





Date : 16 APR 2021

Colour:

■ **BLACK**

■ PANTONE 432 C

■ PANTONE 326 C

**APPROVED BY**

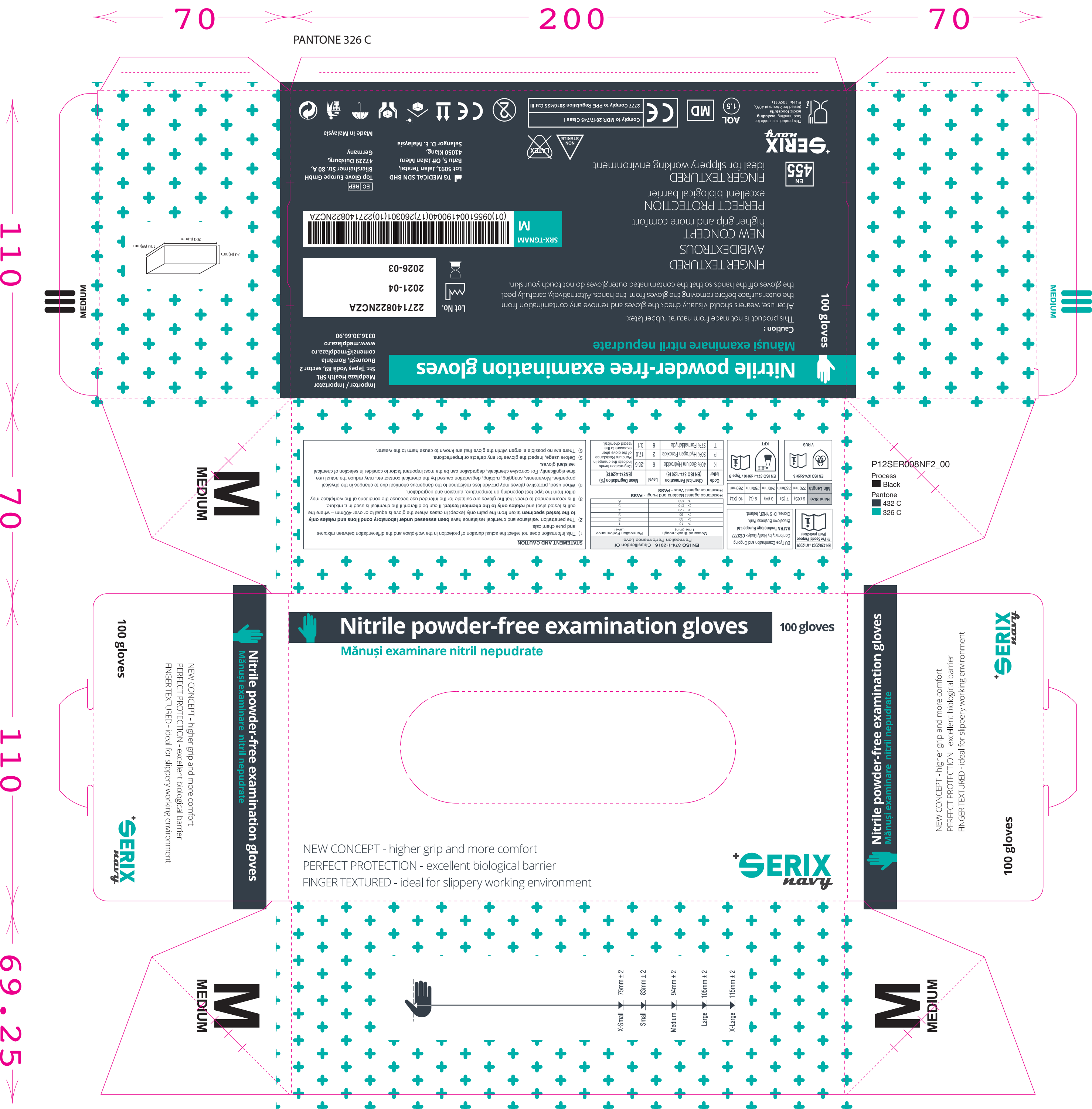
(Chop & Sign)

Date:

## IMPORTANT !

Please note that this colour print is for visual purpose only.  
Output colour might differ in actual production.

**Remark:** *Item Code : P12SER008NF\_00, Butterfly Locking*





# 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:**

EB201

**Description:**

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:**

6 (XS) – 10 (XL)

**Classification:****EN ISO 374-1:2016/Type B**

37% Formaldehyde

40% Sodium Hydroxide

30% Hydrogen Peroxide

**Level**

6

6

2

**EN374-4:2013**

3.1%

-25.6%

17.0%

**EN ISO 374-5:2016**

Resistance to Bacteria and Fungi

Resistance to Virus

Pass

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**

Hannah Coe



Geoff Graham

**Expiry date: 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.

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:

1. 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).
2. Full details of the certification and product 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 manufacturers technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate.
6. 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.



**TOP GLOVE SDN. BHD.** (Company No. 220483-T)  
(SST ID: B16-1808-22000008)  
**The World's Largest Manufacturer of Gloves**  
**GOOD HEALTH, SAFETY FIRST & BE HONEST**

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

**FACTORY 9** : Lot 4969, Jalan Teratai, Batu 6, Off Jalan Meru, 41050 Klang, Selangor D.E., Malaysia.  
☎ +603 3392 1992 📠 +603 3392 1291 📠 +6012 2896 270 ✉ sales@topglove.com.my 🌐 www.topglove.com

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

**FACILITIES** : 42 Factories (Malaysia, Thailand & China), 682 Production Lines, 63.9 Billion Gloves Per Annum, 18,000 Employees.

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

## DECLARATION OF CONFORMITY

Manufacturing Site : TOP GLOVE SDN. BHD.  
Lot 4969, Jalan Teratai, Batu 6,  
Off Jalan Meru, 41050 Klang,  
Selangor Darul Ehsan,  
Malaysia.

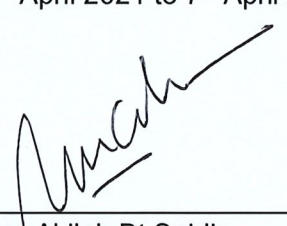
Name of Device : Nitrile Examination Gloves  
Type : Powder Free  
Classification : PPE Category III

I, the undersigned, hereby declare that the disposable device(s) specified above are following 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 and EN 374-5:2016.

Issued by : SATRA Technology Europe Limited,  
Bracetown Business Park,  
Clonee, D15YN2P,  
Ireland.

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 is identical to the PPE (EU) Certificate of Conformity No: **2777/10648-04/E00-00**.

DoC Validity : 8<sup>th</sup> April 2021 to 7<sup>th</sup> April 2022

  
\_\_\_\_\_  
Noor Akilah Bt Saidin  
General Manager, RA  
RA/DOCPPE/R2/009/04/21/03/NPFN/M

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





**TG MEDICAL SDN. BHD.**  
**The World's Largest Manufacturer of Gloves**  
**GOOD HEALTH, SAFETY FIRST & BE HONEST**

Registration No.  
199301028620 (283358-W)  
SST ID: B10-1808-22000011

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

**FACTORY 3** : Lot 5091, Jalan Teratai, Batu 5, Off Jalan Meru, 41050, Klang, Selangor D.E., Malaysia.

☎ +603 3392 7880/7350 📠 +603 3392 9160 📠 +6012 2896 270 ✉ sales@topglove.com.my 🌐 www.topglove.com

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

**FACILITIES** : 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.

Date : 8<sup>th</sup> April 2021

To : Whom It May Concern

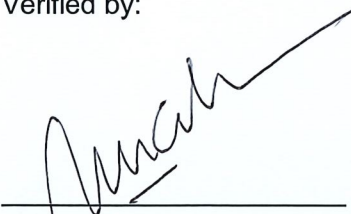
Subject: **LETTER OF DECLARATION**

This is to inform that the below companies are subsidiaries company of Top Glove Corporation Berhad.

Num.	Company	Address
1	TG Medical Sdn. Bhd.	Lot 5091, Jalan Teratai, Batu 5, Off Jalan Meru, 41050 Klang, Selangor D.E. Malaysia
2	Top Glove Sdn. Bhd.	Lot 4969, Jalan Teratai, Batu 6, Off Jalan Meru, 41050 Klang, Selangor D.E. Malaysia

LoD Validity: 8<sup>th</sup> April 2021 to 7<sup>th</sup> April 2022

Verified by:

  
\_\_\_\_\_  
Noor Akilah Bt. Saidin  
General Manager, RA  
RA/LOD/R2/007/04/21/03/M

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

DP 03/11/20/TGT

The management system of

# TG Medical Sdn. Bhd.

Lot 5091, Jalan Teratai, Batu 5, Off Jalan Meru  
41050 Klang, Selangor Darul Ehsan  
MALAYSIA

has been assessed and certified as meeting the requirements of

## Directive 93/42/EEC

on medical devices, Annex V

For the following products

**Sterile Natural Latex Surgical Gloves and Sterile Polyisoprene Surgical Gloves.**

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 16 December 2019 until 06 August 2023  
and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 19 November 1999  
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered MY/KUL/ MY00308

Authorised by



**SGS Belgium NV, Notified Body 1639**

SGS House Noorderlaan 87 2030 Antwerp Belgium  
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5008 - Certificate CE1639 AnnexV\_EN rev. 01

Page 1 of 1





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

**FACTORY 3** : Lot 5091, Jalan Teratai, Batu 5, Off Jalan Meru, 41050, Klang, Selangor D.E., Malaysia.

☎ +603 3392 7880/7350 📠 +603 3392 9160 📠 +6012 2896 270 ✉ sales@topglove.com.my 🌐 www.topglove.com

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

**FACILITIES** : 42 Factories (Malaysia, Thailand & China), 682 Production Lines, 64 Billion Gloves Per Annum, 18,000 Employees.

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

## DECLARATION OF CONFORMITY

Manufacturer's Name : TG MEDICAL SDN. BHD  
Manufacturer's Address : Lot 5091, Jalan Teratai, Batu 5, Off Jalan Meru,  
41050 Klang, Selangor D. E. Malaysia

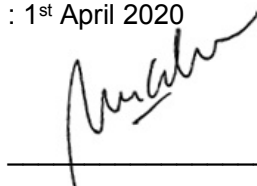
European Authorized Representative: Top Glove Europe GmbH  
Bliersheimer Str. 80, D-47229 Duisburg  
Deutschland/Germany  
Tel.: +49-(0)2065-76421-0,  
Fax: +49-(0)2065-76421-19

Name of Device : Nitrile Examination Gloves  
Type : Powder Free  
Classification : Class I, Non Sterile  
Conformity Assessment Procedure : Annex VII  
Conformity Route : Self Declaration

We herewith declare with our own responsibility that above mentioned product(s) with CE mark are fully compliance with Essential Requirement of the EC Council Directive 93/42/EEC 14<sup>th</sup> June 1993 concerned medical devices, amended by Council Directive 2007/47/EC.

Competent Authority : Bezirksregierung Düsseldorf,  
Postfach 300865, 40408 Düsseldorf.  
Registration Date : 31 March 2010  
Registration No : DE/CA20/02-TOPGLOVEB-01/10

Date : 1<sup>st</sup> April 2020



Name: Pn Noor Akilah Saidin  
Designation: RA Deputy General Manager



## TEST REPORT: 7191143339-CHM16-01-RC

Date: 28 JUL 2016

Tel: +65 68851345 Fax: +65 67732912

Client's Ref: 221410189

Email: Randy.CHIN@tuv-sud-psb.sg

**Note:** This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.



PSB Singapore

Choose certainty.  
Add value.

### **SUBJECT**

Bacteriophage Penetration Test of Gloves

### **CLIENT**

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

Attn : Ms. Azizi Rasidah

### **SAMPLE SUBMISSION DATE / TEST DATE**

05 Jul 2016 / 18 Jul 2016

### **DESCRIPTION OF SAMPLE**

1 sample of gloves was received.

Type of Product	Qty (pcs)	Reference No.
Nitrile Examination Powder Free Glove	10	RA/136/007/2016/E

### **METHOD OF TEST**

ASTM F 1671-13, "Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X 174 Bacteriophage Penetration as a Test System"

Specimen Exposure Procedure B

Test specimens, each of dimensions 75 mm square were cut for the tests.

Tests were performed in triplicates.



Laboratory:  
**TÜV SÜD PSB Pte. Ltd.**  
No.1 Science Park Drive  
Singapore 118221

Phone : +65-6885 1333  
Fax : +65-6776 8670  
E-mail: testing@tuv-sud-psb.sg  
www.tuv-sud-psb.sg  
Co. Reg : 199002667R

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

**TEST REPORT: 7191143339-CHM16-01-RC**

28 JUL 2016



PSB Singapore

**RESULTS****Control Tests**

Control Test	Detection of Phi-X174 Bacteriophage
Airborne Contamination Control Tests	Settle plates each found to have Less than 1 PFU per plate
Negative Control	Less than 1 PFU per ml of assay fluid
Positive Control	Bacteriophage challenge suspension penetrated positive control test specimen

**Test Specimens**

Test Specimens (Triplicates)	Titer of Bacteriophage challenge suspension used (PFU/ml)	Detection of Phi-X174 Bacteriophage in assay fluid from the surface of sample (PFU/ml)	Pass / Fail
<u>Nitrile Examination Powder Free Glove</u>			
#1	360 000 000	Less than 1	Pass
#2	340 000 000	Less than 1	Pass
#3	380 000 000	Less than 1	Pass

**Notes:**

PFU : Plaque Forming Unit

**MS AW HWEE YING**  
TECHNICAL EXECUTIVE**MR RANDY CHIN KOK FEI**  
ASSISTANT PRODUCT MANAGER  
MICROBIOLOGY  
CHEMICAL & MATERIALS

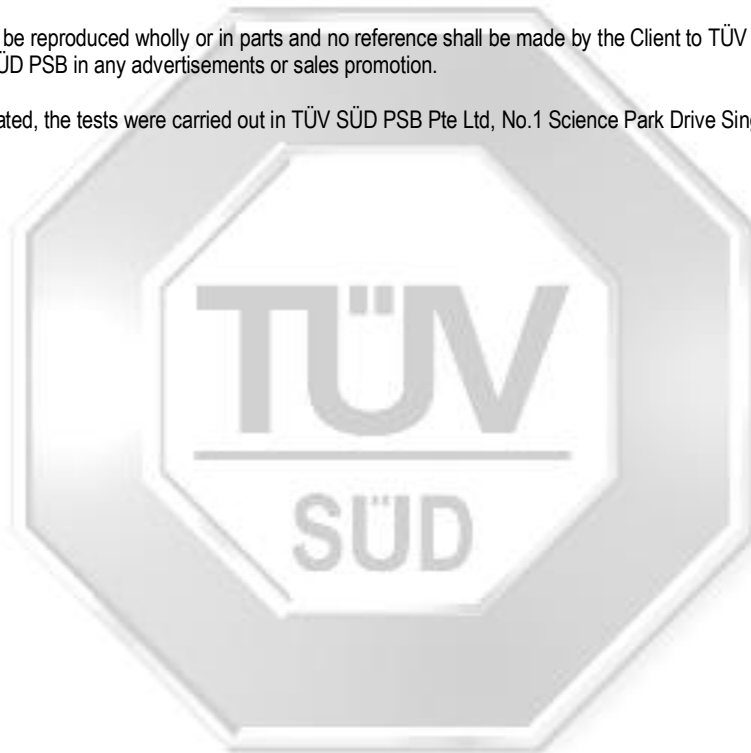




**Please note that this Report is issued under the following terms :**

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

July 2011



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

**FACTORY 3**

: Lot 5091, Jalan Teratai, Batu 5, Off Jalan Meru, 41050, Klang, Selangor D.E., Malaysia.



+603 3392 3378/3433



+603 3392 3372



+6012 2896 270



sales@topglove.com.my



www.topglove.com

**BUSINESS DIRECTION**

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

**FACILITIES**

: 42 Factories (Malaysia, Thailand & China), 682 Production Lines, 64 Billion Gloves Per Annum, 18,000 Employees.

**MARKET**

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

**Agreement under Medical Device Regulation 2017/745**

between: **TG MEDICAL SDN. BHD.** (Legal Manufacturer, hereinafter referred to as 'Manufacturer')  
Lot 5091, Jalan Teratai, Batu 5,  
Off Jalan Meru, 41050 Klang,  
Selangor D.E., Malaysia.

and: **MEDPLAZA HEALTH S.R.L.** (Customer, hereinafter referred to as "Customer")  
Sos De Centura NR 27-28,  
Hala C2, Office 2, Chiajna Ilfov  
077040 Ilfov, Romania.

Dear Sir/Madam,

**Letter of Agreement**

I Cristian Petre as representative of the Customer, am given legal authority to sign on behalf of the company to request TG Medical to register our trade name and products as refer to **Annex 1 (List of trade name, products and glove weight)**

I am fully aware and agree to accept the below condition:

- 1)** The Customer shall assign license (non exclusive) to use the rights for the trade name and product in Annex 1 to TG Medical for the purpose of fulfilling the cooperation obligations by TG Medical and shall be effective once the agreement is signed.
- 2)** The Customer undertake rights for the trade name and products as refer to Annex 1 (List of trade name and products) is owned by the Customer and not allowed to assign trade to any third party (other manufacturer) until the agreement is terminated. This restriction applies only to the product in Annex 1.
- 3)** TG Medical shall not file any objection in the event Customer is desirous to file and register the rights for trade name and product in Annex 1.
- 4)** The Customer undertake that there are no assignment or agreement has been or will be made or entered into by the Customer for trade name and product in Annex 1, which would conflict with this assignment.
- 5)** TG Medical undertake that trade name and product in Annex 1 will be manufactured and supplied to Customer in the territory of Romania.



6) The Customer shall promptly and fully disclose to TG Medical license to use the rights to the trade name. The Customer shall communicate to TG Medical all necessary information and data with respect to trade and shall provide the supporting documents in relation to the trade name.

## **7) Design, Manufacturing and Quality**

TG Medical is responsible that the PRODUCTS shall be designed and manufactured according to the General Safety and Performance Requirements laid down in Annex I of the MDR 2017/745.

Each change of the PRODUCTS which might affect the Technical Documentation, General Safety and Performance Requirements, each change of the intended use and each modification of the manufacturing process / raw materials / packaging / sterilization used has to be agreed on previously in written form.

## **8) Technical Documentation**

TG Medical is required to hold and to keep up to date the full technical documentation according to Annexes II and III of the MDR and assess the conformity of the Products.

TG Medical shall provide upon request by the notified body or the competent authorities of the technical documentation for a period of 10 years from the last date of marketing of the product. This obligation applies even if the contract has already been terminated before. After termination of this agreement, the technical documentation must be kept for at least 10 years.

For avoidance of doubt, any information and documentation disclosed by TG Medical producer shall be kept by Customer as confidential. Customer cannot use the transferred information and documentation for any purposes, except for certification and/or registration of medical devices and/or services provided by TG Medical producer to Customer.

## **9) Vigilance and Complaints**

TG Medical is responsible for compliance with reporting requirements under all applicable laws for adverse events and malfunctions related to the products. TG Medical shall notify Customer of any event without undue delay in writing.

In the event that Customer receives a complaint notification from its customer related to TG Medical's product being distributed by Customer, Customer must notify TG Medical in accordance with the established complaint handling procedures. If the complaint is potentially a reportable event Customer notifies TG Medical without unreasonable delay.

## **10) Post Market Surveillance**

TG Medical shall perform post marketing surveillance activities in accordance with the applicable medical device regulations. Customer shall keep a register of complaints, non-conforming devices, recalls and withdrawals and keeps TG Medical informed of such monitoring and provide them with any information upon their request.

### 11) Labeling, Instruction for Use and Packaging

TG Medical shall confirm that the product labeling comply with regulatory requirements.

Customer will create and provide the artwork draft to TG Medical. TG Medical shall check the regulatory compliance and release the final artwork creation.

The Customer shall inform TG Medical for any changes on the packaging material artwork.

**12)** The Customer shall take full responsibility in Clause 2 and TG Medical shall not be held responsible or liable by any parties herein with regards to this issue. The Customer further irrevocably agree and undertake to fully indemnify and hold TG Medical harmless against all demands, claims, liabilities, fines, compounds, losses, damages, costs and expenses whatsoever against any claims, actions, lawsuits or demands brought against TG Medical including Intellectual Property matters, whether criminal or civil, caused by this issue. If there is any legal action is commenced or threatened against TG Medical, the Customer shall at their own costs and expenses, take all necessary actions to protect and defend TG Medical against such claim, suit or demand. This indemnity shall include but is not limited to all claims, damages awarded, solicitors' costs, out of court settlements, fines and other costs claimed by third parties.

### 13) Product-related responsibilities/Requirements according to the EU Regulation 2017/745 on Medical Devices as of its date of application, May 2021.

Aspects / Operations	Customer	Manufacturer (TG Medical)
Creating / Release instruction for use		X
Creating Labeling	X	
Release Labeling		X
Creating, release and update Technical Documentation Checklist Essential Requirements (with responsibilities for individual aspects) Transaction and documentation of the Clinical Evaluation Transaction and documentation of the Risk Analysis Regulations to the location / availability of the Technical Documentation Part		X
Special processes Example: Cleaning of the products (Cytotoxicity ISO 10993-5) Validation of the cleaning, packaging and sterilization process		X
Subcontractor / Processes of the subcontractor		X
Observation of the products on the market	X	
Accountability of the products		X



Aspects / Operations	Customer	Manufacturer (TG Medical)
Classification		X
Declaration of the conformity		X
Recipient of customer complaints	X	X
Documentation of customer complaints – creation of problem report: <ul style="list-style-type: none"> <li>Type</li> <li>Complexity and amount</li> <li>Critically</li> </ul>		X
Evaluation of customer complaints	X	X
Evaluation of customer complaints regarding MDR and MEDDEV 2.12 <ul style="list-style-type: none"> <li>Customer related information, Name, Address</li> <li>relevance to risk analysis and risk control</li> <li>issuer of request/ report</li> </ul>	X	X
Verification and documentation of changes and modification to the products. Testing and Integration of changes.		X
Approval of changes and modifications to the product.		X
Post Market Surveillance of clinical evaluation and report to the buyer		X
Notification of notified bodies and competent authorities about safety risks and product recalls	X	X
Briefing/ Instruction in the application and training for Customer and Application personnel to products mentioned in this agreement. Regular and as needed.		X
Instructions for packaging		X
Obligation to provide information where there are changes of the status of the certificates of the Legal Manufacturer.		X

**14)** This Agreement shall be effective on the date of signing the agreement by both Parties and is valid for three (3) years. This Agreement may be renewed for one (1) year upon mutual written agreement between Parties by providing six (6) months prior written notice before the expiry of this Agreement. This Agreement may be terminated at any time by either party with thirty (30) days prior written notice to the other Party.

**15)** Any amendments in relation to this Agreement shall be mutually agreed in writing by both Parties.

**16)** This Agreement shall be governed and construed in accordance with the laws of Malaysia. Any dispute or claim arising out of or relating to this Agreement shall be resolved amicably through negotiations between the Parties. In the event Parties cannot come to an agreement, all disputes shall be referred to and Parties shall submit to the exclusive jurisdiction of the Courts of Malaysia.

## **CUSTOMER**

.....  
**Signed for:**  
**MEDPLAZA HEALTH S.R.L.**  
Name: Cristian Petre  
Designation: CEO  
Date:

## **TG MEDICAL SDN. BHD.**

.....  
**Signed for and on behalf of:**  
**TG Medical Sdn. Bhd.**  
Name: Dato' Lee KM  
Designation: Managing Director  
Date:

.....  
**Signed for and on behalf of:**  
**TG Medical Sdn. Bhd.**  
**(Marketing, Head of Region)**  
Name: Leong Chew Mun  
Designation: Senior General Manager  
Date:

.....  
**Signed for and on behalf of:**  
**TG Medical Sdn. Bhd.**  
**(Marketing, Head of Team)**  
Name: Ivy Tee Ai Wei  
Designation: Senior Manager  
Date:

.....  
**Signed for and on behalf of:**  
**TG Medical Sdn. Bhd.**  
Name: Noor Akilah Bt Saidin  
Designation: Deputy General Manager, RA  
Date:

Date received (To be fill in by RA):  
\_\_\_\_\_

**Annex 1: List of products, trade name and glove weight**

No	Products	Trade Name	Glove grade & weight	Date
1	NITRILE POWDER FREE ONLINE SINGLE CHLORINATED GLOVE	SERIX	ENW035	16/03/2021
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				



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

SATRA reference: CHM0265112/1749/EN  
/A/Issue 2

Your reference:

Date of report: 13<sup>th</sup> February 2018

Samples received: 29<sup>th</sup> August 2017

For the attention of: Norahimah Bt Abd Rahim

Date(s) work 15<sup>th</sup> December 2017 to  
carried out: 13<sup>th</sup> 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 13<sup>th</sup> 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  $\neq$  fall outside the UKAS Accreditation Schedule for SATRA. All interpretations of results of such tests and the comments based upon them are outside the scope of UKAS accreditation and are based on current SATRA knowledge.

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

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

Report signed by: Emma Norris  
Position: Chemical Technologist  
Department: Chemical & Analytical Technology

## WORK REQUESTED:

Samples of gloves described as Nitrile Examination Powder Free Glove RA/080/008/2017/C were received on the 29<sup>th</sup> 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
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

## RESULTS AND REQUIREMENTS:

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

Date of determination: 10<sup>th</sup> 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
<b>Requirement</b>	<b>pH value greater than 3.5 and less than 9.5</b>			

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
<b>Requirements: REACH 1907/2006 annex XVII entry number 50</b>	<b>&lt;1mg/kg of each PAH listed in the appendices</b>	-

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)
1	>10
2	>30
3	>60
4	>120
5	>240
6	>480

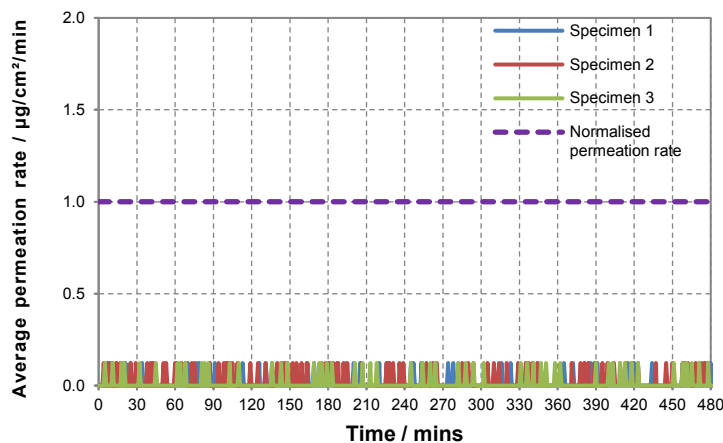
Performance levels are based on the lowest individual result achieved per chemical.



Test/Property	Sample reference:	Nitrile Examination Powder Free Glove		Performance
EN 16523-1:2015 in accordance with SATRA SOP CAT-009	Test information:	Chemical: 40% sodium hydroxide		Level 6
		Normalised permeation rate (NPR): 1 µg/cm <sup>2</sup> /min		
		Detection technique: Conductimetry (continuous measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: 45 – 65 ml/min (each cell constant to within ± 10%)		
		Test temperature: (23 ± 1) °C		
Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm)△	Breakthrough time (mins)	
	1	0.06	>480	
	2	0.06	>480	
	3	0.06	>480	
		Test result:	>480	
		UoM:	<1	
Visual appearance of specimens after testing:		Swollen and discoloured		

## PERMEATION RATE GRAPHS

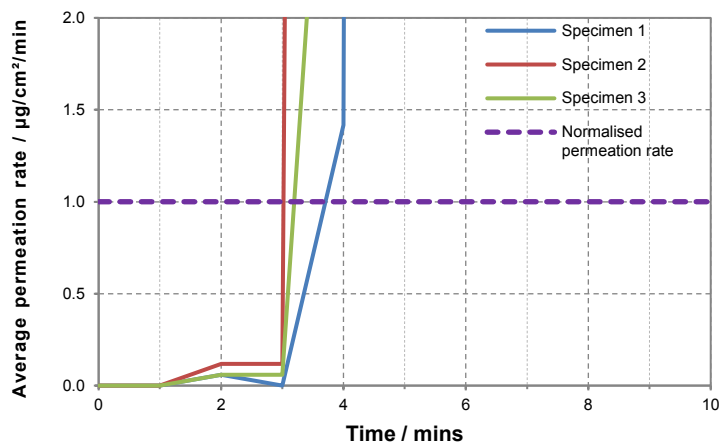
Challenge chemical: 40% sodium hydroxide



Test/Property	Sample reference:	Nitrile Examination Powder Free Glove		Performance
EN 16523-1:2015 in accordance with SATRA SOP CAT-009	Test information:	Chemical: 65% nitric acid		The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
		Normalised permeation rate (NPR): 1 µg/cm²/min		
		Detection technique: Conductimetry (continuous measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: 45 – 65 ml/min (each cell constant to within ± 10%)		
		Test temperature: (23 ± 1) °C		
Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm)△	Breakthrough time (mins)	
	1	0.07	4	
	2	0.06	4	
	3	0.06	3	
		Test result:	3	
		UoM:	<1	
Visual appearance of specimens after testing:		Swollen, brittle and discoloured		

## PERMEATION RATE GRAPHS

Challenge chemical: 65% nitric acid



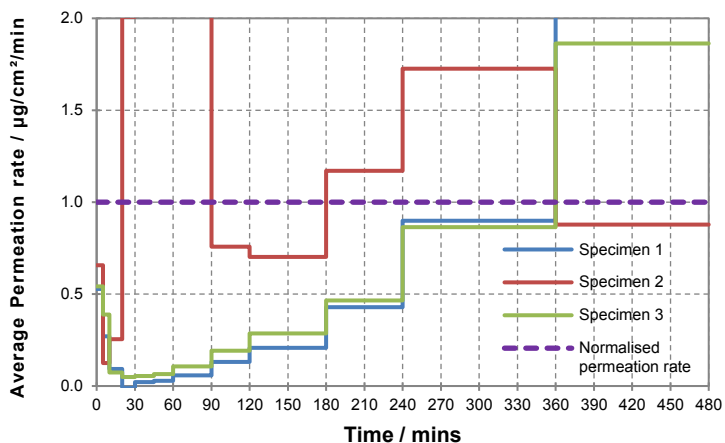
Test/Property	Sample reference:	Nitrile Examination Powder Free Glove		Performance
EN 16523-1:2015 in accordance with SATRA SOP CAT-025  Using PTFE permeation cells with standardised dimensions	Test information:	Chemical: 37% formaldehyde		Level 1
		Normalised permeation rate (NPR): 1 µg/cm²/min		
		Detection technique: HPLC-DAD (periodic measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: 45 – 65 ml/min (each cell constant to within ± 10%)		
		Test temperature: (23 ± 1) °C		
	Specimen	Thickness (mm) <sup>Δ</sup>	Breakthrough time (mins) <sup>▼</sup>	
	1	0.06	Between 361 to 480	
	2	0.06	Between 21 to 30	
	3	0.06	Between 361 to 480	
	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:		Swollen and discoloured		

For SOP CAT-025, where both the P<sub>1</sub> and P<sub>u</sub> 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.



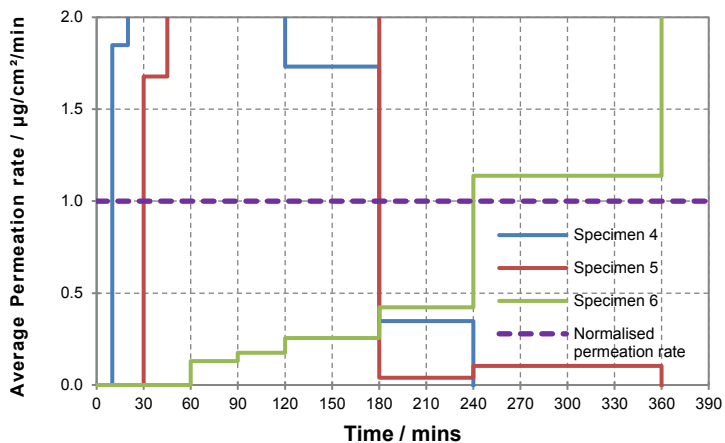
**PERMEATION RATE GRAPHS**

Challenge chemical: 37% formaldehyde



**PERMEATION RATE GRAPHS**

Challenge chemical: 37% formaldehyde

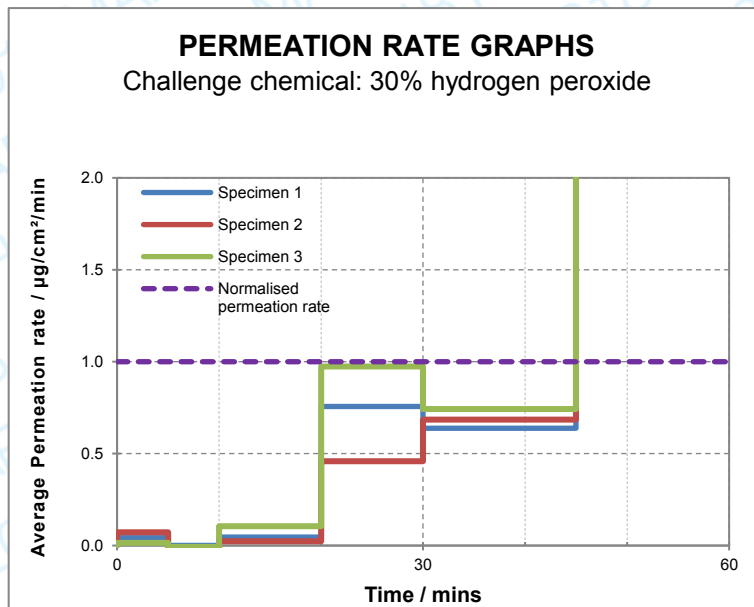


Formaldehyde is determined by discrete sampling; therefore the permeation rate graph is not a smooth curve.



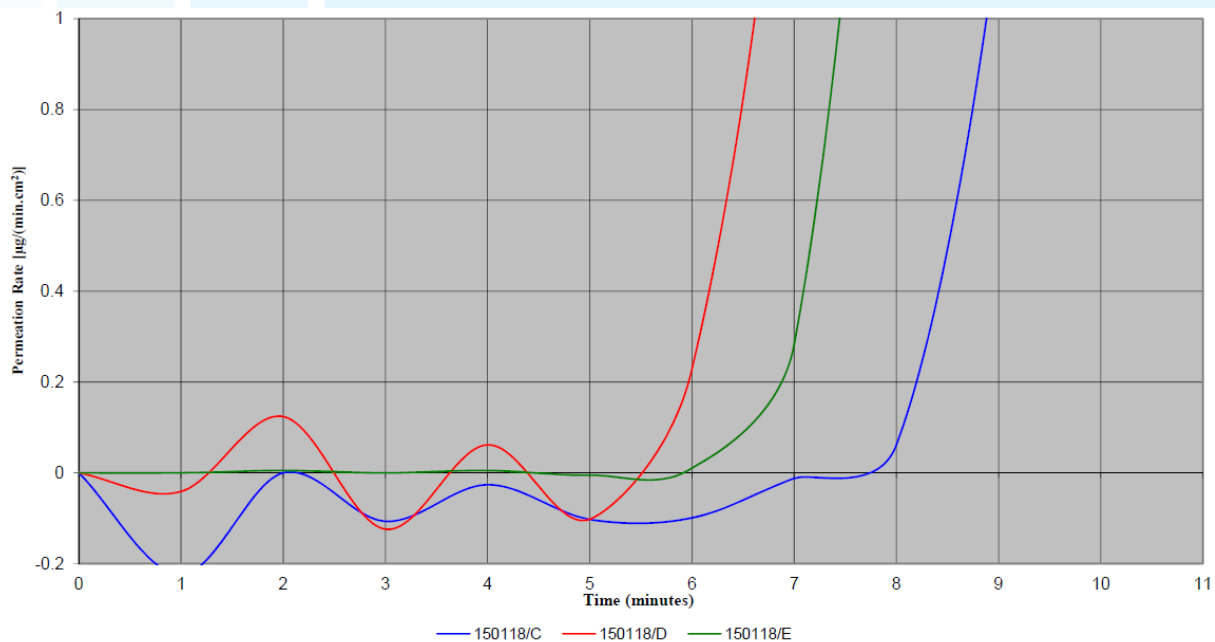
Test/Property	Sample reference:	Nitrile Examination Powder Free Glove		Performance
EN 16523-1:2015 in accordance with SATRA SOP CAT-025	Test information:	Chemical: 30% Hydrogen peroxide		Level 2
		Normalised permeation rate (NPR): 1 µg/cm <sup>2</sup> /min		
		Detection technique: Electrochemical detector (periodic measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: 45 – 65 ml/min (each cell constant to within ± 10%)		
		Test temperature: (23 ± 1) °C		
Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm)△	Breakthrough time (mins)▼	
	1	0.06	Between 46 to 60	
	2	0.07	Between 46 to 60	
	3	0.06	Between 46 to 60	
		Test result:	Between 46 to 60	
		UoM:	See below	
Visual appearance of specimens after testing:		Swollen 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.

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



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

△ 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 supply to the general public, if any of their rubber or plastic components that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, under normal or reasonably foreseeable conditions of use, contain more than 1 mg/kg of any of the listed PAHs.
Chrysene	218-01-9	
Benzo[b]fluoranthene	205-99-2	
Benzo[k]fluoranthene	207-08-9	
Benzo[j]fluoranthene	205-82-3	
Benzo[e]pyrene	192-97-2	
Benzo[a]pyrene	50-32-8	
Dibenzo[a,h]anthracene	53-70-3	



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

### 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 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 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 Client's 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 SATRA's 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 SATRA's 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:
- 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.
- 13.3 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.
- 13.4 Until ownership of Goods has passed to the Client, the Client shall:
- hold the Goods as SATRA's bailee;
  - store the Goods (at no cost to SATRA) separately from all other goods belonging to the Client or any third party in such a way that they remain readily identifiable as SATRA's property (including where the Goods have been sold to a 3rd party);
  - not destroy, deface or obscure any identifying mark or packaging on or relating to the Goods; and
  - maintain the Goods in satisfactory condition and keep them insured on SATRA's behalf for their full price against all risks to the reasonable satisfaction of SATRA. The Client shall obtain an endorsement of SATRA's interest in the goods on its insurance policy. On request the Client shall allow SATRA to inspect such Goods and shall produce the policy of insurance.
- 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:
- 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.
- 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:
- 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 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:
- 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
  - 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;
- 16.7 Where Goods or parts of Goods are not manufactured by SATRA then SATRA shall be liable for defects only to the extent that SATRA obtains redress from the manufacturer or supplier thereof provided that:
- SATRA shall not be obliged to take any step to attempt to obtain such redress except at the request and expense of the Client and upon provision by the Client of a full indemnity as to costs for which SATRA may thereby become liable;
  - 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 – December 2016

Top Glove Sdn Bhd

SATRA Reference: CHM0265112/1749/EN/A/Issue 2

Date: 28<sup>th</sup> March 2018

(Page 12 of 12)

Signed:

