Technical Sheet

Product: Serix Navy Nitrile Powder-Free Examination Gloves
Manufacturer: TG MEDICAL SDN. BHD (a Top Glove Compan
EC REP: Top Glove Europe GmbH

Product Description

Functional Benefits

• Protection from unwanted or dangerous substances
• Beaded cuff makes donning easy and helps prevent roll back
• Superior strength with better puncture resistance
• Full textured enhances wet and dry grip
• Thinner gauger improves tactile sensitivity • Custom design enhances comfort and fit
• Provide an alternative solution for individuals who are allergic to natural rubber late

Quality standards

• Conforms to ASTM D6319 and EN455 Standards
• Manufactured under QSR (GMP), ISO 9001:2015 and ISO 13485:2016 Quality Management System

Physical Dimensions & Properties

Dimensions	Standards		
	Top Glove	ASTM D3578	EN 455
Length (mm)	Min 230, Min 240, 300 ± 10	Min 220 (XS, S) Min 230 (M, L, XL)	Min 240
Palm Width (mm) • XS • S • M • L • XL	 76 ± 3 84 ± 3 94 ± 3 105 ± 3 113 ± 3	 70 ± 10 80 ± 10 95 ± 10 110 ± 10 120 ± 10	 ≤ 80 80 ± 10 95 ± 10 110 ± 10 ≥ 110
Thickness : Single Wall (mm) • Finger • Palm	 Min 0.05 Min 0.05	 Min 0.05 Min 0.05	 N/A N/A

Product specifications

Type: Powdered & Powder-Free, Non-sterile

Material: 100% Synthetic Nitrile Latex

Colour: Blue

Design & Features: Powder-Free: Polymer coated or online single chlorinated, offline double chlorinated, ambidextrous, finger textured or palm textured surface, beaded cuff

Storage: The gloves shall maintain their properties when stored in a dry condition. Avoid direct sunlight

Shelf-life: 5 years from the date of manufacturing

Property	ASTM D6319	EN 455
Tensile Strength (MPa) • Before Aging • After Aging	 Min 14 Min 14	 N/A N/A
Elongation at Break (%) • Before Aging • After Aging	 Min 500 Min 400	 N/A N/A
Median Force at Break (N) • Before Aging • After Aging	 N/A N/A	 Min 6 Min 6

TG MEDICAL
TOP QUALITY, TOP EFFICIENCY

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.

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
Basic UDI – DI	: 955583991000P2
Brand Name	: Serix Navy, Serix Slim & Serix Nero
Size	: XS, S, M, L, XL
Classification (MDR)	: Class I, Non Sterile
Classification (PPER)	: Category III
Conformity Assessment Procedure (MDR)	: Annex I, Annex II and Annex IV (Self declared)
Conformity Assessment Procedure (PPER)	: Annex VII (Module C2)
Rule (MDR)	: Rule 5
Product Group Reference	: EB201
EU Type Examination Certificate Number (PPER)	: 2777/10648-04/E36-01
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

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

i. 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.	ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer	April 2021
6.	EN 62366-1:2015+A1:2020	Medical Devices-Part 1: Application of usability engineering to medical devices	August 2020
7.	EN ISO 14971:2019+A11:2021	Medical device - Application of risk management to medical device.	December 2021
8.	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
9.	EN ISO 10993-1:2020	Biological evaluation for medical device – Part 1: Evaluation and testing within a risk management process	Dec 2020
10.	ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	June 2009
11.	EN ISO 10993-10:2013	Biological evaluation of medical devices - Tests for irritation and skin sensitization.	August 2013
12.	EN ISO 10993-11:2018	Biological evaluation of medical devices. Tests for systemic toxicity	May 2018
13.	ISO 10993-12:2021	Biological evaluation for medical devices - Sample preparation and reference materials	January 2021
14.	ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation	January 2021

No.	Standard	Descriptions	Date Published
15.	ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied : General requirements.	July 2021
16.	MDR 2017/745 (Annex I: Chapter 2)	Requirements Regarding Design and Manufacture	April 2017
17.	MDR 2017/745 (Chapter I: Article 2)	Scope and Definitions	April 2017
18.	MDR 2017/745 (Annex VIII)	Classification rules	April 2017
19.	MDR 2017/745 (Annex II)	Technical Documentation	April 2017
20.	MDR 2017/745 (Chapter II: Article 11&12)	Guideline for Authorized Representative	April 2017
21.	MDR 2017/745 (Annex XIV: Part A)	Clinical Evaluation	April 2017
22.	MEDDEV 2.7/1	2.7/1 Clinical Evaluation	Revision 4, June 2016
23.	MEDDEV 2.12-1 rev 8	Medical Device Vigilance System	January 2013
24.	MEDDEV 2.12/1	2.12/1 Medical Device Vigilance System	Revision 8, January 2013
25.	MDR 2017/745 (Chapter VII: Section 2: Article 87-92)	Vigilance	April 2017
26.	MDR 2017/745 (Annex XIV: Part B)	Post Market Clinical Follow-up Studies	April 2017
27.	MEDDEV 2.12/2	2.12/2 Post Market Clinical Follow-up Studies	Revision 2, January 2012
28.	MDR 2017/745 (Chapter VII: Section 1: Article 83-86) Annex III	Post Marketing Surveillance (PMS)	April 2017
29.	ISO/TR 20416	Medical devices — Post-market surveillance for manufacturers	July 2020
30.	MEDDEV 2.12/Rec 1	2.12 Post - Marketing Surveillance (PMS) post market / production	Revision 11, February 2000
31.	MDR 2017/745	Medical Device Regulation	April 2017

EU DoC Validity Date : 7th July 2022 to 6th July 2023

Name: Pn Noor Akilah Saidin
Designation: RA General Manager

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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.** Lot 5091, Jalan Teratai, Batu 5, Off Jalan Meru, 41050 Klang, Selangor D.E., Malaysia.	(Legal Manufacturer, hereinafter referred to as 'Manufacturer")
and:	**MEDPLAZA HEALTH S.R.L.** Sos De Centura NR 27-28, Hala C2, Office 2, Chiajna Ilfov 077040 Ilfov, Romania.	(Customer, hereinafter referred to as "Customer")

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: • Type • Complexity and amount • Critically		X
Evaluation of customer complaints	X	X
Evaluation of customer complaints regarding MDR and MEDDEV 2.12 • Customer related information, Name, Address • relevance to risk analysis and risk control • issuer of request/ report	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				

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Northamptonshire, NN16 8SD United Kingdom
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Customer details: Top Glove Sdn Bhd
Lot 4969 Jalan Teratai
Batu 6
Off Jalan Meru
41050 KLANG
Selangor D E
Malaysia

For the attention of: Norahimah Bt Abd Rahim

SATRA reference: CHM0265112 /1749 /SPT Issue 2

Your reference: RA/080/008/2017/C

Date of report: 26 March 2018

Samples received: 29 August 2017

Date(s) work carried out: 11 December 2017

TECHNICAL REPORT

Subject: Testing of gloves identified as Nitrile Examination Powder Free gloves in accordance with EN 420: 2003 clauses 5.1 length and fit and 5.2 dexterity and EN 374-2:2014.

This replaces SATRA report SPC0265112 /1749 /SPT dated the 14 February 2018

Report signed by: Adam Mortiboys
Position: PPE Technologist
Department: Safety Product Testing

Work Requested

Samples of gloves, see Table 1, were received by SATRA, for testing in accordance with EN 420:2003+A1:2009. Protective gloves. General requirements and test methods, Clauses 5.1 length and fit and 5.2 dexterity, and EN 374-2:2014. Protective gloves against dangerous chemicals and microorganisms. Determination of resistance to penetration.

Table 1 – Samples Received

Sample description as stated by the client	Sizes submitted for testing	Colour of samples submitted	Approximate weight of one glove
Nitrile Examination Powder Free gloves	6 (XS) – 10 (XL)	Blue	Size: 6 (XS) Weight: 3.3g

Nitrile Examination Powder Free gloves

Conclusion

Standard	Clause / Property		Result
EN 420: 2003 + A1: 2009	5.1	Length and fit	Pass
	5.2	Dexterity	Level 5
EN 374-2: 2014	7.2	Air leak	Pass
	7.3	Water leak	Pass

Testing

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

Requirements

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

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

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

Table 3 - Requirements for EN 374-2: 2014

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

Test Results

Table 4 - EN 420:2003 + A1:2009 Test Results for gloves identified as Nitrile Examination Powder Free gloves

Clause / Test	Test Results			UoM	Result
5.1 Glove length, comfort and fit		Length /mm		± 0.3 mm	Pass
	Size	Left	Right		
	6 (XS)	257	254		
	Comments on fit: Satisfactory				
	7 (S)	239	244		
	Comments on fit: Satisfactory				
	8 (M)	255	258		
	Comments on fit: Satisfactory				
	9 (L)	251	253		
	Comments on fit: Satisfactory				
	10 (XL)	262	264		
	Comments on fit: Satisfactory				
5.2 Dexterity	Size	Minimum pin diameter / mm		N/A	Level 5
	6 (XS)	5.0			
	7 (S)	5.0			
	8 (M)	5.0			
	9 (L)	5.0			
	10 (XL)	5.0			

Table 5 - EN 374-2:2014 Test Results of gloves identified as

Clause / Test	Test Results		UoM	Result
7.2 Air leak test	Total Air Pressure Used	2.61 kPa	± 2.8 mmH_2O	Pass
	Sample size	Leaks		
	6	No leaks detected		
	7	No leaks detected		
	8	No leaks detected		
	9	No leaks detected		
	10	No leaks detected		
7.3 Water leak test	Sample size	Leaks	N/A	Pass
	6	No leaks detected		
	7	No leaks detected		
	8	No leaks detected		
	9	No leaks detected		
	10	No leaks detected		

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0248

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

For the attention of: Norahimah Bt Abd Rahim

SATRA reference: CHM0272621/1826/JS

Your reference:

Date of report: 12th July 2018

Samples received: 28th June 2018

Date(s) work carried out: 2nd to 9th July 2018

TECHNICAL REPORT

Subject: EN 16523-1: 2015 resistance to permeation by chemicals on nitrile examination powder free gloves described as RA/052/006/2018/C

Report signed by: Jennifer Shearer
Position: Chemical Technologist
Department: Chemical & Analytical Technology

WORK REQUESTED:

Samples of nitrile examination powder free gloves described as RA/052/006/2018/C were received on the 28th June 2018 for testing in accordance with EN 16523-1:2015 and assessment in accordance with the requirements of EN ISO 374-1: 2016.

CONCLUSION:

When assessed in accordance with the requirements of EN ISO 374-1:2016 the samples of nitrile examination powder free gloves described as RA/052/006/2018/C achieved the following performance levels:

Chemical	Performance level
37% Formaldehyde (CAS: 50-00-0)	6

Full results are reported in the following tables.

TESTING REQUIRED:

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

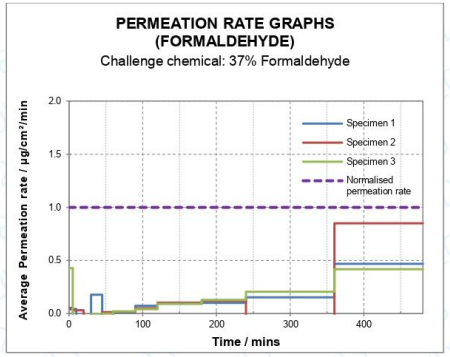
RESULTS AND REQUIREMENTS:

EN 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:	RA/052/006/2018/C		Performance
EN 16523-1:2015 in accordance with SATRA SOP CAT-025	Test information:	Chemical: 37% Formaldehyde		Level 6
		Normalised permeation rate (NPR): 1 µg/cm²/min		
		Detection technique: Spectrophotometry (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		
Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm)⌂	Breakthrough time (mins)▼	
	1	0.06	>480	
	2	0.06	>480	
	3	0.07	>480	
		Test result:	>480	
		UoM:	<1	
Visual appearance of specimens after testing:		Swollen and discoloured		



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

⌂ 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.

SATRA TECHNOLOGY TECHNICAL REPORT

APPENDICES:

Nitrile examination powder free gloves described as RA/052/006/2018/C

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www.satra.com

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

For the attention of: Norahimah Bt Abd Rahim

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

Your reference:

Date of report: 13th February 2018

Samples received: 29th August 2017

Date(s) work carried out: 15th December 2017 to 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.

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 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
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: 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**	-

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.

SATRA TECHNOLOGY

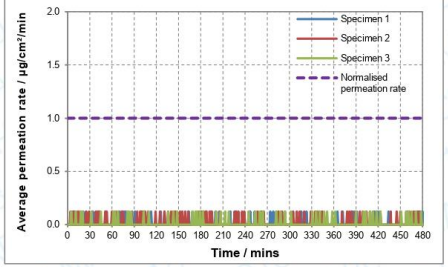
TECHNICAL REPORT

UKAS TESTING 0248

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/cm²/min		
		Detection technique: Conductimetry (continuous 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		
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

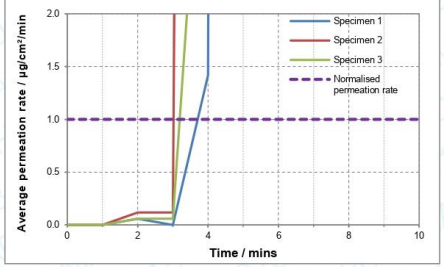
Challenge chemical: 40% sodium hydroxide



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: (each cell constant to within ± 10%) 45 – 65 ml/min		
		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		

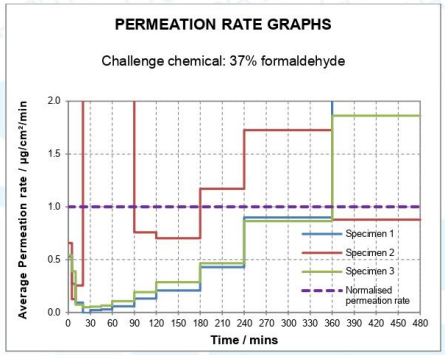
PERMEATION RATE GRAPHS

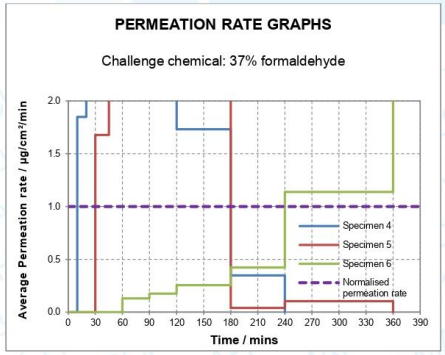
Challenge chemical: 65% nitric acid



Test/Property	Sample reference:	Nitrile Examination Powder Free Glove		Performance
EN 16523-1:2015 in accordance with SATRA SOP CAT-025	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: (each cell constant to within ± 10%) 45 – 65 ml/min		
		Test temperature: (23 ± 1) °C		
Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm)⌂	Breakthrough time (mins)▼	
	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_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.

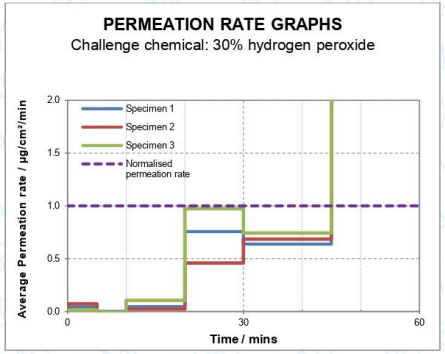




Formaldehyde is determined by discrete sampling; therefore the permeation rate graph is not a smooth curve.

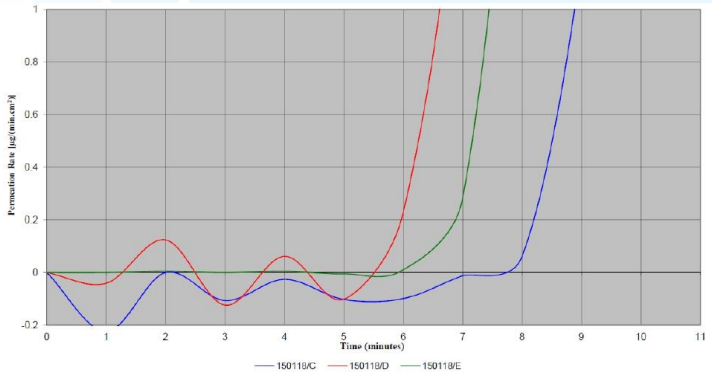
Test/Property	Sample reference:	Nitrile Examination Powder Free Glove		Performance
EN 16523-1:2015 in accordance with SATRA SOP CAT-025	Test information:	Chemical: 30% Hydrogen peroxide		Level 2
		Normalised permeation rate (NPR): 1 µg/cm²/min		
		Detection technique: Electrochemical detector (periodic 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		
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.

SATRA TECHNOLOGY

TECHNICAL REPORT

UKAS TESTING 0248

⌂ 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

TG MEDICAL SDN BHD

Test Report

Customer	MEDPLAZA HEALTH S.R.L.
Brand	SERIX NAVY
Sales Order	2000141019
Customer PO	-
Type of Glove	NITRILE POWDER FREE ONLINE SINGLE CHLORINATED GLOVE (Finger Textured, Blue)
AQL Required	1.5
Date of release	18.06.2021
Reference Standard	The above consignment of goods have been inspected against EN 455-1:2020, EN 455-2:2015 and EN 455-3:2015 standards where samples selected at random using Single Sampling Plans for Normal Inspection of ISO 2859-1 and also complied with EN455-4:2009 requirement (maximum 5 years)
Declared	Quantity, Size, Lot No., Manufacturing Date, Expiry Date

COA59A1/2000141019/000

Size	Quantity (Carton)	Quantity (Pieces)	Lot No.	Manufacturing Date	Expiry Date
S	815	815,000	209141019NCZA	2021-06	2026-05
M	1,223	1,223,000	209141019NCZA	2021-06	2026-05
L	1,223	1,223,000	209141019NCZA	2021-06	2026-05
XL	815	815,000	209141019NCZA	2021-06	2026-05
TOTAL	**4,076**	**4,076,000**			

Characteristics	Size	Unit	Inspection Level	Acceptance	Result
Freedom From Holes					
	S	PC	GI	AQL 1.5	PASS
	M	PC	GI	AQL 1.5	PASS
	L	PC	GI	AQL 1.5	PASS
	XL	PC	GI	AQL 1.5	PASS

Characteristics	Size	Unit	Inspection Level	Acceptance	Result
Major Visual Defect					
	S	PC	GI	AQL 2.5	PASS
	M	PC	GI	AQL 2.5	PASS
	L	PC	GI	AQL 2.5	PASS
	XL	PC	GI	AQL 2.5	PASS

Characteristics	Size	Unit	Inspection Level	Acceptance	Result
Minor Visual Defect					
	S	PC	GI	AQL 4.0	PASS
	M	PC	GI	AQL 4.0	PASS
	L	PC	GI	AQL 4.0	PASS
	XL	PC	GI	AQL 4.0	PASS

Characteristics	Size	Unit	Sample Size	Median Value	Result
Glove Length					
	S	mm	13	245	PASS
	M	mm	13	245	PASS
	L	mm	13	245	PASS
	XL	mm	13	244	PASS

Characteristics	Size	Unit	Sample Size	Median Value	Result
Glove Palm Width					
	S	mm	13	88	PASS
	M	mm	13	98	PASS
	L	mm	13	107	PASS
	XL	mm	13	115	PASS

Characteristics	Size	Unit	Sample Size	Median Value	Result
Fingertip Thickness					
	S	mm	13	0.10	PASS
	M	mm	13	0.10	PASS
	L	mm	13	0.10	PASS
	XL	mm	13	0.09	PASS

Characteristics	Size	Unit	Sample Size	Median Value	Result
Palm Thickness					
	S	mm	13	0.07	PASS
	M	mm	13	0.07	PASS
	L	mm	13	0.07	PASS
	XL	mm	13	0.07	PASS

Characteristics	Size	Unit	Sample Size	Median Value	Result
Cuff Thickness					
	S	mm	13	0.05	PASS
	M	mm	13	0.06	PASS
	L	mm	13	0.06	PASS
	XL	mm	13	0.06	PASS

EN 455-2:2015 Requirement:

Median Length (mm):
Min. 240 mm

Median Width (mm) :
XS : <= 80
S : 80 ± 10
M : 95 ± 10
L : 110 ± 10
XL : >=110

Characteristics	Size	Unit	Sample Size	Median Value	Result
Force at Break Before Aging					
	S	N	13	6.9	PASS
	M	N	13	6.1	PASS
	L	N	13	6.3	PASS
	XL	N	13	6.9	PASS

Characteristics	Size	Unit	Sample Size	Median Value	Result

Characteristics	Size	Unit	Sample Size	Median Value	Result
Force at Break After Aging					
	S	N	13	6.1	PASS
	M	N	13	6.2	PASS
	L	N	13	6.7	PASS
	XL	N	13	7.1	PASS

EN 455-2:2015 Requirement:

Before Aging :
Median Value of Force at Break : >= 6 N

After Aging :
Median Value of Force at Break : >= 6 N

Characteristics	Size	Unit	Sample Size	Mean Value	Result
Powder Free Residue (Powderfree Glove)			**FIXTR_5**		
	S	mg/glo	5	0.14	PASS
	M	mg/glo	5	0.12	PASS
	L	mg/glo	5	0.10	PASS
	XL	mg/glo	5	0.16	PASS

Requirement : Max. 2mg/glove

Conclusion

We hereby certify that glove consignment of goods were determined to meet the acceptable limit of the specifications as referring to the above findings of randomly selected samples.

Prepared By
IVANESWAARY A/P. AMARAVENDAN
EXECUTIVE, QA

Approved By
CHEONG FATT YAN
SNR. MANAGER, QA

This is a computer generated test report, no signature is required.

ZERTIFIKAT ◆ CERTIFICATE ◆ СЕРТИФИКАТ ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
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ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 055729 0008 Rev. 01

Manufacturer: **Top Glove Sdn. Bhd.**
Lot 4969, Jalan Teratai Batu 6
Off Jalan Meru
41050 Klang, Selangor D. E.
MALAYSIA

Product Category(ies): **Latex and Nitrile Surgical Powder free Glove, Sterile**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: MYQMH0319070Rev2-721423225

Valid from: 2020-02-19
Valid until: 2024-05-26

Date, 2020-02-19

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

A4 / 07.17

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Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 055729 0008 Rev. 01

Facility(ies): Top Glove Sdn. Bhd.
Lot 4969, Jalan Teratai Batu 6, Off Jalan Meru, 41050 Klang,
Selangor D. E., MALAYSIA

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

A4 / 07.17

Test Report No. : CRSSA/200437126-CA36672
Company : Top Glove Sdn Bhd
Lot 4969, Jalan Teratai, 6th Miles,
Off Jalan Meru, 41050 Klang, Selangor.

TEST REPORT

Sample Description	:	Nitrile Examination Powder Free Glove
Other Detail	:	RA/031/02/2020/D1
Size	:	Medium
Quantity Tested	:	200 pieces
Test Conducted	:	Freedom from holes
Test Method	:	EN455 Part 1:2000
Testing Period	:	02 Apr 2020 – 15 Apr 2020

Based on submitted samples, the following results obtained :-

Acceptable Quality Limit (AQL) : 1.5 Accept : 7 Found : 2

Result : Within AQL

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SGS (MALAYSIA) SDN BHD

CHEE TUCK CHOON
SECTION HEAD
IKM No. M/3983/6401/12/14

JOB REF NO. : 2020-04-02-003
DATE RECEIVED : APR 02, 2020
DATE REPORTED: APR 15, 2020

Test Report No. : CRSSA/200437126-CA36672
Company : Top Glove Sdn Bhd
Lot 4969, Jalan Teratai, 6th Miles,
Off Jalan Meru, 41050 Klang, Selangor.

TEST REPORT

Sample Description	:	Nitrile Examination Powder Free Glove
Other Detail	:	RA/031/02/2020/D1
Size	:	Medium
Quantity Tested	:	13 pieces
Test Conducted	:	Dimensions
Test Method	:	EN 455 Part 2:2015
Testing Period	:	02 Apr 2020 – 15 Apr 2020

Based on submitted samples, the following results obtained :-

Size	M	M	M	M	M	M	M	M	M	M	M	M	M	Median
Width Median: 95±10mm	92	92	94	92	93	94	93	92	92	92	93	92	92	92
Length Median: ≥ 240mm	256	256	253	260	259	258	254	260	254	251	256	251	254	256

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CHEE TUCK CHOON
SECTION HEAD
IKM No. M/3983/6401/12/14

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SGS (Malaysia) Sdn.Bhd. (Company No. 10871-T) | Lot 4, Persiaran Jubli Perak, Seksyen 22, 40300 Shah Alam, Selangor Darul Ehsan, Malaysia.
t +6(03) 7627 0080 f +6 (03) 7627 0082 www.sgs.com
Member of the SGS Group (SGS SA)

Test Report No. : **CRSSA/200437126-CA36672**
Company : **Top Glove Sdn Bhd**
Lot 4969, Jalan Teratai, 6th Miles,
Off Jalan Meru, 41050 Klang, Selangor.

TEST REPORT

Sample Description	:	Nitrile Examination Powder Free Glove
Other Detail	:	RA/031/02/2020/D1
Size	:	Medium
Quantity Tested	:	13 pieces per each
Test Conducted	:	Force at Break During Shelf Life and After Challenge
Test Method	:	EN 455 Part 2:2015
Ageing	:	70 ± 2 Deg C for 168 hrs
Testing Period	:	02 Apr 2020 – 15 Apr 2020

		Force at Break, N	
SIZE	**SAMPLE NO.**	**BEFORE AGING**	**AFTER AGING**
M	1	8.1	6.7
	2	7.4	6.4
	3	7.4	8.3
	4	7.7	6.3
	5	7.8	7.4
	6	8.3	7.6
	7	8.4	6.6
	8	6.4	8.4
	9	7.8	8.7
	10	9.0	6.5
	11	8.4	8.7
	12	8.0	7.3
	13	7.9	6.2
Median		7.9	7.3
Requirement		≥ 6.0	≥ 6.0

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SGS (MALAYSIA) SDN BHD

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SECTION HEAD
IKM No. M/3983/6401/12/14

JOB REF NO. : 2020-04-02-003
DATE RECEIVED : APR 02, 2020
DATE REPORTED: APR 15, 2020

Test Report No. : **CRSSA/200437126-CA36672**
Company : **Top Glove Sdn Bhd**
Lot 4969, Jalan Teratai, 6th Miles,
Off Jalan Meru, 41050 Klang, Selangor.

TEST REPORT

Sample Description	:	Nitrile Examination Powder Free Glove
Other Detail	:	RA/031/02/2020/D1
Size	:	Medium
Quantity Tested	:	5 pieces
Test Conducted	:	Powder Content
Test Method	:	EN455 Part 3:2015
Testing Period	:	02 Apr 2020 – 15 Apr 2020

On testing the samples, the following results were obtained:-

SIZE	**Average Powder Mass per Glove**
M	0.08mg

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CHEE TUCK CHOON
SECTION HEAD
IKM No. M/3983/6401/12/14

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SATRA TECHNOLOGY

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: 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	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: Hannah Coe Geoff Graham

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

Expiry date: 25/06/2023

SATRA Technology Europe Limited. Bracetown Business Park. Clonee. D15YN2P. Republic of Ireland.

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.

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

PSB Singapore

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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.

TÜV SÜD PSB

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Singapore 118221

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
Nitrile Examination Powder Free Glove			
#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

PSB Singapore

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

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July 2011

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July 19, 2011

· TEST REPORT ·

PN 97365

CHEMICAL ANALYTICAL SERVICES

Prepared For:

Wardah Mohd Paudzi
Top Glove Sdn. Bhd.
Lot 4967, Jalan Teratai,
Batu 6, Off Jalan Meru
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Prepared By: _____
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Approved By: _____
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TESTING CONDITIONS:

Standard Test Method Used:	ASTM D 6978-05
Analytical Method:	UV/VIS Spectrometry
Testing Temperature:	35.0°C ± 2.0
Collection System:	Closed Loop
Specimen Area Exposed:	5.067 cm2
Selected Data Points:	25/test
Number of Specimens Tested:	3/test
Location Sampled From:	Cuff area
Comments/Other Conditions:	Magnetic stir bar was used in the sampling chamber

DETECTION METHOD OF CHEMICAL PERMEATION; UV/VIS ABSORPTION SPECTROMETRY:

Instrument: Perkin Elmer UV/VIS Spectrometer Lambda 25

UV/VIS Absorption Spectrometry was used to measure the absorbance of test chemicals which permeated through the specimens into the collection medium. The collection medium was circulated in a closed loop at 11 ml/minute of flow rate through the testing period. Data collection was performed according to the programmed schedule by means of UV Winlab software from the Perkin Elmer Corporation. The list of the characteristic wavelengths is shown below.

Table 3. Characteristic Wavelengths used in UV/VIS Absorption Spectrometry

TESTING CHEMOTHERAPY DRUGS	WAVELENGTH (nm)
Carmustine (BCNU)	229
Cisplatin	199
Cyclophosphamide (Cytoxan)	200
Dacarbazine (DTIC)	320
Doxorubicin Hydrochloride	232
Etoposide (Toposar)	205
Fluorouracil	269
Paclitaxel (Taxol)	231
Thiotepa	199
Methotrexate	303
Mitomycin C	217
Vincristine Sulfate	220

SAMPLE CHARACTERISTICS:

Table 4. Thickness characteristics for the tested specimens on: Powder Free Blue Nitrile Patient Examination Gloves, Size Medium.

Testing Chemotherapy Drugs	Thickness (mm)			Average (mm)	Weight/Unit Area (g/m2)
	#1	#2	#3		
Carmustine (BCNU)	0.062	0.065	0.069	0.065	62.3
Cisplatin	0.065	0.062	0.070	0.066	62.3
Cyclophosphamide (Cytoxan)	0.062	0.068	0.060	0.063	62.3
Dacarbazine (DTIC)	0.063	0.063	0.065	0.064	62.3
Doxorubicin Hydrochloride	0.064	0.060	0.060	0.061	62.3
Etoposide (Toposar)	0.067	0.064	0.063	0.065	62.3
Fluorouracil	0.067	0.062	0.061	0.063	62.3
Paclitaxel (Taxol)	0.063	0.057	0.067	0.062	62.3
Thiotepa	0.062	0.063	0.062	0.062	62.3
Methotrexate	0.059	0.059	0.057	0.058	62.3
Mitomycin C	0.061	0.060	0.059	0.060	62.3
Vincristine Sulfate	0.063	0.058	0.059	0.060	62.3

RESULTS:

Table 5. Permeation Test Results on: Powder Free Blue Nitrile Patient Examination Gloves, Size Medium.

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	AVERAGE BREAKTHROUGH DETECTION TIME (Specimen1/2/3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Specimen1/2/3) (µg/cm^2/minute)	OTHER OBSERVATIONS
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	15.47 (15.28,15.97,15.15)	1.6 (1.4,1.7,1.7)	Moderate swelling and no degradation
Cisplatin, 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	No breakthrough up to 240 min.	N/A	Moderate swelling and no degradation
Fluorouracil, 50.0 mg/ml (50,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	No breakthrough up to 240 min.	N/A	Moderate swelling and no degradation
Thiotepa, 10.0 mg/ml (10,000 ppm)	3.39 (3.26,3.09,3.82)	1.3 (1.4,1.1,1.3)	Slight swelling and no degradation
Methotrexate, 25 mg/ml, (25,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Mitomycin C, 0.5 mg/ml (500 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation

Tiffany L. Heller
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Thank you!

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