1/2"	

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

Permeation performance level	Measured breakthrough time (minutes)	
(a) 25189 ENR	>10	
2	>30	
3	>60	
4	>120	
5	>240	
6	>480	

Performance levels are based on the lowest individual result achieved per chemical.

Top Glove Sdn Bhd SATRA Reference:

Date: 28th March

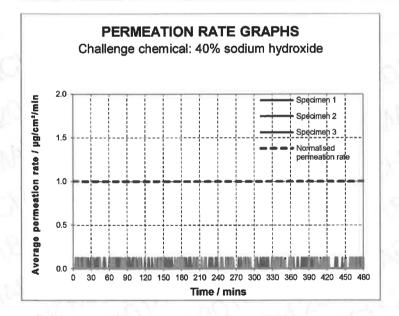
CHM0265112/1749/EN/A/Issue 2 28th March 2018 (Page 3 of 12) Signed:

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Test/Property	Sample reference:	Nitrile Examination	Performance	
		Chemical: 40%	6 sodium hydroxide	
	-	Normalised permeation	A.	
EN	Test	Detection technique:		
16523-1:2015	information:	Collection medium: De	ionised water (closed loop)	
in accordance with SATRA	/	Collection medium stirring rate: (each cell constant to within ± 10%) 45 – 65 ml/min		
SOP CAT-009		Test temperature:	(23 ± 1) °C	Level 6
Using PTFE permeation cells	Specimen	Thickness (mm)∆	Breakthrough time (mins)	
with standardised	1	0.06	>480	
dimensions	2	0.06	>480	
	3	0.06	>480	Y of the Year
		Test result:	>480	
		UoM:	<1	
Visual appearance of specimens after testing:		Sw	rollen and discoloured	



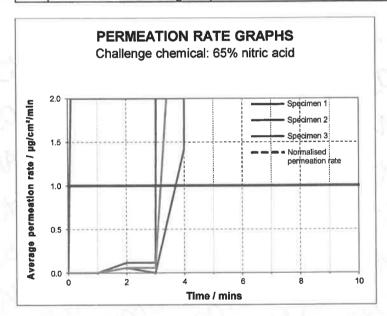
Top Glove Sdn Bhd SATRA Reference: Date:

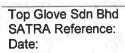
CHM0265112/1749/EN/A/Issue 2 28th March 2018 (Page 4 of 12)





Test/Property	Sample reference:	Nitrile Examination	Performance	
		Chemical:	65% nitric acid	
		Normalised permeation		
EN	Test	Detection technique:	Conductimetry (continuous measurement)	The samples
16523-1:2015	information:	Collection medium: D	eionised water (closed loop)	tested did not
in accordance with SATRA		Collection inculation stilling rate. AE _ EE milmin		meet with the minimum
SOP CAT-009	1	Test temperature:	(23 ± 1) °C	breakthrough
Using PTFE	Specimen	Thickness (mm)∆	Breakthrough time (mins)	time for a performance
permeation cells with standardised	1	0.07	4	level 1 to be
dimensions	2	0.06	4	achieved
	3	0.06	3	Yateh, Ad
		Test result:	3	
		UoM:	<1	
Visual appearance of specimens after testing:		Swol	llen, brittle and discoloured	





CHM0265112/1749/EN/A/Issue 2 28th March 2018 (Page 5 of 12)







Test/Property	Sample reference:	Nitrile Examination Powder Free Glove		Performance
EN 16523-1:2015 in accordance with SATRA SOP CAT-025 Using PTFE	Test information:	Chemical: 37% formaldehyde		Д
		Normalised permeation rate (NPR): 1 µg/cm²/min		
		Detection technique: HPLC-DAD (periodic measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: (each cell constant to within ± 10%) 45 – 65 ml/min		
		Test temperature:	(23 ± 1) °C	
	Specimen	Thickness (mm)∆	Breakthrough time (mins)▼	Level 1
	1	0.06	Between 361 to 480	
permeation cells	2	0.06	Between 21 to 30	
with standardised	3	0.06	Between 361 to 480	Y new X.T.d
dimensions	4	0.05	Between 11 to 20	
	5	0.05	Between 31 to 45	
	6	0.06	Between 241 to 360	
		Test result:	Between 11 to 20	
		UoM:	See below	
Visual appearance of specimens after testing:		Sw	ollen and discoloured	د پر د

For SOP CAT-025, where both the P_1 and P_u are observed in the same sampling range, uncertainty is expressed as the time difference between the mid-point of the range and the previous sampling time. This uncertainty is included in the reported result.

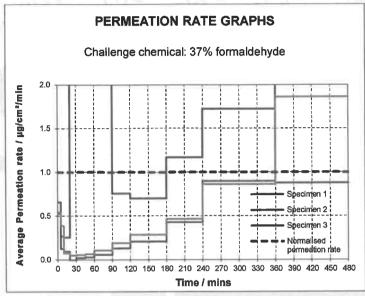
Top Glove Sdn Bhd SATRA Reference: Date:

CHM0265112/1749/EN/A/Issue 2 28th March 2018 (Page 6 of 12)

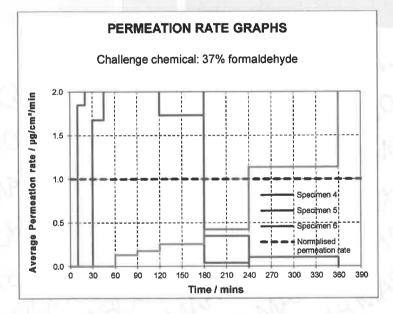












Formaldehyde is determined by discrete sampling; therefore the permeation rate graph is not a smooth curve.

Top Glove Sdn Bhd SATRA Reference: Date:

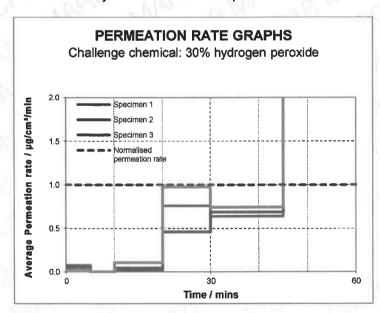
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Test/Property	Sample reference:	Nitrile Examination Powder Free Glove		Performance
EN 16523-1:2015 in accordance with SATRA SOP CAT-025	Test information:	Chemical: 30% Hydrogen peroxide		AU .
		Normalised permeation rate (NPR): 1 µg/cm²/min		
		Detection technique:	echnique: Electrochemical detector (periodic measurement)	
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: (each cell constant to within ± 10%)		
		Test temperature:	(23 ± 1) °C	Level 2
Using PTFE permeation cells with standardised	Specimen	Thickness (mm)∆	Breakthrough time (mins)▼	
		0.06	Between 46 to 60	
dimensions	2	0.07	Between 46 to 60	
	3	0.06	Between 46 to 60	
		Test result:	Between 46 to 60	
		UoM:	See below	
Visual appe specimens a		S	wollen and discoloured	

For SOP CAT-025, where both the P_1 and P_u are observed in the same sampling range, uncertainty is expressed as the time difference between the mid-point of the range and the previous sampling time. This uncertainty is included in the reported result.



Hydrogen peroxide is determined by discrete sampling; therefore the permeation rate graph is not a smooth curve.

Top Glove Sdn Bhd SATRA Reference: Date:

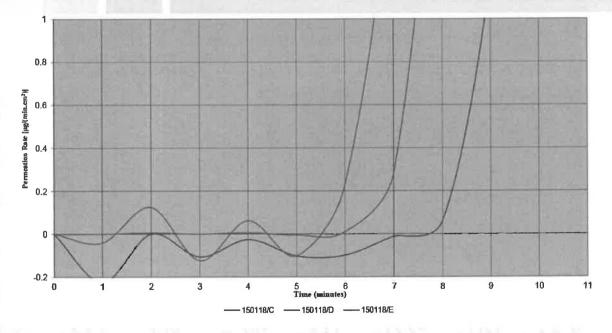
CHM0265112/1749/EN/A/Issue 2 28th March 2018 (Page

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Test/Property	Sample reference:	Nitrile Examination Powder Free Glove		Performance
EN 16523-1:2015	Test information:	Chemical: 40% hydrofluoric acid		
		Normalised permeation rate (NPR): 1 µg/cm²/min		
		Detection technique:	Electrical conductivity	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
		Collection medium:	TISAB solution	
		Test temperature:	(23 ± 1) °C	
	Specimen	Thickness (mm)	Breakthrough time (mins)	
	С	0.06	8	
	D	0.06	6	
	E	0.06	7	
	The state of the	Test result:	6	2
		UoM:	± 2	
Visual appe specimens a		S	Swollen and discoloured	



Testing carried out at a subcontract laboratory and results reported under their reference CP151217C/VL.

Top Glove Sdn Bhd SATRA Reference: Date:

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- △ EN 16523-1:2015 does not require the test specimen thicknesses to be reported, this information is indicative only.
- Breakthrough expressed as a range between discrete sampling points where the average permeation rate exceeds the NPR. Due to the complexity of the detection technique, the minimum sampling frequency as specified in table 1 of EN 16523-1:2015 is not possible.

APPENDICES:

REACH Regulation (EC) No 1907/2006 Annex XVII entry number 50 as amended by regulation 1272/2013

PAH	CAS Number	Requirements
Benzo[a]anthracene	56-55-3	Articles shall not be placed on the market for
Chrysene	218-01-9	supply to the general public, if any of their
Benzo[b]fluoranthene	205-99-2	rubber or plastic components that come into
Benzo[k]fluoranthene	207-08-9	direct as well as prolonged or short-term
Benzo[j]fluoranthene	205-82-3	repetitive contact with the human skin or the
Benzo[e]pyrene	192-97-2	oral cavity, under normal or reasonably
Benzo[a]pyrene	50-32-8	foreseeable conditions of use, contain more
Dibenzo[a,h]anthracene	53-70-3	than 1 mg/kg of any of the listed PAHs.



Gloves described as Nitrile Examination Powder Free Glove RA/080/008/2017/C





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 entitles (public, private or governmental) issuing instructions (hereinafter termed the "Client"). Each elso known individually as a Party, or jointly as Parties. 12
- 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 1.3
- 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

- (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 itsms 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 from 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

- 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 accruting 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 proforms 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 deared 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. Atthough SATRA will by and provide an estimate of such expenses these may change as a result of circumstances out of SATRA's control. 2.3
- 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 writing.
- 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 mories 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. 2.7
- 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 cou action. All fees associated with such actions shall be paid for by the Client including legal fees and relate costs.
- 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. 2.10

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 lews 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 whatever medium) produced by SATRA pursuant to this Contract shall belong to SATRA. The Client's 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 Timeine, SATRASUMM and SATRA Visionstitch, provided that the Client is a member of SATRA and has paid its annual Samateare fee then the Client will be entitled to use the software for its own Internat 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 visible to support. The Client's rights to use the software and receive software upgrades are not included within the entitlement to upgrades but may be offered by SATRA from time to time for an additional 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 loss, destruction or damage to such date).

SURDENSION 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 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. 4.2

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 dates 6.2, neither SATRA nor any of its employees, agents or subcontractors shall be fisble 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 artsing as a result of unclear, erroneous, incomplets, misleading or false information provided to SATRA. 5.1
- 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; freud 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, 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 Savices or the price of the Goode (excluding any value added as or other sales tax or expenses) payable by the Client to SATRA under the Contract or £100,000 whichever 5.4

MISCELLANEOUS

- 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.
- 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, colleteral 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 dause, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance. 6.5
- 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. 6.6

CONFIDENTIALITY

- 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 7.2 consent of SATRA.
- Where SATRA has given consent to disclosure of any service deliverables referred to in clause 7.1, the Client shell 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 faiture to do so. 7.3
- 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 consent of SATRA.

8.

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.

DISPUTE RESOLUTION 9.

- 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. 9.1
- 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 fall 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 erbitration shall be Employed. 93

Signed:

Top Glove Sdn Bhd

SATRA Reference: Date:

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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 judgment in such courts shall be entitled to enforce it in
- 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. 10 3
- 104 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 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 material affect the nature or quality of the provision of these Services or where they are necessary in order to ensu that any applicable laws or safety requirements are complied 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. 10.9
- 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 at
- 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. 11.3
- 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 compiled and may require the Client to reimburse SATRA the amount of any additional costs arising from the suspension. 11.4
- 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.
- 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. 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.
- 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 126
- 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.
- b)
- 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. b)
- ship of Goods has passed to the Client, the Client shall:

- hold the Goods as SATRA's balles; 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.
- 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.
- 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: 13.6
- 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.
- 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
- 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
- PATENTS 14.
- 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 meterial 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 sald 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
- 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 15.1
- 16. DEFECTIVE GOODS
- Subject to clauses 16.6 and 16.7 if: 16.1
- 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 SATRA is given a reasonable opportunity of examining such Goods; and the Client (if eaked 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.
- 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. 16.2
- 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
- SATRA will pay the reasonable costs of carriage, packaging and insurance for any defective Good are returned by the Client provided that SATRA is liable under clause 16.1 to repair or replace the di Goods. If SATRA determines that the Goods are not defective or if SATRA is not liable to repair or the Goods due to the circumstances under clauses 16.8 or 16.7 then the Client will be responsible 16.5
- SATRA shall not be under any liability to repair or at its option replace or pay for the repair or replace 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)
- b)
- 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;
- 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: 16.7
- 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 (6.7 shall have effect as to impose upon SATRA any additional liability or obligations other than those referred to in condition 16.1.
- 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. 16.8

Terms and conditions - December 2016

Top Glove Sdn Bhd SATRA Reference:

Date:

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Certificate

No. Q6 055729 0010 Rev. 03

Holder of Certificate:

Top Glove Sdn. Bhd.

Lot 4969, Jalan Teratai Batu 6

Off Jalan Meru

41050 Klang, Selangor D. E.

MALAYSIA

Facility(ies):

Top Glove Sdn. Bhd.

Lot 4969, Jalan Teratai Batu 6, Off Jalan Meru, 41050 Klang,

Selangor D. E., MALAYSIA

Certification Mark:



Scope of Certificate:

Manufacture and Supply of

1. Non-Sterile Natural Rubber Latex Examination Glove

2. Non-Sterile Synthetic Rubber Latex Examination

Glove

3. Sterile Natural Rubber Latex Surgical Glove

4. Sterile Synthetic Rubber Latex Surgical Glove

Applied Standard(s):

EN ISO 13485:2016

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

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

Report No.:

MYQMH1119039-721424093

Valid from:

2020-05-01

Valid until:

2023-04-30

Date,

2020-04-15

Christoph Dicks

Head of Certification/Notified Body





STANDARDS

CREDITED CERTIFICATION BY QS 02121999 CB 01

SIRIM QAS International hereby certifies that

TOP GLOVE SDN. BHD. **LOT 4969, JALAN TERATAI BATU 6, OFF JALAN MERU 41050 KLANG SELANGOR DARUL EHSAN MALAYSIA**

has implemented a Quality Management System complying with

ISO 9001: 2015

QUALITY MANAGEMENT SYSTEMS - Requirements



Scope of certification

MANUFACTURE & SUPPLY; AND DISTRIBUTION OF

- 1) NON-STERILE NATURAL RUBBER LATEX EXAMINATION GLOVE;
- 2) NON-STERILE SYNTHETIC RUBBER LATEX EXAMINATION GLOVE;
- 3) STERILE NATURAL RUBBER LATEX SURGICAL GLOVE;
- 4) STERILE SYNTHETIC RUBBER LATEX SURGICAL GLOVE.



Issue date 12 April 2020

30 December 2019 Original certification date

Expiry date 30 April 2023

Certificate no. QMS 03514

SIRIM QAS INTERNATIONAL SDN. BHD.

(Co. No. 410334 - x) 1, Persiaran Dato' Menteri Section 2, P.O. Box 7035 40700 Shah Alam Selangor Darul Ehsan MALAYSIA

Tel: 06-3-55446404 Fax: 06-3-55446787

http://www.sirim-qas.com.my http://www.malaysiancertified.com.my

Mohd Azanuddin Salleh Chief Executive Officer

SIRIM QAS International Sdn. Bhd.

This certificate is granted subject to the terms and conditions as stated in the Certification Agreement.