

# Disposable Gloves



Product File

Grixx  
Medical<sup>1</sup>



### **Optimal fit**

Easy to put on and take off



### **Beaded cuff**

Offers drip protection for the forearm



## • Disposable Gloves

- Nitrile
- Finger textured
- Ambidextrous
- Non-sterile

### **Textured surface**

For optimal grip



# Content

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## Disposable gloves – Nitrile – Regular Cuff

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## EU Declaration of Conformity

Manufacturer's Name	: QUBE MEDICAL PRODUCTS SDN. BHD.
Manufacturer's Address	: No. 9, Jalan KPK 1/3, Kawasan Perindustrian Kundang, 48020, Kundang Jaya, Selangor Darul Ehsan, Malaysia
European Authorized Representative	: Grixx B.V. Curieweg 15 2408 BZ Alphen aan den Rijn The Netherlands Tel.: +31 (0)172 63 66 66
Product Description	: Qube Nitrile Disposable Examination Gloves
Device Classification (MDR)	: Class I, according to Annex VIII of EU Regulation 2017/745
Device Classification (PPER)	: Category III (Type C)
EU Type-Examination Certificate Number (PPER)	: 2777/15373-01/E00-00
EU Type Conformity PPE Module D	: 2797
Product Part Numbers Conformity	: Attachment A
Overview	: Attachment B

The manufacturer declares under full responsibility that the products listed in Attachment A are:

- In conformity with the Medical Device Regulation (EU) 2017/745
- In conformity with the provisions of the Regulation (EU) 2016/425 on personal protective equipment
- In conformity with the Regulation (EC) 1935/2004 and (EU) 10/2011 on materials and articles intended to come into contact with food, (EC) 2023/2006 on good manufacturing practices for materials and articles intended to come into contact with food
- Subject to the conformity assessment Module B set out in Annex II of Regulation (EU) 2016/425, under approval of the notified body SATRA Technology Europe Limited (Notified Body number 2777).
- Subject to the conformity assessment procedure Module D set out in Annex VIII of Regulation (EU) 2016/425, under the surveillance of the notified body BSI Group The Netherlands B.V (Notified Body number 2797).

and are in compliance with EN/ISO norms as listed in Attachment B.

Place and date of issue : 3<sup>rd</sup> of August, 2021 at Selangor, Malaysia.

Signed : Qube Medical Products Sdn Bhd



Name : NURFITRIYAH ABDUL KADIR

Position : QA/QC SENIOR EXECUTIVE

**Qube Medical Products Sdn Bhd**  
**(827379-P)**  
**No. 9, Jalan KPK 1/3**  
**Kawasan Perindustrian Kundang**  
**48020 Kundang, Selangor.**  
**Tel: 03-60345857 Fax: 03-60345859**

## Attachment A

### Overview of Product References

Trade name	MPN	Size	REF	Pcs/ box
Nitrile Examination Gloves Long Cuff	-	XS	NBR12PFFTSC1	100
	-	S	NBR12PFFTSC2	100
	-	M	NBR12PFFTSC3	100
	-	L	NBR12PFFTSC4	100
	-	XL	NBR12PFFTSC5	100
Nitrile Examination Gloves	QUBE-NPF-XS-TP(HK)	XS	NBR9PFFTSC1	100
	QUBE-NPF-S-TP(HK)	S	NBR9PFFTSC2	100
	QUBE-NPF-M-TP(HK)	M	NBR9PFFTSC3	100
	QUBE-NPF-L-TP(HK)	L	NBR9PFFTSC4	100
	QUBE-NPF-XL-TP(HK)	XL	NBR9PFFTSC5	100
	QUBE-NPF-XS-TP(HK)	XS	NBR9PFFTSC1	200
	QUBE-NPF-S-TP(HK)	S	NBR9PFFTSC2	200
	QUBE-NPF-M-TP(HK)	M	NBR9PFFTSC3	200
	QUBE-NPF-L-TP(HK)	L	NBR9PFFTSC4	200
	QUBE-NPF- XL-TP(HK)	XL	NBR9PFFTSC5	180
	QUBE-NPF-XS-TP(HK)	XS	NBR9PFFTSC1	150
	QUBE-NPF-S-TP(HK)	S	NBR9PFFTSC2	150
	QUBE-NPF-M-TP(HK)	M	NBR9PFFTSC3	150
	QUBE-NPF-L-TP(HK)	L	NBR9PFFTSC4	150
	QUBE-NPF- XL-TP(HK)	XL	NBR9PFFTSC5	135

# Attachment B

## Conformity Overview

Standard	Scope
EN 455-1:2000	Medical Gloves for Single Use. Part 1: Requirements and testing for freedom from holes.
EN 455-2:2015	Medical Gloves for Single Use. Part 2: Requirements and testing for physical properties.
EN 455-3:2015	Medical Gloves for Single Use. Part 3: Requirements and testing for biological evaluation.
EN 455-4:2009	Medical Gloves for Single Use. Part 4: Requirements and testing for shelf life determination.
EN ISO 374-1:2016+A1:2018	Protective gloves against dangerous chemicals and micro-organisms. Part 1: Terminology and performance requirements for chemical risks.
EN ISO 374-2:2019	Protective gloves against dangerous chemicals and micro-organisms. Part 2: Determination of resistance to penetration.
EN ISO 374-4:2019	Protective gloves against dangerous chemicals and micro-organisms. Part 4: Determination of resistance to degradation by chemicals.
EN ISO 374-5:2016	Protective gloves against dangerous chemicals and micro-organisms. Part 5: Terminology and performance requirements for micro-organisms risks.
EN 16523-1:2015+A1:2018	Determination of material resistance to permeation by chemicals. Part 1: Permeation by potentially hazardous liquid chemicals under conditions of continuous contact.
EN ISO 21420:2020	Protective gloves - General requirements and test methods.
EN 1186-1:2002	Materials and articles in contact with foodstuffs. Plastics. Part 1: Guide to the selection of conditions and test methods for overall migration.
EN 1186-9:2002	Materials and articles in contact with foodstuffs. Plastics. Part 9: Test methods for overall migration into aqueous simulants by article filling.
EN 13130-1:2004	Materials and articles in contact with foodstuffs. Plastics substances subject to limitation. Part 1: Guide to test methods for the specific migration of substances from plastics to foods and food simulants and the determination of substances in plastics and the selection of conditions of exposure to food simulants.
ASTM F1671	Resistance of materials to penetration by blood-borne pathogens.
ASTM D6978	Resistance to permeation by chemotherapy drugs.
ISO 9001:2015	Quality management systems. Requirements.
ISO 13485:2016	Medical devices. Quality management systems. Requirements for regulatory purposes.



## Declaration of Conformity

Manufacturer's Name : QUBE MEDICAL PRODUCTS SDN. BHD.

Manufacturer's Address : No. 9, Jalan KPK 1/3, Kawasan Perindustrian Kundang,  
48020, Kundang Jaya, Selangor Darul Ehsan, Malaysia

European Authorized Representative : Grix B.V.  
Curieweg 15  
2408 BZ Alphen aan den Rijn  
The Netherlands  
Tel.: +31 (0)172 63 66 66

Product Description : Qube Nitrile Disposable Examination Gloves

Product Part Numbers : Attachment A



QUBE MEDICAL PRODUCTS SDN. BHD. can confirm that the products listed in Attachment A are free of latex and latex derivatives.

The product(s) supplied may contain traces of antioxidants, but these have not been intentionally added during production and are however, present in the raw materials.

The product(s) supplied are free of biocides.

The product(s) supplied are comply with essential health and safety requirements under Annex II of the PPE Regulation (EU) 2016/425 as Category III product.

The product(s) supplied are tested against with standard specifications of EN 374: Part 1, 2, 4, & 5 and EN ISO 21420:2020.

For further queries, kindly contact QUBE MEDICAL PRODUCTS SDN. BHD.'s QA department via email: [thongsc@qubemedic.com](mailto:thongsc@qubemedic.com) or [qa@qubemedic.com](mailto:qa@qubemedic.com)

Date of issue : 27.11.2023

Signed : Qube Medical Products Sdn Bhd

A handwritten signature in blue ink is written over a horizontal line. To the right of the signature is a blue circular stamp. The stamp contains the text "Qube Medical Products Sdn Bhd" around the perimeter and "427379-F" in the center.

Name : Thong Seng Choon

Position : QA/QC Executive

Attachment A

Overview of Product References

Trade name	MPN	Size	REF	Pcs/ box
Nitrile Examination Gloves Long Cuff	-	XS	NBR12PFFTSC1	100
	-	S	NBR12PFFTSC2	100
	-	M	NBR12PFFTSC3	100
	-	L	NBR12PFFTSC4	100
	-	XL	NBR12PFFTSC5	100
	-	XS	55101Q1	100
	-	S	55101Q2	100
	-	M	55101Q3	100
	-	L	55101Q4	100
	-	XL	55101Q5	90
Nitrile Examination Gloves	QUBE-NPF-XS-TP(HK)	XS	NBR9PFFTBCS1	100
	QUBE-NPF-S-TP(HK)	S	NBR9PFFTBCS2	100
	QUBE-NPF-M-TP(HK)	M	NBR9PFFTBCS3	100
	QUBE-NPF-L-TP(HK)	L	NBR9PFFTBCS4	100
	QUBE-NPF-XL-TP(HK)	XL	NBR9PFFTBCS5	100
	QUBE-NPF-XS-TP(HK)	XS	NBR9PFFTBCS1	200
	QUBE-NPF-S-TP(HK)	S	NBR9PFFTBCS2	200
	QUBE-NPF-M-TP(HK)	M	NBR9PFFTBCS3	200
	QUBE-NPF-L-TP(HK)	L	NBR9PFFTBCS4	200
	QUBE-NPF- XL-TP(HK)	XL	NBR9PFFTBCS5	200/180
	-	XS	NBR9PFFTBCS1	150
	-	S	NBR9PFFTBCS2	150
	-	M	NBR9PFFTBCS3	150
	-	L	NBR9PFFTBCS4	150
	-	XL	NBR9PFFTBCS5	135

## Declaration of Conformity

Manufacturer's Name	: QUBE MEDICAL PRODUCTS SDN. BHD.
Manufacturer's Address	: No. 9, Jalan KPK 1/3, Kawasan Perindustrian Kundang, 48020, Kundang Jaya, Selangor Darul Ehsan, Malaysia
European Authorized Representative	: Grix B.V. Curieweg 15 2408 BZ Alphen aan den Rijn The Netherlands Tel.: +31 (0)172 63 66 66
Product Description	: Qube Nitrile Disposable Examination Gloves
Product Part Numbers	: Attachment A

QUBE MEDICAL PRODUCTS SDN. BHD. can confirm that the products listed in Attachment A may contain traces of accelerators, but these have not been intentionally added during production and are however, present in the raw materials.

The product(s) supplied are comply with essential health and safety requirements under Annex II of the PPE Regulation (EU) 2016/425 as Category III product.

The product(s) supplied are tested against with standard specifications of EN 374: Part 1, 2, 4, & 5 and EN ISO 21420:2020.

For further queries, kindly contact QUBE MEDICAL PRODUCTS SDN. BHD.'s QA department via email: [thongsc@qubemedic.com](mailto:thongsc@qubemedic.com) or [qa@qubemedic.com](mailto:qa@qubemedic.com)

Date of issue : 27.11.2023

Signed : Qube Medical Products Sdn Bhd

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Name : Thong Seng Choon

Position : QA/QC Executive

## Overview of Product References

Trade name	MPN	Size	REF	Pcs/ box
Nitrile Examination Gloves Long Cuff	-	XS	NBR12PFFTSC1	100
	-	S	NBR12PFFTSC2	100
	-	M	NBR12PFFTSC3	100
	-	L	NBR12PFFTSC4	100
	-	XL	NBR12PFFTSC5	100
	-	XS	55101Q1	100
	-	S	55101Q2	100
	-	M	55101Q3	100
	-	L	55101Q4	100
	-	XL	55101Q5	90
Nitrile Examination Gloves	QUBE-NPF-XS-TP(HK)	XS	NBR9PFFTSC1	100
	QUBE-NPF-S-TP(HK)	S	NBR9PFFTSC2	100
	QUBE-NPF-M-TP(HK)	M	NBR9PFFTSC3	100
	QUBE-NPF-L-TP(HK)	L	NBR9PFFTSC4	100
	QUBE-NPF-XL-TP(HK)	XL	NBR9PFFTSC5	100
	QUBE-NPF-XS-TP(HK)	XS	NBR9PFFTSC1	200
	QUBE-NPF-S-TP(HK)	S	NBR9PFFTSC2	200
	QUBE-NPF-M-TP(HK)	M	NBR9PFFTSC3	200
	QUBE-NPF-L-TP(HK)	L	NBR9PFFTSC4	200
	QUBE-NPF- XL-TP(HK)	XL	NBR9PFFTSC5	200/180
	-	XS	NBR9PFFTSC1	150
	-	S	NBR9PFFTSC2	150
	-	M	NBR9PFFTSC3	150
	-	L	NBR9PFFTSC4	150
	-	XL	NBR9PFFTSC5	135

Test Report No. : CPSA/210766874-CA68659  
Company : Qube Medical Products Sdn. Bhd.  
No. 9, Jalan KPK 1/3, Kawasan Perindustrian Kundang,  
48020 Kundang, Selangor, Malaysia.

**TEST REPORT**

Sample Description : 9" Powder Free Nitrile Gloves, Finger Textured  
Size : M  
Quantity Tested : 200 pieces  
Test Conducted : Freedom from holes  
Test Method : EN455 Part 1:2000  
Testing Period : 26 July 2021 - 02 August 2021

Based on submitted samples, the following results obtained: -

Acceptable Quality Limit (AQL) : 1.5      Accept : 7      Found : 0

Result : Within AQL

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SGS (MALAYSIA) SDN BHD



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

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

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**Test Report No.** : CPSA/210663467-CA65017  
**Company** : Qube Medical Products Sdn. Bhd.  
 No. 9, Jalan KPK 1/3,  
 Kawasan Perindustrian Kundang,  
 48020 Kundang, Selangor, Malaysia.

**TEST REPORT**

Sample Description : 9' Powder Free Nitrile Gloves, Finger Textured  
 Quantity Tested : 13 pieces  
 Test Conducted : Dimensions  
 Test Method : EN 455 Part 2:2015  
 Testing Period : 24 May 2021 - 04 June 2021

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	95	95	95	97	96	96	96	96	96	96	96	96	96	96
Length Median: > 240mm	261	255	252	257	249	254	251	246	251	249	254	254	246	252

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

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**Test Report No.** : CPSA/210663467-CA65017  
**Company** : Qube Medical Products Sdn. Bhd.  
 No. 9, Jalan KPK 1/3,  
 Kawasan Perindustrian Kundang,  
 48020 Kundang, Selangor, Malaysia.

### TEST REPORT

Sample Description : 9' Powder Free Nitrile Gloves, Finger Textured  
 Quantity Tested : 13 pieces per test  
 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 : 24 May 2021 - 04 June 2021

SIZE	SAMPLE NO.	Force at Break, N	
		<u>BEFORE AGING</u>	<u>AFTER AGING</u>
	1	8.9	9.5
	2	7.2	8.2
	3	8.5	9.0
	4	9.2	7.3
	5	9.7	10.3
	6	8.5	9.0
	7	9.1	7.8
	8	6.0	8.3
	9	9.1	7.8
	10	8.7	8.1
	11	6.4	9.3
	12	9.2	9.1
	13	9.4	7.9
Median		8.9	8.3
Requirement		> 6.0	> 6.0

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Test Report No. : CPSA/210663467-CA65017  
Company : Oube Medical Products Sdn. Bhd.  
No. 9, Jalan KPK 1/3,  
Kawasan Perindustrian Kundang,  
48020 Kundang, Selangor, Malaysia.


### TEST REPORT

Sample Description : 9' Powder Free Nitrile Gloves, Finger Textured  
Quantity Tested : 5 pieces  
Test Conducted : Powder Content  
Test Method : EN455 Part 3:2015  
Testing Period : 24 May 2021 - 04 June 2021

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

<u>SIZE</u>	<u>Average Powder Mass per Glove</u>
-	0.32 mg

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**Test Report No.** : CPSA/210663467-CA65017  
**Company** : Qube Medical Products Sdn. Bhd.  
 No. 9, Jalan KPK 1/3,  
 Kawasan Perindustrian Kundang,  
 48020 Kundang, Selangor, Malaysia.

**TEST REPORT**

Sample Description : 9' Powder Free Nitrile Gloves, Finger Textured  
 Quantity Tested : 8 pieces  
 Test Conducted : Aqueous Extractable Protein Content  
 Test Method : EN455 Part 3:2015  
 Testing Period : 24 May 2021 - 04 June 2021

**EXTRACTABLE PROTEIN CONTENT**

Analysis had been carried out as per your request. We report the following results:

SIZE	AQUEOUS EXTRACTABLE PROTEIN CONTENT, µg/g
-	NOT DETECTED

Note: Detection limit = 10 µg/g

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 SGS (MALAYSIA) SDN BHD



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 SECTION HEAD  
 #KM No. M/3983/6401/12/14

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

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**SUBJECT: REAL TIME SHELF LIFE STUDY REPORT – POWDER FREE NITRILE EXAMINATION GLOVES**

**Date:** 5th of April, 2019.

**Objective** : To perform Real Time Shelf Life Study according to EN 455–Part 4: Requirements and Testing for Shelf Life Determination Standard to determine the shelf life of the Powder Free Nitrile Examination Gloves.

**Method** : Packed Powder Free Nitrile Examination Gloves were conditioned at 25° ± 2° C for the intended shelf life period and samples are then tested at pre-determined intervals for Force at Break Before Accelerated Aging according to EN 455–Part 2: Requirements & Testing for Physical Properties Standard and for Watertightness according to EN 455–Part 1: Requirements & Testing for Freedom From Holes.

Samples were taken from the following batches:

Lot	Batch No.	Gloves Size	Lot Size	Date of Test
Lot A	4124115B1	S	12,000 pcs	1st of April, 2014 – 1st of April, 2019
Lot B	4124113A2	M	12,000 pcs	1st of April, 2014 – 1st of April, 2019
Lot C	4124112B2	L	12,000 pcs	1st of April, 2014 - 1st of April, 2019

The sample were stored under ambient conditions of (25° ± 2°C) and relative humidity of (50 ± 5%) for a specified period (5 years). Every 6 months, 13 pieces were removed from the lot sample and tested as per requirements of EN 455–Part 2: Requirements & Testing for Physical Properties Standard. Also, another 32 pieces were removed from the lot sample and tested as per requirements of EN 455–Part 1: Requirements & Testing for Freedom From Holes Standard. After 5 years, the results obtained are as following:

**Results:**

**Part A: Force at Break Before Accelerated Aging**

Specification: Force at Break = 6.0 N (Median)

Sample Size: 13 pieces

Date Of Sampling	Median Force at Break (N)	Average Sample Thickness (mm)
1st of April, 2014 (Initial)	7.26	0.101
1st of October, 2014	7.65	0.102
1st of April, 2015	7.73	0.097

<b>1st of October, 2015</b>	8.12	0.097
<b>1st of April, 2016</b>	8.16	0.102
<b>1st of October, 2016</b>	7.93	0.101
<b>1st of April, 2017</b>	7.49	0.098
<b>1st of October, 2017</b>	7.33	0.102
<b>1st of April, 2018</b>	7.18	0.102
<b>1st of October, 2018</b>	7.03	0.104
<b>1st of April, 2019</b>	6.84	0.101

**Observation / Comment:** The force at break for each interval increased in a small fraction over the first two years of storage period and started to decline slowly from the second year till end of the storage period of 5 years. The result shows that the powder free nitrile examination gloves complies to the requirement of EN 455–Part 2: Requirements & Testing for Physical Properties Standard over the 5 years study period.

**Part B: Watertightness**

Maximum Permitted Defective: AQL 1.5 ; G1 (Accept: 1 piece, Reject: 2 pieces)

Sample Size: 32 pieces

<b>Date Of Sampling</b>	<b>Defect Found (pieces)</b>
<b>1st of April, 2014 (Initial)</b>	0
<b>1st of October, 2014</b>	0
<b>1st of April, 2015</b>	0

<b>1st of October, 2015</b>	0
<b>1st of April, 2016</b>	1
<b>1st of October, 2016</b>	0
<b>1st of April, 2017</b>	0
<b>1st of October, 2017</b>	0
<b>1st of April, 2018</b>	1
<b>1st of October, 2018</b>	0
<b>1st of April, 2019</b>	0

**Observation / Comment:** The samples tested meet the requirement of EN 455–Part 1: Requirements & Testing for Freedom From Holes Standard over the 5 years study period.

**Discussion & Conclusion:**

EN 455–Part 4: Requirements and Testing for Shelf Life Determination Standard is an harmonised standard for the requirement and testing for shelf life determination of medical gloves for single use. The standard requires manufacturer to test the properties of the glove that can alter during natural aging (shelf life of the product). The properties that require testing shall include, but are not limited to; Force at Break (EN 455-Part 2) and Freedom from Holes (EN 455-Part 1).

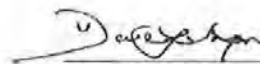
The result above showed that our Powder Free Nitrile Examination Gloves are complied to the requirement of EN 455–Part 2: & EN 455–Part 1 over the 5 years study period, thus the gloves are claimed to have a shelf life of 5 years based on the Real Time Shelf Life Study test results above which conform to EN 455 – Part 4 standard.

Reported By:



Nurfitriyah  
QA Executive

Verified By:



Davendran  
QA Manager



## Conformity to Type based on Quality Assurance of the Production Process

This is to certify that:

Qube Medical Products Sdn. Bhd.  
No 9, Jalan KPK 1/3,  
Kawasan Perindustrian Kundang,  
Kundang Jaya,  
Rawang,  
Selangor  
48020  
Malaysia

Holds Certificate Number: CE 739508

In respect of:

**For the manufacture of gloves to the standards specified on the continuation sheet.**

on the basis that BSI carried out the quality assurance assessment under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex VIII (Module D)

For and on behalf of BSI, a Notified  
Body for the above Regulation  
(Notified Body Number 2797):

Drs. Dave Hagenaaars, Managing Director

First Issued: 2021-01-21

Latest Issue: 2021-01-21

Effective Date: 2021-01-21

Expiry Date: 2026-01-21

Page: 1 of 3



...making excellence a habit.™

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To check its validity telephone +31 20 3460780. An electronic certificate can be authenticated [online](#).

BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands  
A member of BSI Group of Companies.

# Conformity to Type based on Quality Assurance of the Production Process

No. CE 739508

This Module D Certificate references the Quality Assurance of the Production Process activities at the manufacturing sites in respect of hand protection certified products. The Table below details the manufacturing site and site identifier.

The details of the product type and the site at which they are produced are presented in a separate Table. In this Table the type of product Certified is referenced by detailing the Technical Specification against which it was assessed at the PPE Regulation Module B Type-Examination stage.

## Manufacturing site.

Qube Medical Products Sdn. Bhd.  
No 9, Jalan KPK 1/3,  
Kawasan Perindustrian Kundang,  
Kundang Jaya,  
Rawang,  
Selangor  
48020  
Malaysia

## Technical Specifications:

### European Standards:

EN ISO 21420:2020	Protective gloves. General requirements and test methods.
EN ISO 374 -1:2016+A1:2018	Protective gloves against dangerous chemicals and micro-organisms. Part 1: Terminology and performance requirements for chemical risks.
EN ISO 374-2:2019	Protective gloves against dangerous chemicals and micro-organisms. Part 2: Determination of resistance to penetration
EN ISO 374-4:2019	Protective gloves against dangerous chemicals and micro-organisms. Part 4: Determination of resistance to degradation by chemicals.
EN ISO 374 -5:2016	Protective gloves against dangerous chemicals and micro-organisms. Part 5: Terminology and performance requirements for micro-organisms risks.
EN 16523-1:2015	Determination of material resistance to permeation by chemicals. Part 1: Permeation by liquid chemical under conditions of continuous contact.

- Last item -

First Issued: 2021-01-21  
Latest Issue: 2021-01-21

Effective Date: 2021-01-21  
Expiry Date: 2026-01-21

Page: 2 of 3

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# Conformity to Type based on Quality Assurance of the Production Process

No. CE 739508

## Certificate Amendment Record:

Issue date	Comments	BSI Review No.
January 2021	First issue	2797:21:3326603

## Certificate validity

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

The validity of the Certificate is also dependent on the maintenance of an ISO 9001 quality system certified by a recognized certification organisation.

First Issued: 2021-01-21  
Latest Issue: 2021-01-21

Effective Date: 2021-01-21  
Expiry Date: 2026-01-21

Page: 3 of 3

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A member of BSI Group of Companies.





Issued to:

Qube Medical Products Sdn. Bhd.  
No. 9 & 10, Jalan KPK 1/3  
Kawasan Perindustrian Kundang  
Kundang Jaya, Rawang  
Selangor Darul Ehsan  
Malaysia

Notified Body: 2777

SATRA customer number: P1513

## EU Type-Examination Certificate

### Certificate number: 2777/15373-02/E00-00

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

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

Product reference:	Description:
NBR9PFFTSC	Five finger blue powder free nitrile examination gloves – length of 240mm
NBR12PFFTSC	Five finger blue powder free nitrile examination gloves – length of 290mm

Sizes:	Classification:	Level	EN ISO 374-4:2019
6 (XS) -10 (XL)	EN ISO 374-1:2016+A1:2018 Type C	6	23.9%
NBR9PFFTSC1 – XS	Sodium hydroxide 40% (K)	1	34.6%
NBR9PFFTSC2 – S	Hydrogen Peroxide 30% (P)	5	33.9%
NBR9PFFTSC3 – M	Formaldehyde 37% (T)		
NBR9PFFTSC4 – L			
NBR9PFFTSC5 - XL	EN ISO 374-5:2016		
NBR12PFFTSC1 – XS	Protection against bacteria and fungi - Pass		
NBR12PFFTSC2 – S	Protection against viruses – Pass		
NBR12PFFTSC3 – M			
NBR12PFFTSC4 – L			
NBR12PFFTSC5 - XL			

Standards/Technical specifications applied:

EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:

SATRA: CHM0301504/2034/JS/B, CHM0301504/2034/JS/A, CHM0298827/2023/EN/A, CHM0298827/2023/EN/B, CHM0298827/2023/EN/C, CHM0298827/2023/SPT

Signed on behalf of SATRA:

Quincey Brown

Date first issued: 30/11/2020

Date of issue: 17/09/2021

Expiry date: 30/11/2025

Customer details: Qube Medical Products Sdn. Bhd.  
No. 9 & 10, Jalan KPK 1/3  
Kawasan Perindustrian Kundang  
Kundang Jaya, Rawang  
Selangor Darul Ehsan  
Malaysia

SATRA reference: CHM0298827/2023/EN  
/A

Your reference: NSPO-20/07/0053

Date of report: 11<sup>th</sup> August 2020

Samples received: 21<sup>st</sup> July 2020

Date(s) work carried out: 27<sup>th</sup> July to 11<sup>th</sup> August  
2020

## TECHNICAL REPORT

Subject: Chemical innocuousness testing in accordance with EN ISO 21420:2020 and EN 16523-1:2015+A1:2018 resistance to permeation by chemicals on gloves described as Powder Free Nitrile Examination Gloves - Blue. Lot number 0231611B1

### Conditions of Issue:

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

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

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

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

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

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

(Page 1 of 13)



**WORK REQUESTED:**

Samples of gloves described as Powder Free Nitrile Examination Gloves - Blue. Lot number 0231611B1 were received on the 21<sup>st</sup> July 2020 for testing in accordance with the innocuousness requirements of EN ISO 21420:2020 and EN 16523-1:2015+A1:2018 and assessment in accordance with the requirements of EN ISO 374-1:2016+A1:2018.

**SAMPLES SUBMITTED:**



Samples described as Powder Free Nitrile Examination Gloves - Blue. Lot number 0231611B1

**CONCLUSION:**

The samples of gloves described as Powder Free Nitrile Examination Gloves - Blue. Lot number 0231611B1 were assessed in accordance with the innocuousness requirements of EN ISO 21420:2020 and were found to meet with the requirements for pH value and PAHs. When assessed in accordance with the requirements of EN ISO 374-1:2016+A1:2018 the samples of gloves described as Powder Free Nitrile Examination Gloves - Blue. Lot number 0231611B1 achieved the following performance levels:

Chemical	Performance level
Methanol (CAS: 67-56-1)	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
40% Sodium hydroxide (CAS: 1310-73-2)	6
96% Sulphuric acid (CAS: 7664-93-9)	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
99% Acetic acid (CAS: 64-19-7)	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
30% Hydrogen peroxide (CAS: 7722-84-1)	1
37% Formaldehyde (CAS: 50-00-0)	5

### TESTING REQUIRED:

- EN ISO 21420:2020 - Clause 4.2 c) pH Value (EN ISO 3071:2006 - Textiles - Determination of pH of aqueous extract).
- EN ISO 21420:2020 - Clause 4.2 f) Polycyclic aromatic hydrocarbons (PAHs) (#PD CEN ISO/TS 16190:2013 - Footwear - Critical substances potentially present in footwear and footwear components. Test method to quantitatively determine polycyclic aromatic hydrocarbons (PAH) in footwear materials in accordance with SATRA SOP CAT-047 (modified for the detection of those PAH listed in the appendices)).
- EN 16523-1:2015+A1:2018 - Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact.

### RESULTS AND REQUIREMENTS:

EN ISO 3071:2006 - Textiles - Determination of pH of aqueous extract.

Date of determination: 28<sup>th</sup> July 2020

Sample	Method	pH Value	UoM	Pass/Fail
Powder Free Nitrile Examination Gloves - Blue. Lot number 0231611B1	ISO 3071:2006 (water extraction)	6.9	± 0.1	Pass
<b>Requirement</b>	<b>pH value greater than 3.5 and less than 9.5</b>			

The extraction solution temperature was 23°C and at pH 7.4

#PD CEN ISO/TS 16190:2013 - Footwear - Critical substances potentially present in footwear and footwear components. Test method to quantitatively determine polycyclic aromatic hydrocarbons (PAH) in footwear materials in accordance with SATRA SOP CAT-047 (modified for the detection of those PAH listed in the appendices)

Testing completed 31<sup>st</sup> July 2020

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

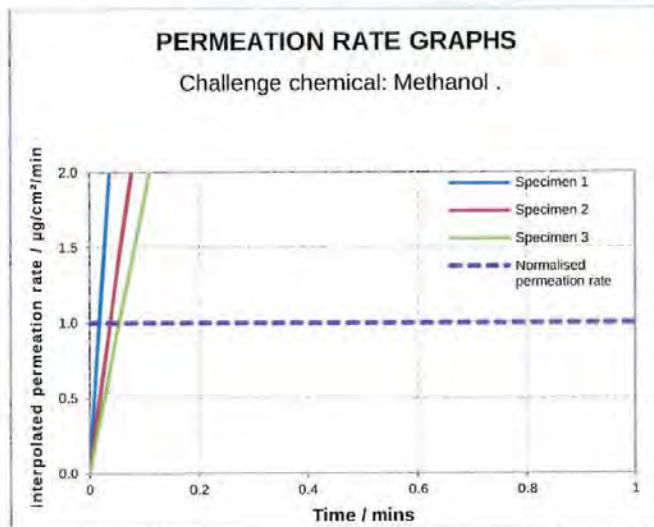
Sample	PAHs detected (mg/kg)	Pass/Fail
Powder Free Nitrile Examination Gloves - Blue. Lot number 0231611B1	<0.2 (of each PAH listed in the appendices)	Pass
<b>Requirement</b>	<b>≤ 1mg/kg (0.0001% by mass of this component) of each PAH listed in the appendices</b>	

EN ISO 374-1:2016+A1:2018 - Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks. Table 1: Permeation performance levels.

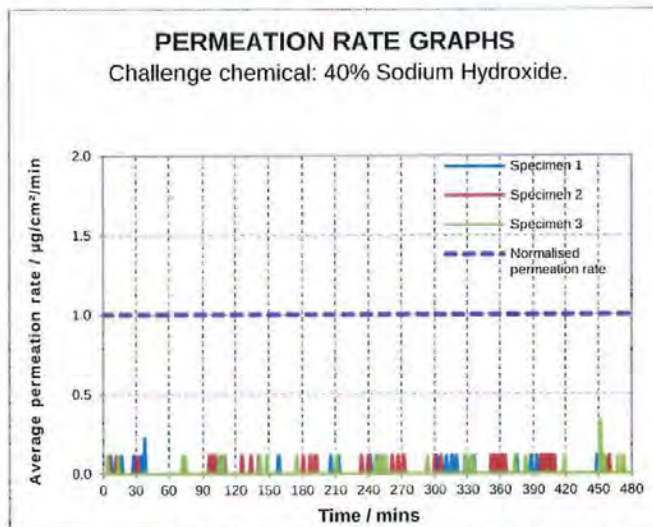
Permeation performance level	Measured breakthrough time (minutes)
1	>10
2	>30
3	>60
4	>120
5	>240
6	>480

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

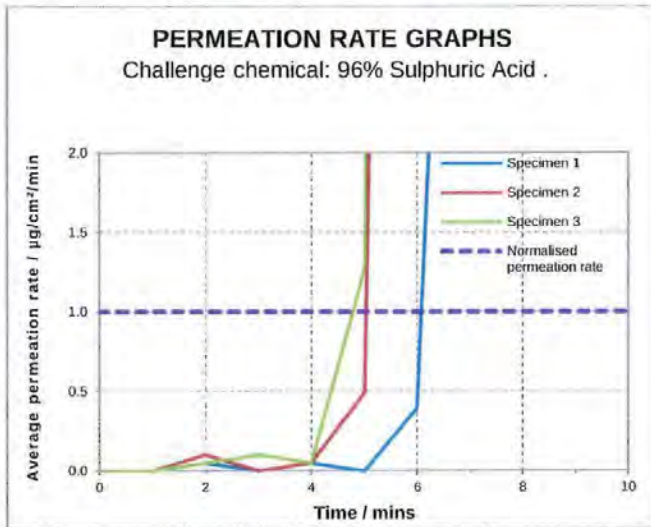
Test/Property	Sample reference:	Powder Free Nitrile Examination Gloves – Blue Lot number 0231611B1		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-005  Using stainless steel permeation cells with standardised dimensions	<b>Test information:</b>	Chemical: Methanol		The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
		Normalised permeation rate (NPR): 1 µg/cm <sup>2</sup> /min		
		Detection technique: GC-FID (periodic measurement)		
		Collection medium: Dry air (open loop)		
		Collection medium flow rate: 335 – 380 ml/min		
	Test temperature: (23 ± 1) °C			
	<b>Specimen</b>	<b>Thickness (mm)<sup>Δ</sup></b>	<b>Breakthrough time (mins)<sup>▲</sup></b>	
	1	0.08	<1	
	2	0.08	<1	
	3	0.08	<1	
<b>Test result:</b>		<b>&lt;1</b>		
<b>UoM:</b>		<b>&lt;1</b>		
Visual appearance of specimens after testing:		Severely swollen		



Test/Property	Sample reference:	Powder Free Nitrile Examination Gloves – Blue Lot number 0231611B1		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-009  Using PTFE permeation cells with standardised dimensions	<b>Test information:</b>	Chemical: 40% Sodium hydroxide		<b>Level 6</b>
		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			
	<b>Specimen</b>	<b>Thickness (mm)<sup>Δ</sup></b>	<b>Breakthrough time (mins)</b>	
	1	0.08	>480	
	2	0.08	>480	
	3	0.07	>480	
	<b>Test result:</b>	<b>&gt;480</b>		
	<b>UoM:</b>	<b>&lt;1</b>		
Visual appearance of specimens after testing:		Swollen		

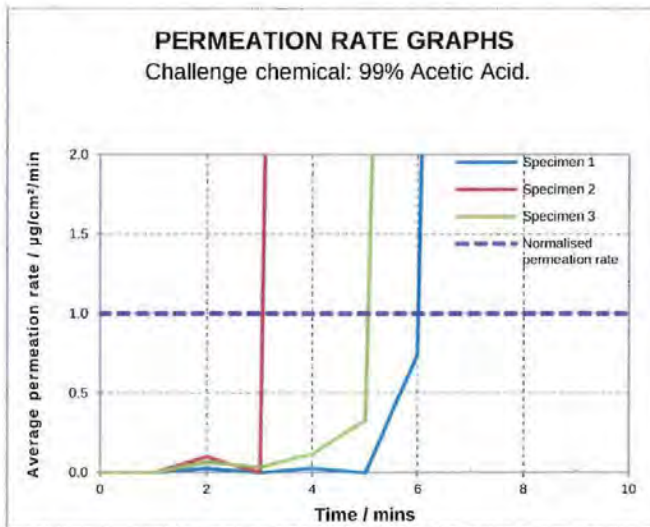


Test/Property	Sample reference:	Powder Free Nitrile Examination Gloves – Blue Lot number 0231611B1		Performance	
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-009  Using PTFE permeation cells with standardised dimensions	<b>Test information:</b>	Chemical: 96% Sulphuric acid		<b>The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved</b>	
		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				
	<b>Specimen</b>	<b>Thickness (mm)Δ</b>	<b>Breakthrough time (mins)</b>		
	1	0.08	7		
	2	0.07	6		
	3	0.07	5		
	<b>Test result:</b>	<b>5</b>			
	<b>UoM:</b>	<b>&lt;1</b>			
Visual appearance of specimens after testing:		Swollen, brittle, disintegrated, discoloured and hardened			



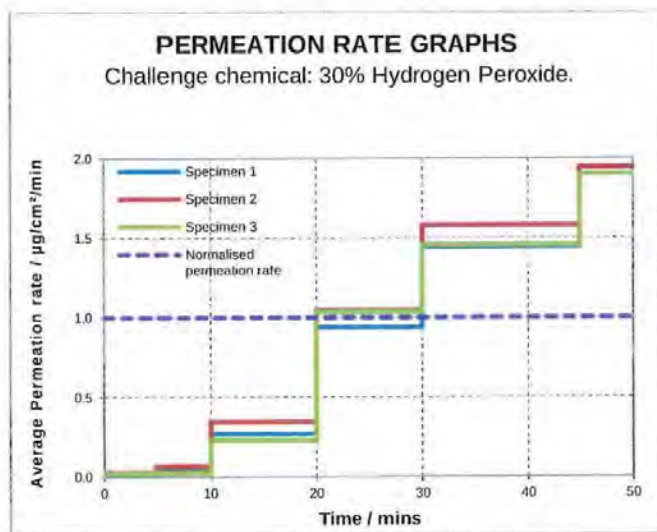


Test/Property	Sample reference:	Powder Free Nitrile Examination Gloves – Blue Lot number 0231611B1		Performance	
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-009  Using PTFE permeation cells with standardised dimensions	<b>Test information:</b>	Chemical: 99% Acetic acid		The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved	
		Normalised permeation rate (NPR): 1 µg/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				
	<b>Specimen</b>	<b>Thickness (mm)<sup>Δ</sup></b>	<b>Breakthrough time (mins)</b>		
		1	0.07		7
		2	0.08		4
		3	0.07		6
<b>Test result:</b>		<b>4</b>			
<b>UoM:</b>		<b>&lt;1</b>			
Visual appearance of specimens after testing:		Not observed			



Test/Property	Sample reference:	Powder Free Nitrile Examination Gloves – Blue Lot number 0231611B1		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-025  Using PTFE permeation cells with standardised dimensions	<b>Test information:</b>	Chemical: 30% Hydrogen peroxide		<b>Level 1</b>
		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		
	<b>Specimen</b>	<b>Thickness (mm)<sup>Δ</sup></b>	<b>Breakthrough time (mins)<sup>▼</sup></b>	
	1	0.07	Between 31 to 45	
	2	0.07	Between 21 to 30	
	3	0.07	Between 21 to 30	
	<b>Test result:</b>	<b>Between 21 to 30</b>		
	<b>UoM:</b>	<b>See below</b>		
Visual appearance of specimens after testing:	Swollen			

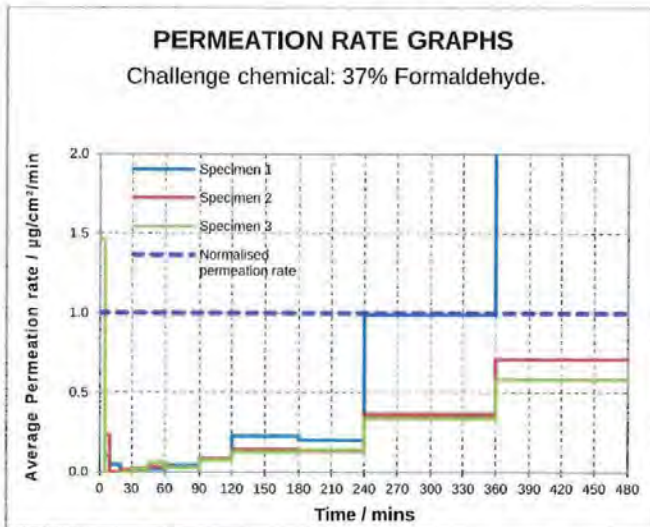
For SOP CAT-025, where both the  $P_1$  and  $P_U$  are observed in the same sampling range, uncertainty is expressed as the time difference between the mid-point of the range and the previous sampling time. This uncertainty is included in the reported result



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

Test/Property	Sample reference:	Powder Free Nitrile Examination Gloves – Blue Lot number 0231611B1		Performance
<p>EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-025</p> <p>Using PTFE permeation cells with standardised dimensions</p>	<b>Test information:</b>	Chemical: 37% Formaldehyde		<b>Level 5</b>
		Normalised permeation rate (NPR): 1 µg/cm <sup>2</sup> /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		
	<b>Specimen</b>	<b>Thickness (mm)<sup>Δ</sup></b>	<b>Breakthrough time (mins)<sup>▼</sup></b>	
	1	0.08	Between 361 to 480	
	2	0.08	>480	
	3	0.07	>480	
	<b>Test result:</b>	<b>Between 361 to 480</b>		
	<b>UoM:</b>	<b>See below</b>		
Visual appearance of specimens after testing:		Swollen and discoloured		

For SOP CAT-025, where both the P<sub>1</sub> and P<sub>0</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



Formaldehyde is determined by discrete sampling; therefore the permeation rate graph is not a smooth curve. The reading from specimen 3 after 5 minutes was considered to be an outlier and not a breakthrough.

- △ EN 16523-1:2015+A1:2018 does not require the test specimen thicknesses to be reported, this information is indicative only.
- ▲ The collection medium from each cell is analysed once every 6 minutes. Due to the complexity of the detection technique, the minimum sampling frequency for final results  $\leq 60$  minutes as specified in table 1 of EN 16523-1:2015+A1:2018 is not possible. Breakthrough time is calculated using linear interpolation between the discrete sampling points.
- ▼ 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+A1:2018 is not possible.

## APPENDICES:

### Restricted polycyclic aromatic hydrocarbons (PAHs)

PAH	CAS Number
Benzo[a]pyrene	50-32-8
Benzo[e]pyrene	192-97-2
Benzo[a]anthracene	56-55-3
Chrysene	218-01-9
Benzo[b]fluoranthene	205-99-2
Benzo[j]fluoranthene	205-82-3
Benzo[k]fluoranthene	207-08-9
Dibenzo[a,h]anthracene	53-70-3

## 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 according to 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 prices quoted which is not in writing. Prices for the sale of Goods include packing costs 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 monies 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 property 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 Timelapse, SATRASUMM and SATRA VisionTech, provided that the Client is a member of SATRA and has paid its annual Subscription 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 other 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 Subscription fee. Major upgrades are not included within the entitlement to upgrades but may be offered by SATRA from time to time for an additional fee.
- 3.6 SATRA shall observe all statutory provisions with regard to data protection including but not limited to the provisions of the Data Protection Act 2018 and the EU General Data Protection Regulation (GDPR) Regulation (EU) 2016/679. In the event that SATRA processes or gets access to personal data in connection with the Services or otherwise in connection with the 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-recoverable 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 incurred 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, fraud or fraudulent misrepresentation;
- (b) breach of the terms invoked by Section 12 of the Sale of Goods Act 1979;
- (c) defective products under the Consumer Protection Act 1987; or
- (d) 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 not 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 (parent 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, notes 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 losses 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 Chartered Court Rules of the

Qube Medical Products Sdn. Bhd.

SATRA Reference: CHM0298827/2023/EN/A

Date: 11<sup>th</sup> August 2020

(Page 12 of 13)

Signed:



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

- 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.
- 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 Client's 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 8 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, licences or authorisations then risk in the Goods shall pass to the Client, the Goods and/or Services shall be deemed to have been delivered, and SATRA may store the Goods until delivery, whereupon the Client shall be liable for all related costs and expenses (including, without limitation, storage and insurance).
13. RISK/TITLE OF GOODS
- 13.1 Subject to clause 12.6 the risk in the Goods will transfer to the Client on delivery of the Goods unless SATRA and the Client have agreed that the sale of the Goods will be governed by Incoterms 2010 (or any subsequent revision thereto) in which case risk will transfer to the Client in accordance with the Incoterms mode of transport which is agreed by SATRA and the Client.
- 13.2 The Company shall not accept responsibility for loss or damage in transit unless:
- a) in the case of sales where delivery of Goods is made in the United Kingdom SATRA is notified by the Client within 10 days of the invoice date of non-arrival of Goods and within 3 days of the invoice date of receipt of Goods damaged in transit; or
- b) in all other cases the Client notifies SATRA on the non-arrival or damage in transit within a reasonable period of time as determined by SATRA.
- 13.3 Time to the Goods shall not pass to the Client until the earlier of when -
- a) SATRA receives payment in full (in cash or cleared funds) for the Goods and any other Goods that SATRA has supplied to the Client in which case title to the Goods shall pass at the time of payment of all such sums; and
- b) the Client receives the Goods in accordance with clause 13.5 in which case title shall pass to the Client immediately before the time at which the results by the Client occur.
- 13.4 Until ownership of Goods has passed to the Client, the Client shall:
- a) hold the Goods as SATRA's bailee;
- b) store the Goods (at no cost to SATRA) separately from all other goods belonging to the Client or any third party in such a way that they remain readily identifiable as SATRA's property (including where the Goods have been sold to a third party);
- c) not destroy, deface or obscure any identifying mark or packaging on or relating to the Goods; and
- d) maintain the Goods in satisfactory condition and keep them insured on SATRA's behalf for their full price against all risks to the reasonable satisfaction of SATRA. The Client shall obtain an endorsement of SATRA's interest in the goods on its insurance policy. On request the Client shall allow SATRA to inspect such Goods and shall produce the policy of insurance.
- 13.5 The Client may re-sell 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 2.5 then without limiting any other right or remedy SATRA may have:
- a) the Client's right to re-sell the Goods or use them in the ordinary course of its business ceases immediately; and
- b) SATRA may at any time require the Client to deliver up all Goods in its possession that have not been re-sold or irrevocably incorporated into another product; and
- c) if the Client fails to do so promptly SATRA may exercise its rights under clause 13.7.
- 13.7 The Client grants SATRA, its agents and employees an irrevocable licence at any time to enter any premises where the Goods are or may be stored in order to inspect them, or, where the Client's right to possession has terminated, to recover them.
- 13.8 On termination of the Contract, however 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 15.6 and 16.7 it
- a) the Client gives notice in writing to SATRA in accordance with clause 16.3 and during the period referred to in clause 15.1 that the Goods do not comply with the warranty in that clause; and
- b) SATRA is given a reasonable opportunity of examining such Goods; and
- c) the Client (if asked to do so by SATRA) returns such Goods to SATRA's place of business (then SATRA will, at its option, repair or replace the defective Goods or refund the price of the defective Goods in full. SATRA reserves the right to repair the Goods at the Client's premises).
- 16.2 The Client must inspect all Goods upon delivery. Failure to do so may result in further charges being applied in the event of a return.
- 16.3 If Goods are found to be faulty, defective or damaged the Client must inform SATRA in writing as soon as reasonably possible and in any event within 10 working days of the fault, damage or defect being discovered.
- 16.4 Without prejudice to clause 16.1 if no notice of rejection has been received by SATRA within 3 months of delivery, the Client shall be deemed to have accepted the Goods.
- 16.5 SATRA will pay the reasonable costs of carriage, packaging and insurance for any defective Goods which are returned by the Client provided that SATRA is liable under clause 16.1 to repair or replace the defective Goods. If SATRA determines that the Goods are not defective or if SATRA is not liable to repair or replace the Goods due to the circumstances under clauses 16.5 or 16.7 then the Client will be responsible for the payment of such costs.
- 16.6 SATRA shall not be under any liability to repair or at its option replace or pay for the repair or replacement of any Goods which are found to be defective if:
- a) the defect is caused or substantially caused by wear and tear, overloading, misuse, neglect, modification or attempted modification carried out by any organisation other than by SATRA or their approved agents, or use with ancillary equipment not approved in writing by SATRA, or default in proper maintenance or cleaning; or
- b) the Client authorises or carries out any repair or replacement of any Goods without first affording SATRA a reasonable opportunity to repair or replace them; or
- c) the Client has breached any of the terms of the Contract under which the Goods were supplied; or
- d) the Goods have been manufactured to a design or specification or in compliance with other information provided by the Client and the defect has arisen as a result of that design, specification or information.
- 16.7 Where Goods or parts of Goods are not manufactured by SATRA then SATRA shall be liable for defects only to the extent that SATRA obtains redress from the manufacturer or supplier thereof provided that:
- a) SATRA shall not be obliged to take any step to attempt to obtain such redress except at the request and expense of the Client and upon provision by the Client of a full indemnity as to costs for which SATRA may thereby become liable;
- b) nothing in this condition 16.7 shall have effect as to impose upon SATRA any additional liability or obligations other than those referred to in condition 16.1.
- 16.8 Except as provided in clause 16.1 SATRA shall have no liability to the Client arising from any failure of the Goods to comply with the warranty in clause 15.1.

Customer details: Qube Medical Products Sdn. Bhd.  
No. 9 & 10, Jalan KPK 1/3  
Kawasan Perindustrian Kundang  
Kundang Jaya, Rawang  
Selangor Darul Ehsan  
Malaysia

SATRA reference: CHM0298827  
/2023/SPT  
Your reference: NSPO-20/07/0053  
Date of report: 7 August 2020  
Samples received: 21 July 2020  
Date(s) work carried out: 7 August 2020

## TECHNICAL REPORT

Subject: Testing of nitrile gloves described as "Powder Free Nitrile Examination Gloves- Blue. Lot number 0231611B1" in accordance with EN 374-2: 2019 and EN ISO 21420: 2020 sizing and dexterity

### 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 a coverage probability of approximately 95%.

Report signed by: Daniel Harrison  
Position: Business Area Manager  
Department: Safety Product Testing

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## Work Requested

Samples of gloves, see Table 1, were received by SATRA, for testing in accordance with EN ISO 374-2: 2019 and #EN ISO 21420: 2020 Protective gloves. General requirements and test methods, Clauses 5.1 sizing and 5.2 dexterity

Table 1 – Samples Received

Sample description as stated by the client	Sizes submitted for testing	Colour of samples submitted	Approximate weight of one glove
Powder Free Nitrile Examination Gloves- Blue. Lot number 0231611B1	7 – 10	Blue	Size: 7 Weight: 4.2g



Powder Free Nitrile Examination Gloves- Blue. Lot number 0231611B1

## Conclusion

Standard	Clause / Property	Result
#EN ISO 21420: 2020	5.1 Sizing	N / A
	5.2 Dexterity	Level 5
EN ISO 374-2: 2019	7.2 Air leak	PASS
	7.3 Water leak	PASS



## Testing

Samples for testing in accordance with EN ISO 21420: 2020 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 ISO 21420: 2020 Clause 5.2 Dexterity

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 ISO 374-2: 2019

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

## Test Results

Table 4 – EN ISO 21420: 2020 Test Results for gloves identified as Powder Free Nitrile Examination Gloves-Blue. Lot number 0231611B1

Clause / Test	Test Results				UoM	Result
5.1 Sizing	Size	Length /mm			± 0.3 mm	N / A
	7	1	2	3		
		260	259	257		
	Comments on fit: Satisfactory					
	8	260	260	257		
	Comments on fit: Satisfactory					
9	257	254	256			
Comments on fit: Satisfactory						
10	260	266	260			
Comments on fit: Satisfactory						
5.2 Dexterity	Size	Minimum pin diameter / mm			N/A	Level 5
	7	5.0				
	8	5.0				
	9	5.0				
	10	5.0				

Table 5 – EN ISO 374-2:2019 Test Results of gloves identified as Powder Free Nitrile Examination Gloves-Blue. Lot number 0231611B1

Clause / Test	Test Results		UoM	Result
7.2 Air leak test	Total Air Pressure Used	2.54kPa	± 2.8 mmH <sub>2</sub> O	PASS
	Sample size	Leaks		
	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
	7	No leaks detected		
	8	No leaks detected		
	9	No leaks detected		
	10	No leaks detected		

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

### 1. GENERAL

- 1.1 Work done, Services undertaken or the sale of Goods are subject to the terms and conditions detailed below and (subject to clause 5.2) all other conditions, warranties and representations, expressed or implied by statute relating thereto are hereby excluded.
- 1.2 SATRA Technology Centre Limited, its subsidiaries and associated companies (hereinafter referred to as "SATRA") may perform Services for or supply Goods to persons or entities (public, private or governmental) issuing instructions (hereinafter termed the "Client"). Each also known individually as a Party, or jointly as Parties.
- 1.3 These terms and conditions will apply to the Contract between SATRA and the Client to the exclusion of any other terms which the Client may seek to impose or which may be implied by trade, custom, practice or course of dealing.
- 1.4 Unless otherwise agreed in writing no party other than the Client is entitled to provide instructions or information relating to the Goods or Services required or to the delivery of goods, results, reports or certificates.
- 1.5 All references in these terms and conditions to
- (a) the "Contract" is the contract between SATRA and the Client for the supply of Goods or Services which is made subject to these terms and conditions; and
  - (b) "Services" are the work or services to be supplied or performed under the Contract (including where relevant the supply of software, components and consumables); and
  - (c) "Goods" are the equipment, consumables or other physical items sold under the Contract (including documents, drawings or other information required in order to operate the equipment).
- 1.6 All drawings, descriptive material, 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 the 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 proprietary 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 VisionSicht, provided that the Client is a member of SATRA and has paid its annual Sustaincare 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 other 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 Sustaincare fee. Major upgrades are not included within the entitlement to upgrades but may be offered by SATRA from time to time for an additional fee.
- 3.6 SATRA shall observe all statutory provisions with regard to data protection including but not limited to the provisions of the Data Protection Act 2018 and the EU General Data Protection Regulation (GDPR) Regulation (EU) 2016/679. To the extent that SATRA processes or gets access to personal data in connection with the Services or otherwise in connection with this Contract, it shall take all reasonable technical and organisational measures to ensure the security of such data (and guard against unauthorised or unlawful processing, accidental loss, destruction or damage to such data).

### 4. SUSPENSION OR TERMINATION OF SERVICES

- 4.1 Cancellation by the Client of orders for Goods or Services will only be acceptable by prior agreement with SATRA and a charge will usually be made.
- 4.2 SATRA shall not be liable for any delay or failure in providing the Goods or Services due to circumstances beyond its reasonable control (including any failure by the Client to comply with its obligations). If any such circumstances arise which prevent SATRA from delivering the Goods or completing the Services, then SATRA will be entitled to cancel or reschedule the delivery of Goods or Services at its discretion. In the event of cancellation SATRA will be entitled to retain all fees paid by the Client for Goods or Services already supplied but will refund to the Client any fees paid by the Client for Goods or Services which have not yet been supplied. The Client will not be liable for any non-refundable expenses already incurred by SATRA in relation to Goods or Services not yet supplied unless the cancellation is due to the 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 on it seen 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 this 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 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 concurred in writing. The arbitration shall be governed by both the Arbitration Act 1996 and the Controlled Cost Rules of the

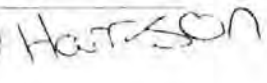
Qube Medical Products Sdn. Bhd.

SATRA Reference: CHM0298827 /2023/SPT

Date: 7 August 2020

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Signed



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

- 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.
- 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 any 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 Client's 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 special 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, licences or authorisations then risk in the Goods shall pass to the Client, the Goods and/or Services shall be deemed to have been delivered, and SATRA may store the Goods until delivery, whereupon the Client shall be liable for all related costs and expenses (including, without limitation, storage and insurance).
13. **RISK/TITLE OF GOODS**
- 13.1 Subject to clause 12.6 the risk in the Goods will transfer to the Client on delivery of the Goods unless SATRA and the Client have agreed that the sale of the Goods will be governed by Incoterms 2010 (or any subsequent revision thereto) in which case risk will transfer to the Client in accordance with the Incoterms mode of transport which is agreed by SATRA and the Client.
- 13.2 The Company shall not accept responsibility for loss or damage in transit unless:
- a) In the case of sales where delivery of Goods is made in the United Kingdom SATRA is notified by the Client within 10 days of the invoice date of non-arrival of Goods and within 3 days of the invoice date of receipt of Goods damaged in transit; or
  - b) In all other cases the Client notifies SATRA on the non-arrival or damage in transit within a reasonable period of time as determined by SATRA.
- 13.3 Title to the Goods shall not pass to the Client until the earlier of when -
- a) SATRA receives payment in full (in cash or cleared funds) for the Goods and any other Goods that SATRA has supplied to the Client in which case title to the Goods shall pass at the time of payment of all such sums, and
  - b) the Client resells the Goods in accordance with clause 13.5 in which case title shall pass to the Client immediately before the time at which the resale by the Client occurs.
- 13.4 Until ownership of Goods has passed to the Client, the Client shall:
- a) hold the Goods as SATRA's bailee;
  - b) store the Goods (at no cost to SATRA) separately from all other goods belonging to the Client or any third party in such a way that they remain readily identifiable as SATRA's property (including where the Goods have been sold to a 3rd party);
  - c) not destroy, deface or obscure any identifying mark or packaging on or relating to the Goods; and
  - d) maintain the Goods in satisfactory condition and keep them insured on SATRA's behalf for their full price against all risks to the reasonable satisfaction of SATRA. The Client shall obtain an endorsement of SATRA's interest in the goods on its insurance policy. On request the Client shall allow SATRA to inspect such Goods and shall produce the policy of insurance.
- 13.5 The Client may resell the Goods before ownership has passed to it solely on condition that sale shall be effected in the ordinary course of the Client's business at full market value.
- 13.6 If before title to the Goods passes to the Client, the Client becomes subject to any of the events referred to in clause 2.6 then without limiting any other right or remedy SATRA may have:
- a) the Client's right to resell the Goods or use them in the ordinary course of its business ceases immediately; and
  - b) SATRA may at any time require the Client to deliver up all Goods in its possession that have not been resold or irrevocably incorporated into another product; and
  - c) if the Client fails to do so promptly SATRA may exercise its rights under clause 13.7.
- 13.7 The Client grants SATRA, its agents and employees an irrevocable licence at any time to enter any premises where the Goods are or may be stored in order to inspect them, or where the Client's right to possession has terminated, to recover them.
- 13.8 On termination of this Contract, however 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 applied to the Client. If its use is impossible without infringement of Letters Patent, Registered Design, Trade Mark or Copyright published at the date of the contract, SATRA will refund to the Client the purchase price of the said article or material provided that it is returned to SATRA free of charge. The Client warrants that any design or instruction furnished or given by the Client shall not be such as will cause SATRA to infringe any Letters Patent, Registered Design, Trade Mark or Copyright in the execution of the Client's order.
15. **WARRANTY OF GOODS**
- 15.1 SATRA warrants that on delivery and for a period of 12 months from the date of delivery or within the shelf life of the Goods (whichever is the shorter period) the Goods shall be free from defects in design, material and workmanship.
16. **DEFECTIVE GOODS**
- 16.1 Subject to clauses 16.6 and 16.7 if:
- a) the Client gives notice in writing to SATRA in accordance with clause 16.3 and during the period referred to in clause 15.1 that the Goods do not comply with the warranty in that clause; and
  - b) SATRA is given a reasonable opportunity of examining such Goods; and
  - c) the Client if asked to do so by SATRA returns such Goods to SATRA's place of business then SATRA will, at its option, repair or replace the defective Goods or refund the price of the defective Goods in full. SATRA reserves the right to repair the Goods at the Client's premises.
- 16.2 The Client must inspect all Goods upon delivery. Failure to do so may result in further charges being applied in the event of a return.
- 16.3 If Goods are found to be faulty, defective or damaged the Client must inform SATRA in writing as soon as reasonably possible and in any event within 10 working days of the fault, damage or defect being discovered.
- 16.4 Without prejudice to clause 16.1 if no notice of rejection has been received by SATRA within 3 months of delivery, the Client shall be deemed to have accepted the Goods.
- 16.5 SATRA will pay the reasonable costs of carriage, packaging and insurance for any defective Goods which are returned by the Client provided that SATRA is liable under clause 16.1 to repair or replace the defective Goods. If SATRA determines that the Goods are not defective or if SATRA is not liable to repair or replace the Goods due to the circumstances under clauses 16.6 or 16.7 then the Client will be responsible for the payment of such costs.
- 16.6 SATRA shall not be under any liability to repair or at its option replace or pay for the repair or replacement of any Goods which are found to be defective if:
- a) the defect is caused or substantially caused by wear and tear, overloading, misuse, neglect, modification or attempted modification carried out by any organisation other than by SATRA or their approved agents, or use with auxiliary equipment not approved in writing by SATRA, or default in proper maintenance or cleaning; or
  - b) the Client authorises or carries out any repair or replacement of any Goods without first affording SATRA a reasonable opportunity to replace or repair them; or
  - c) the Client has breached any of the terms of the Contract under which the Goods were supplied; or
  - d) the Goods have been manufactured to a design or specification or in compliance with other information provided by the Client and the defect has arisen as a result of that design, specification or information.
- 16.7 Where Goods or parts of Goods are not manufactured by SATRA then SATRA shall be liable for defects only to the extent that SATRA obtains redress from the manufacturer or supplier thereof provided that:
- a) SATRA shall not be obliged to take any step to attempt to obtain such redress except at the request and expense of the Client and upon provision by the Client of a full indemnity as to costs for which SATRA may thereby become liable;
  - b) nothing in this condition 16.7 shall have effect as to impose upon SATRA any additional liability or obligations other than those referred to in condition 16.1.
- 16.8 Except as provided in clause 16.1 SATRA shall have no liability to the Client (arising from any failure of the Goods to comply with the warranty in clause 15.1).

Customer details: Qube Medical Products Sdn. Bhd.  
No. 9 & 10, Jalan KPK 1/3  
Kawasan Perindustrian Kundang  
Kundang Jaya, Rawang  
Selangor Darul Ehsan  
Malaysia

SATRA reference: CHM0298827/2023/EN  
/B

Your reference: NSPO-20/07/0053

Date of report: 11<sup>th</sup> August 2020

Samples received: 21<sup>st</sup> July 2020

Date(s) work carried out: 27<sup>th</sup> to 29<sup>th</sup> July 2020

## TECHNICAL REPORT

Subject: EN ISO 374-4:2019 determination of resistance to degradation by dangerous chemicals on gloves described as Powder Free Nitrile Examination Gloves - Blue. Lot number 0231611B1.

### 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 a coverage probability of approximately 95%.

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

(Page 1 of 6)



**WORK REQUESTED:**

Samples of gloves described as Powder Free Nitrile Examination Gloves - Blue. Lot number 0231611B1 were received on the 21<sup>st</sup> July 2020 for testing in accordance with EN ISO 374-4:2019.

**SAMPLE SUBMITTED:**



Samples described as Powder Free Nitrile Examination Gloves - Blue. Lot number 0231611B1

**CONCLUSION:**

When assessed in accordance with EN ISO 374-4:2019 the samples of gloves described as Powder Free Nitrile Examination Gloves - Blue. Lot number 0231611B1 achieved the following degradation results:

Chemical	Mean degradation / %
Methanol (CAS: 67-56-1)	67.8
40% Sodium hydroxide (CAS: 1310-73-2)	23.9
96% Sulphuric acid (CAS: 7664-93-9)	100.0
99% Acetic acid (CAS: 64-19-7)	95.4
37% Formaldehyde (CAS: 50-00-0)	33.9
30% Hydrogen peroxide (CAS: 7722-84-1)	34.6

**TESTING REQUIRED:**

- EN ISO 374-4:2019. Protective gloves against dangerous chemicals and micro-organisms. Part 4: Determination of resistance to degradation by chemicals.

**RESULTS:**

<b>Sample description:</b>	Powder Free Nitrile Examination Gloves – Blue Lot number 0231611B1		
<b>Challenge chemical:</b>	Methanol (CAS: 67-56-1)		
<b>Test temperature / °C:</b>	(23 ± 1)		
<b>Degradation / %:</b>	<b>Glove 1</b>	<b>Glove 2</b>	<b>Glove 3</b>
	65.0	68.4	69.8
<b>Mean degradation (DR) / %:</b>	67.8		
<b>Standard deviation (<math>\sigma_{DR}</math>) / %:</b>	2.5		
<b>UoM / ± %:</b>	14.2		
<b>Appearance of samples after testing:</b>	No change		

<b>Sample description:</b>	Powder Free Nitrile Examination Gloves – Blue Lot number 0231611B1		
<b>Challenge chemical:</b>	40% Sodium hydroxide (CAS: 1310-73-2)		
<b>Test temperature / °C:</b>	(23 ± 1)		
<b>Degradation / %:</b>	<b>Glove 1</b>	<b>Glove 2</b>	<b>Glove 3</b>
	30.2	30.3	11.3
<b>Mean degradation (DR) / %:</b>	23.9		
<b>Standard deviation (<math>\sigma_{DR}</math>) / %:</b>	11.0		
<b>UoM / ± %:</b>	8.0		
<b>Appearance of samples after testing:</b>	No change		

<b>Sample description:</b>	Powder Free Nitrile Examination Gloves – Blue Lot number 0231611B1		
<b>Challenge chemical:</b>	96% Sulphuric acid (CAS: 7664-93-9)		
<b>Test temperature / °C:</b>	(23 ± 1)		
<b>Degradation / %:</b>	<b>Glove 1</b>	<b>Glove 2</b>	<b>Glove 3</b>
	100.0	100.0	100.0
<b>Mean degradation (DR) / %:</b>	100.0		
<b>Standard deviation (<math>\sigma_{DR}</math>) / %:</b>	N/A		
<b>UoM / ± %:</b>	<5		
<b>Appearance of samples after testing:</b>	Brittle, disintegrated and discoloured		

<b>Sample description:</b>	Powder Free Nitrile Examination Gloves – Blue Lot number 0231611B1		
<b>Challenge chemical:</b>	99% Acetic acid (CAS: 64-19-7)		
<b>Test temperature / °C:</b>	(23 ± 1)		
<b>Degradation / %:</b>	<b>Glove 1</b>	<b>Glove 2</b>	<b>Glove 3</b>
	94.9	96.7	94.5
<b>Mean degradation (DR) / %:</b>	95.4		
<b>Standard deviation (<math>\sigma_{DR}</math>) / %:</b>	1.2		
<b>UoM / ± %:</b>	91.1		
<b>Appearance of samples after testing:</b>	Swollen		

<b>Sample description:</b>	Powder Free Nitrile Examination Gloves – Blue Lot number 0231611B1		
<b>Challenge chemical:</b>	37% Formaldehyde (CAS: 50-00-0)		
<b>Test temperature / °C:</b>	(23 ± 1)		
<b>Degradation / %:</b>	<b>Glove 1</b>	<b>Glove 2</b>	<b>Glove 3</b>
	35.1	40.0	26.5
<b>Mean degradation (DR) / %:</b>	33.9		
<b>Standard deviation (<math>\sigma_{DR}</math>) / %:</b>	6.9		
<b>UoM / ± %:</b>	8.6		
<b>Appearance of samples after testing:</b>	No change		

<b>Sample description:</b>	Powder Free Nitrile Examination Gloves – Blue Lot number 0231611B1		
<b>Challenge chemical:</b>	30% Hydrogen peroxide (CAS: 7722-84-1)		
<b>Test temperature / °C:</b>	(23 ± 1)		
<b>Degradation / %:</b>	<b>Glove 1</b>	<b>Glove 2</b>	<b>Glove 3</b>
	25.4	44.3	34.1
<b>Mean degradation (DR) / %:</b>	34.6		
<b>Standard deviation (<math>\sigma_{DR}</math>) / %:</b>	9.5		
<b>UoM / ± %:</b>	8.7		
<b>Appearance of samples after testing:</b>	No change		



## 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 obliged to provide instructions or information relating to the Goods or Services required or in 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 not 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 according to 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 directed 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 enforcement 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 the 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 property 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 licensor. With respect to the sale of SATRA Training, SATRASUJAM and SATRA Visionsoft, provided that the Client is a member of SATRA and has paid its annual Subscription 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 other 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 Subscription fee. Major upgrades are not included within the entitlement to upgrades but may be offered by SATRA from time to time for an additional fee.
- 3.6 SATRA shall observe all statutory provisions with regard to data protection including but not limited to the provisions of the Data Protection Act 2018 and the EU General Data Protection Regulation (GDPR) Regulation (EU) 2016/679. To the extent that SATRA processes or gets access to personal data in connection with the Services or otherwise in connection with this Contract, it shall take all reasonable technical and organisational measures to ensure the security of such data (and guard against unauthorised or unlawful processing, accidental loss, destruction or damage to such data).

### 4. SUSPENSION OR TERMINATION OF SERVICES

- 4.1 Cancellation by the Client of orders for Goods or Services will only be acceptable by prior agreement with SATRA and a charge will usually be made.
- 4.2 SATRA shall not be liable for any delay or failure in providing the Goods or Services due to circumstances beyond its reasonable control (including any failure by the Client to comply with its obligations). If any such circumstances arise which prevent SATRA from delivering the Goods or completing the Services, then SATRA will be entitled to cancel or reschedule the delivery of Goods or Services at its discretion. In the event of cancellation SATRA will be entitled to retain all fees paid by the Client for Goods or Services already supplied but will refund to the Client any fees paid by the Client for Goods or Services which have not yet been supplied. The Client will not be liable for any non-recoverable 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 deassemble, 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 mediator 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 Arbitrator shall be governed by both the Arbitration Act 1996 and the Confidential Cost Rules of the

Qube Medical Products Sdn. Bhd.

SATRA Reference: CHM0298827/2023/EN/B

Date: 11<sup>th</sup> August 2020

(Page 5 of 6)

Signed:



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

- Children's 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.
- 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 Client's 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 full reports of 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 special 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 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 commitment 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, licences 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 made of transport which is agreed by SATRA and the Client.
- 13.2 The Company shall not accept responsibility for loss or damage in transit unless:
- a) in the case of sales where delivery of Goods is made in the United Kingdom SATRA is notified by the Client within 10 days of the invoice date of non-arrival of Goods and within 3 days of the invoice date of receipt of Goods damaged in transit; or
- b) in all other cases the Client notifies SATRA of the non-arrival or damage in transit within a reasonable period of time as determined by SATRA.
- 13.3 Title to the Goods shall not pass to the Client until the earlier of when:
- a) SATRA receives payment in full (in cash or cleared funds) for the Goods and any other Goods that SATRA has supplied to the Client in which case title to the Goods shall pass at the time of payment of all such sums; and
- b) the Client resells the Goods in accordance with clause 13.5 in which case title shall pass to the Client immediately before the time at which the resale by the Client occurs.
- 13.4 Until ownership of Goods has passed to the Client, the Client shall:
- a) hold the Goods as SATRA's bailee;
- b) store the Goods (at no cost to SATRA) separately from all other goods belonging to the Client or any third party in such a way that they remain readily identifiable as SATRA's property (including where the Goods have been sold to a 3rd party);
- c) not destroy, deface or obscure any identifying mark or packaging on or relating to the Goods; and
- d) maintain the Goods in satisfactory condition and keep them insured on SATRA's behalf for their full price against all risks to the reasonable satisfaction of SATRA. The Client shall obtain an endorsement of SATRA's interest in the goods on its insurance policy. On request the Client shall allow SATRA to inspect such Goods and shall produce the policy of insurance.
- 13.5 The Client may resell the Goods before ownership has passed to it solely on condition that sale shall be effected in the ordinary course of the Client's business at full market value.
- 13.6 If before title to the Goods passes to the Client, the Client becomes subject to any of the events referred to in clause 2.6 then without limiting any other right or remedy SATRA may have:
- a) the Client's right to resell the Goods or use them in the ordinary course of its business ceases immediately; and
- b) SATRA may at any time require the Client to deliver up all Goods in its possession that have not been resold or irrevocably incorporated into another product; and
- c) if the Client fails to do so promptly SATRA may exercise its rights under clause 13.7.
- 13.7 The Client grants SATRA, its agents and employees an irrevocable licence at any time to enter any premises where the Goods are or may be stored in order to inspect them, or, where the Client's right to possession has terminated, to recover them.
- 13.8 On termination of the Contract, however caused, SATRA's (but not the Client's) rights contained in this clause 13 shall remain in effect.
14. **PATENTS**
- 14.1 SATRA gives no indemnity against any claim of infringement of Letters Patent, Registered Design, Trade Mark or Copyright by the use of or sale of any article or material supplied to the Client. If its use is impossible without infringement of Letters Patent, Registered Design, Trade Mark or Copyright published at the date of the contract, SATRA will refund to the Client the purchase price of the said article or material provided that it is returned to SATRA free of charge. The Client warrants that any design or instruction furnished or given by the Client shall not be such as will cause SATRA to infringe any Letters Patent, Registered Design, Trade Mark or Copyright in the execution of the Client's order.
15. **WARRANTY OF GOODS**
- 15.1 SATRA warrants that on delivery and for a period of 12 months from the date of delivery or within the shelf life of the Goods (whichever is the shorter period) the Goods shall be free from defects in design, material and workmanship.
16. **DEFECTIVE GOODS**
- 16.1 Subject to clauses 16.6 and 16.7 if:
- a) the Client gives notice in writing to SATRA in accordance with clause 16.3 and during the period referred to in clause 15.1 that the Goods do not comply with the warranty in that clause; and
- b) SATRA is given a reasonable opportunity of examining such Goods; and
- c) the Client if asked to do so by SATRA returns such Goods to SATRA's place of business then SATRA will, at its option, repair or replace the defective Goods or refund the price of the defective Goods in full. SATRA reserves the right to repair the Goods at the Client's premises.
- 16.2 The Client must inspect all Goods upon delivery. Failure to do so may result in further charges being applied in the event of a return.
- 16.3 If Goods are found to be faulty, defective or damaged the Client must inform SATRA in writing as soon as reasonably possible and in any event within 10 working days of the fault, damage or defect being discovered.
- 16.4 Without prejudice to clause 16.1 if no notice of rejection has been received by SATRA within 3 months of delivery, the Client shall be deemed to have accepted the Goods.
- 16.5 SATRA will pay the reasonable costs of carriage, packaging and insurance for any defective Goods which are returned by the Client provided that SATRA is liable under clause 16.1 to repair or replace the defective Goods. If SATRA determines that the Goods are not defective or if SATRA is not liable to repair or replace the Goods due to the circumstances under clauses 16.6 or 16.7 then the Client will be responsible for the payment of such costs.
- 16.6 SATRA shall not be under any liability to repair or at its option replace or pay for the repair or replacement of any Goods which are found to be defective if:
- a) the defect is caused or substantially caused by wear and tear, overloading, misuse, neglect, modification or attempted modification carried out by any organisation other than by SATRA or their appointed agents, or use with auxiliary equipment not approved in writing by SATRA, or default in proper maintenance or cleaning; or
- b) the Client authorises or carries out any repair or replacement of any Goods without first affording SATRA a reasonable opportunity to repair or replace them; or
- c) the Client has breached any of the terms of the Contract under which the Goods were supplied; or
- d) the Goods have been manufactured to a design or specification or in compliance with other information provided by the Client and the defect has arisen as a result of that design, specification or information.
- 16.7 Where Goods or parts of Goods are not manufactured by SATRA then SATRA shall be liable for defects only to the extent that SATRA obtains address from the manufacturer or supplier thereof provided that:
- a) SATRA shall not be obliged to take any step to attempt to obtain such address except at the request and expense of the Client and upon provision by the Client of a bill indorsed as to costs by which SATRA may thereby become liable;
- b) nothing in this condition 16.7 shall have effect as to impose upon SATRA any additional liability or obligations other than those referred to in condition 16.1.
- 16.8 Except as provided in clause 16.1 SATRA shall have no liability to the Client arising from any failure of the Goods to comply with the warranty in clause 15.1.



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No. 9 & 10, Jalan KPK 1/3  
Kawasan Perindustrian Kundang  
Kundang Jaya, Rawang  
Selangor Darul Ehsan  
Malaysia

SATRA reference: CHM0298827/2023/EN  
/C

Your reference: NSPO-20/07/0053

Date of report: 11<sup>th</sup> August 2020

Samples received: 21<sup>st</sup> July 2020

Date(s) work carried out: 4<sup>th</sup> to 7<sup>th</sup> August 2020

## TECHNICAL REPORT

Subject: Testing in accordance with ISO 16604:2004 to meet the requirements of EN ISO 374-5:2016 for resistance to penetration by blood-borne pathogens on gloves described as Powder Free Nitrile Examination Gloves - Blue. Lot number 0231611B1.

### 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.

**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.**

Please note uncertainty of measurement has not been applied to the results in this report. SATRA uncertainty of measurement values are available on request.

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

(Page 1 of 5)

**WORK REQUESTED:**

Samples of gloves described as Powder Free Nitrile Examination Gloves - Blue. Lot number 0231611B1 were received on the 21<sup>st</sup> July 2020 for testing in accordance with ISO 16604:2004 to meet the requirements of EN ISO 374-5:2016 for resistance to penetration by blood-borne pathogens-test method using Phi-X174 bacteriophage. Testing was completed at an external laboratory and reported under their reference 20RA08881.

**SAMPLE SUBMITTED**

Samples described as Powder Free Nitrile Examination Gloves - Blue. Lot number 0231611B1

**TESTING REQUIRED:**

- ISO 16604:2004 for resistance to penetration by blood-borne pathogens-test method using Phi-X174 bacteriophage

**RESULTS:**

The positive control sample showed the bacteriophages passed through a microporous film whilst the negative control samples showed no passage through the polyethylene film.

Test specimen	Result	Pass/Fail
1	No penetration	Pass
2	No penetration	Pass
3	No penetration	Pass

**APPENDICES:**

Resistance to penetration by blood-borne pathogens-Test method using Phi-X174 bacteriophage

Standard used	ISO 16604 (2004)
Product standard	EN ISO 374-5 (2016)
Dimension of the test specimens	75mm x 75mm
Number of test specimens	3
Test procedure used	Procedure B
Used bacteriophage	<i>Bacteriophage Phi-X174 (ATCC 13706-B1 LOT CNCM 14812)</i>
Penetration survey method	Plaque-forming units (PFU)
Pre-test bacteriophage titre	4.1x10 <sup>8</sup> PFU/ml
Post-test bacteriophage titre	4.0x10 <sup>8</sup> PFU/ml

## 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 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 proprietary 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 Terevite, SATRASUMM and SATRA Visionmatch, provided that the Client is a member of SATRA and has paid its annual Sintercare 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 other 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 Sintercare fee. Major upgrades are not included within the entitlement to upgrades but may be offered by SATRA from time to time for an additional fee.
- 3.6 SATRA shall observe all statutory provisions with regard to data protection including but not limited to the provisions of the Data Protection Act 2018 and the EU General Data Protection Regulation (GDPR) Regulation (EU) 2016/679. To the extent that SATRA processes or gets access to personal data in connection with the Services or otherwise in connection with this Contract, it shall take all reasonable technical and organisational measures to ensure the security of such data (and guard against unauthorised or unlawful processing, accidental loss, destruction or damage to such data).

### 4. SUSPENSION OR TERMINATION OF SERVICES

- 4.1 Cancellation by the Client of orders for Goods or Services will only be acceptable by prior agreement with SATRA and a charge will usually be made.
- 4.2 SATRA shall not be liable for any delay or failure in providing the Goods or Services due to circumstances beyond its reasonable control (including any failure by the Client to comply with its obligations). If any such circumstances arise which prevent SATRA from delivering the Goods or completing the Services, then SATRA will be entitled to cancel or reschedule the delivery of Goods or Services at its discretion. In the event of cancellation SATRA will be entitled to retain all fees paid by the Client for Goods or Services already supplied but will refund to the Client any fees paid by the Client for Goods or Services which have not yet been supplied. The Client will not be liable for any non-reimbursable 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 on it. 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-reimbursable 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.
- 5.2 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, fraud or fraudulent misrepresentation;
  - (b) breach of the terms implied by Section 12 of the Sale of Goods Act 1979;
  - (c) defective products under the Consumer Protection Act 1987; or
  - (d) 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 of 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 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 those 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 Chartered Institute of Arbitrators (CIAA) Rules of the Chartered Institute of Arbitrators (2010 Edition), or any amendments thereto, 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 Client's 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 state 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 4 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 (undamaged 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 rescinds 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 notified at the date of this 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.

**QUBE MEDICAL PRODUCTS SDN. BHD.  
NO 9 & 10, JALAN KPK 1/3, KAWASAN PERINDUSTRIAN KUNDANG  
48020 KUNDANG JAYA, SELANGOR**

The following sample(s) was/were submitted and identified by the applicant as:

**Powder Free Nitrile Examination Gloves**

Job Ref No. : 2021-07-01-012  
Date of Sample Received : 01<sup>st</sup> July 2021  
Testing Period : 01<sup>st</sup> July 2021 - 12<sup>th</sup> July 2021

Test Requested : Please refer to the results summary

Test Method & Results : Please refer to next page(s).

Result Summary :

Test Requested	Conclusion
Council of Europe Resolution AP (2004) 4	--
Rubber – Overall Migration	PASS

SIGNED FOR AND ON BEHALF OF  
SGS (MALAYSIA) SDN BHD



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

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Test Results:

Testing as per Council of Europe Resolution AP (2004) 4

Rubber – Overall Migration

Method: With reference to Commission Regulation (EU) No 10/2011 of 14 January 2011 Annex III and Annex V for selection of condition and EN 1186-1:2002 for selection of test methods (1<sup>st</sup> Migration); EN 1186-9:2002 aqueous food simulants by article filling method.

Simulant Used	Test Condition	Result (mg/dm <sup>2</sup> )	Reporting Limit (mg/dm <sup>2</sup> )	Permissible Limit (mg/dm <sup>2</sup> )
D.I Water	10 minutes at 40°C	N.D.	3.0	10
3% Acetic Acid (W/V) Aqueous Solution	10 minutes at 40°C	10.1	3.0	10
10% Ethanol (V/V) Aqueous Solution	10 minutes at 40°C	N.D.	3.0	10
20% Ethanol (V/V) Aqueous Solution	10 minutes at 40°C	N.D.	3.0	10
50% Ethanol (V/V) Aqueous Solution	10 minutes at 40°C	N.D.	3.0	10
<b>Comment</b>	—	<b>PASS</b>	—	—

Sample Description : Powder Free Nitrile Examination Gloves

- Note :
1. mg/dm<sup>2</sup> = milligram per square decimeter
  2. °C = degree Celsius
  3. N.D. = Not Detected
  4. Permissible Limit is according to Council of Europe Resolution AP (2004) 4.

Remark:

1. Analytical tolerance of aqueous simulants is 2mg/dm<sup>2</sup> or 12mg/kg
2. Analytical tolerance of fatty food simulants is 3mg/dm<sup>2</sup> or 20mg/kg
3. Test condition & simulant were specified by client.

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Sample Photo:



SGS authenticate the photo on the original report only

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

SIGNED FOR AND ON BEHALF OF  
SGS (MALAYSIA) SDN BHD

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SECTION HEAD  
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**QUBE MEDICAL PRODUCTS SDN. BHD.**  
**NO 9 & 10, JALAN KPK 1/3, KAWASAN PERINDUSTRIAN KUNDANG**  
**48020 KUNDANG JAYA, SELANGOR**

The following sample(s) was/were submitted and identified by the applicant as:

**Powder Free Nitrile Examination Gloves**

Job Ref No. : 2021-07-01-012  
Date of Sample Received : 01<sup>st</sup> July 2021  
Testing Period : 01<sup>st</sup> July 2021 - 12<sup>th</sup> July 2021

Test Requested : Please refer to the results summary

Test Method & Results : Please refer to next page(s).

Result Summary :

Test Requested	Conclusion
Council of Europe Resolution AP (2004) 4	--
Rubber – Overall Migration	PASS

SIGNED FOR AND ON BEHALF OF  
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Test Results:

**Testing as per Council of Europe Resolution AP (2004) 4**

Rubber – Overall Migration

Method: With reference to Commission Regulation (EU) No 10/2011 of 14 January 2011 Annex III and Annex V for selection of condition and EN 1186-1:2002 for selection of test methods (1<sup>st</sup> Migration);  
 EN 1186-9:2002 aqueous food simulants by article filling method;  
 EN 1186-14:2002 substitute test.

Simulant Used	Test Condition	Result (mg/dm <sup>2</sup> )	Reporting Limit (mg/dm <sup>2</sup> )	Permissible Limit (mg/dm <sup>2</sup> )
Fatty food substitute				
Iso-octane	10 minutes at 20°C	N.D.	3.0	10
<b>Comment</b>	--	<b>PASS</b>	--	--

Sample Description : **Powder Free Nitrile Examination Gloves**

- Note :
1. mg/dm<sup>2</sup> = milligram per square decimeter
  2. °C = degree Celsius
  3. N.D. = Not Detected
  4. Permissible Limit is according to Council of Europe Resolution AP (2004) 4.

Remark:

1. Analytical tolerance of aqueous simulants is 2mg/dm<sup>2</sup> or 12mg/kg
2. Analytical tolerance of fatty food simulants is 3mg/dm<sup>2</sup> or 20mg/kg
3. Test condition & simulant were specified by client.

SIGNED FOR AND ON BEHALF OF  
 SGS (MALAYSIA) SDN BHD



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

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Sample Photo:



SGS authenticate the photo on the original report only

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

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SGS (MALAYSIA) SDN BHD

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

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# TEST REPORT: 7191239507-CHM20-01-RC

Date: 30 JUN 2020

Tel: +65 68851345 Fax: +65 67732912

Client's Ref:

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

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## SUBJECT

Bacteriophage Penetration Test

## CLIENT

Qube Medical Products Sdn Bhd  
No. 9 & 10, Jalan KPK 1/3  
Kawasan Perindustrian Kundang,  
48020 Kundang Jaya, Selangor

Attn: Mr. Davendran

## SAMPLE SUBMISSION DATE / TEST DATE

29 May 2020 / 08 Jun 2020

## DESCRIPTION OF SAMPLE

One sample of gloves was received, labelled as below.

Product Description
Powder Free Nitrile Gloves Finger Texture Single Chlorinated, Blue

## 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 – Retaining screen : Metal square mesh

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

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E-mail: enquiries@tuv-sud-psb.sg  
www.tuv-sud-psb.sg  
Co. Reg : 199002667R

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



**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
Compatibility ratio	1.13

Test Specimens

Product Description : Powder Free Nitrile Gloves  
Finger Texture Single Chlorinated, Blue

Test Specimens (Triplicates)	Starting Bacteriophage challenge Titer (PFU/ml)	Ending Bacteriophage challenge Titer (PFU/ml)	Detection of Phi-X174 Bacteriophage in assay fluid from the surface of sample (PFU/ml)	Pass / Fail
#1	140 000 000	130 000 000	Less than 1	Pass
#2		140 000 000	Less than 1	Pass
#3		130 000 000	Less than 1	Pass

Notes:

PFU : Plaque Forming Unit

Remarks :

The above test results relate to the samples as received.

**MS GERMAINE KHONG**  
TECHNICAL EXECUTIVE

**MR RANDY CHIN KOK FEI**  
PRODUCT MANAGER  
MICROBIOLOGY  
CHEMICAL & MATERIALS

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July 2011





July 7, 2020

## •TEST REPORT•

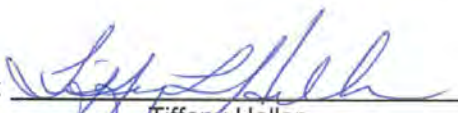
**PN 154589**

### PHARMACEUTICAL SERVICES


Prepared For:

Nur Hamizah Auni Zainal  
Qube Medical Products SDN BHD  
No 9 & 10 Jalaan KPK 1/3 Kawasan Perindustrian Kundang  
Kundang Jaya, Selangor 48020  
Malaysia

Prepared By:

  
Tiffany Heller  
Manager, Pharmaceutical Services

Approved By:

  
Ana C Barbur, M.S.  
Vice President, Analytical & Chemical Services

Rev 101218



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July 7, 2020

Nur Hamizah Auni Zainal  
Qube Medical Products SDN BHD

Page 2 of 4  
PN 154589

**SUBJECT:** Permeation testing per ASTM D6978 on sample submitted by the above company.

**RECEIVED:** One (1) glove identified as; 9" Powder-Free Nitrile Examination Gloves, Finger Textured, Blue, Lot No. 0231611B1, Size Medium.

**TEST CHEMICALS:**

Table 1. List of the Testing Drugs and their Sources

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	Sigma Aldrich; Lot# 059M4075V; Expiration 04/2021
Cisplatin, 1.0 mg/ml (1,000 ppm)	Accord; Lot# P2001296; Expiration 01/2022
Cyclophosphamide (Cytosan), 20.0 mg/ml (20,000 ppm)	Accord; Lot# 19112225; Expiration 10/2021
Dacarbazine, 10.0 mg/ml (10,000 ppm)	Teva; Lot# 31325414B; Expiration 09/2021
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	WestWard; Lot# BJ0051; Expiration 06/2021
Etoposide, 20.0 mg/ml (20,000 ppm)	Teva; Lot# 31325485B; Expiration 07/2021
Fluorouracil, 50.0 mg/ml (50,000 ppm)	Accord; Lot# P2001167; Expiration 01/2022
Methotrexate, 25 mg/ml (25,000 ppm)	Teva; Lot# 19F06NB; Expiration 06/2021
Mitomycin C, 0.5 mg/ml (500 ppm)	Sigma Aldrich; Lot# MKCD6056; Expiration 05/2021
Paclitaxel, 6.0 mg/ml (6,000 ppm)	Hospira; Lot# F066865AA; 08/31/2020
ThioTepa, 10.0 mg/ml (10,000 ppm)	USP; Lot # R11380; Expiration 04/2021
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	USP; Lot# Y06331; Expiration 05/2021

**COLLECTION MEDIA:**

Table 2. Collection Media for Test Drug

TEST DRUG AND CONCENTRATION	COLLECTION MEDIUM
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	10% Ethanol Aqueous Solution
Cisplatin, 1.0 mg/ml (1,000 ppm)	Distilled Water
Cyclophosphamide (Cytosan), 20.0 mg/ml (20,000 ppm)	Distilled Water
Dacarbazine, 10.0 mg/ml (10,000 ppm)	Distilled Water
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	Distilled Water
Etoposide, 20.0 mg/ml (20,000 ppm)	Distilled Water
Fluorouracil, 50.0 mg/ml (50,000 ppm)	9.20 pH Sodium Hydroxide Solution
Methotrexate, 25 mg/ml (25,000 ppm)	Distilled Water
Mitomycin C, 0.5 mg/ml (500 ppm)	Distilled Water
Paclitaxel, 6.0 mg/ml (6,000 ppm)	30% Methanol Aqueous Solution
ThioTepa, 10.0 mg/ml (10,000 ppm)	Distilled Water
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	Distilled Water

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NOTE: Non-ISO 17025 accredited test methods are designated with the ^ symbol to differentiate from ISO 17025 accredited methods in the body of the test report.\*

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July 7, 2020

Nur Hamizah Auni Zainal  
Qube Medical Products SDN BHD

Page 3 of 4  
PN 154589

**TESTING CONDITIONS:**

Standard Test Method Used: ASTM D6978  
 Deviation from Standard Test Method: Used 1" Permeation Cell  
 Analytical Method: UV/VIS Spectrometry  
 Testing Temperature: 35.0°C ± 2.0  
 Collection System: Closed Loop  
 Specimen Area Exposed: 5.067 cm<sup>2</sup>  
 Selected Data Points: 25/test  
 Number of Specimens Tested: 3/test  
 Location Sampled From: Cuff

**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 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 DRUG	WAVELENGTH (nm)
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	229
Cisplatin, 1.0 mg/ml (1,000 ppm)	199
Cyclophosphamide (Cytosan), 20.0 mg/ml (20,000 ppm)	200
Dacarbazine, 10.0 mg/ml (10,000 ppm)	320
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	232
Etoposide, 20.0 mg/ml (20,000 ppm)	205
Fluorouracil, 50.0 mg/ml (50,000 ppm)	269
Methotrexate, 25 mg/ml (25,000 ppm)	303
Mitomycin C, 0.5 mg/ml (500 ppm)	217
Paclitaxel, 6.0 mg/ml (6,000 ppm)	232
ThioTepa, 10.0 mg/ml (10,000 ppm)	199
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	220

**SAMPLE CHARACTERISTICS:**

Table 4. Thickness characteristics for the tested: 9" Powder-Free Nitrile Examination Gloves, Finger Textured, Blue, Lot No. 0231611B1, Size Medium.

Testing Drug	Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Carmustine (BCNU)	0.069	0.067	0.068	0.068
Cisplatin	0.069	0.067	0.070	0.069
Cyclophosphamide (Cytosan)	0.070	0.069	0.065	0.068
Dacarbazine	0.068	0.068	0.066	0.067
Doxorubicin	0.067	0.065	0.069	0.067
Etoposide	0.065	0.066	0.069	0.067
Fluorouracil	0.067	0.066	0.067	0.067
Methotrexate	0.067	0.064	0.067	0.066
Mitomycin C	0.069	0.066	0.068	0.068
Paclitaxel	0.067	0.064	0.067	0.066
ThioTepa	0.066	0.069	0.069	0.068
Vincristine Sulfate	0.069	0.068	0.068	0.068
<b>Weight/Unit Area (g/m<sup>2</sup>)</b>	<b>65.6</b>			

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July 7, 2020

Nur Hamizah Auni Zainal  
Qube Medical Products SDN BHD

Page 4 of 4  
PN 154589

**RESULTS:**

Table 5. Permeation Test Results on testing of: 9" Powder-Free Nitrile Examination Gloves, Finger Textured, Blue, Lot No. 0231611B1, Size Medium.

TEST CHEMOTHERAPY DRUGS	AVERAGE BREAKTHROUGH DETECTION TIME (Specimen1/2/3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Specimen1/2/3) ( $\mu\text{g}/\text{cm}^2/\text{minute}$ )	OTHER OBSERVATIONS
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	55.3 (56.7,56.2,55.3)	0.5 (0.5,0.5,0.5)	Moderate swelling and degradation
Cisplatin, 1.0 mg/ml (1,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Cyclophosphamide (Cytosan), 20.0 mg/ml (20,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Dacarbazine, 10.0 mg/ml (10,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Etoposide, 20.0 mg/ml (20,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Fluorouracil, 50.0 mg/ml (50,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Methotrexate, 25 mg/ml (25,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Mitomycin C, 0.5 mg/ml (500 ppm)	>240 min.	N/A	Slight swelling and no degradation
Paclitaxel, 6.0 mg/ml (6,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
ThioTepa, 10.0 mg/ml (10,000 ppm)	49.3 (49.3,69.7,98.4)	0.2 (0.2,0.2,0.2)	Slight swelling and no degradation
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	>240 min.	N/A	Slight swelling and no degradation

Prepared By:



Tiffany Heller  
Manager, Pharmaceutical Services

Approved By:



Ana C Barbur, M.S.  
Vice President, Analytical & Chemical Services

**qube** Qube Medical Products Sdn. Bhd.  
SAMPLE

- Powder Latex  9" Glove
- Powder - Free Latex  12" Glove
- Powder - Free Nitrile  Others: \_\_\_\_\_

Product Code : \_\_\_\_\_  
Description : NITRILE EXAMINATION  
GLOVE, FINGER TEXTURED

Lot No : \_\_\_\_\_  
Quantity : 50 PCS

- Size :  XXS  XS  S  M  L  XL  
Colour :  Natural  White  
 Blue  Others: \_\_\_\_\_

Remarks : \_\_\_\_\_

"NOT FOR COMMERCIAL SALES OR DISTRIBUTION"

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Qube Medical Products Sdn. Bhd.  
No. 9, Jalan KPK 1/3,  
Kawasan Perindustrian Kundang,  
Kundang Jaya,  
Selangor  
48020  
Malaysia

Holds Certificate No:

**FM 600013**

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

The manufacture of non- sterile powder-free and non-sterile powdered latex medical examination gloves, and non-sterile powder-free nitrile medical examination gloves

For and on behalf of BSI:

Michael Lam - Managing Director Assurance, APAC

Original Registration Date: 2014-02-23

Effective Date: 2023-02-23

Latest Revision Date: 2023-02-07

Expiry Date: 2026-02-22



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Certificate No: **FM 600013**

Location	Registered Activities
Qube Medical Products Sdn. Bhd. No 9, Jalan KPK 1/3, Kawasan Perindustrian Kundang, Kundang Jaya, Rawang, Selangor 48020 Malaysia	The manufacture of non-sterile powder-free latex medical examination gloves and non-sterile powder-free nitrile medical examination gloves
Qube Medical Products Sdn. Bhd. No. 10, Jalan KPK 1/1, Kawasan Perindustrian Kundang, Kundang Jaya, Selangor 48020 Malaysia	The manufacture of non-sterile powdered latex medical examination gloves.



Original Registration Date: 2014-02-23

Effective Date: 2023-02-23

Latest Revision Date: 2023-02-07

Expiry Date: 2026-02-22

Page: 2 of 2

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Kawasan Perindustrian Kundang,  
Kundang Jaya,  
Selangor  
48020  
Malaysia

Holds Certificate No:

**MD 600017**

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

The manufacture of non-sterile powder-free and non-sterile powdered latex medical examination gloves, and non-sterile powder-free nitrile medical examination gloves

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2014-03-06

Latest Revision Date: 2023-01-25

Effective Date: 2023-03-06

Expiry Date: 2026-03-05

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Certificate No: **MD 600017**

Location	Registered Activities
Qube Medical Products Sdn. Bhd. No 9, Jalan KPK 1/3, Kawasan Perindustrian Kundang, Kundang Jaya, Rawang, Selangor 48020 Malaysia	The manufacture of non- sterile powder- free latex and non-sterile powder-free nitrile medical examination gloves.
Qube Medical Products Sdn. Bhd. No. 10, Jalan KPK 1/1, Kawasan Perindustrian Kundang, Kundang Jaya, Selangor 48020 Malaysia	The manufacture of non- sterile powdered latex medical examination gloves.

Original Registration Date: 2014-03-06

Latest Revision Date: 2023-01-25

Effective Date: 2023-03-06

Expiry Date: 2026-03-05

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Malaysia Headquarters: Suite 29.01 Level 29, The Gardens North Tower, Mid Valley City, Lingkaran Syed Putra, 59200 Kuala Lumpur.  
Tel: +603 9212 9638 A Member of the BSI Group of Companies.

## Disposable Nitrile Gloves

Non-sterile, Powder-free

These multi-purpose disposable examination gloves are suitable in work environments where there is possible contact with bodily fluids, microorganisms or chemicals. The gloves can also be used for patient examination and treatment to prevent cross-contamination. These gloves are puncture resistant and offer superior performance to oil, grease and many other substances. The beaded cuff offers drip protection for the forearm and increased glove strength when donning. Due to their elasticity the gloves fit well to the contours of the skin and are easy to put on and take off. The textured surface offers optimal grip and a high dexterity. The gloves do not contain natural rubber latex which minimalizes the chance of allergic reactions.

### Beaded cuff

Offers drip protection for the forearm



### Suitable for use in:

healthcare, - wellness, -  
food industry, -  
household

Recommended for use by  
persons with a natural  
latex allergy.

### Textured surface

For optimal grip



### Optimal fit

Easy to put on and take off



# Specifications

## Disposable Nitrile Gloves – Non-sterile, Powder-free

### Features

- 100% Latex-free
- Non-sterile
- Powder-free
- Puncture resistant
- Optimal fit
- Thin and lightweight
- Ambidextrous, for left and right-handed use
- Textured surface for optimal grip
- Available sizes: S, M, L and XL

### Physical Specifications

Color	: Blue
Material Type	: Nitrile
Antimicrobial	: Biostat G8
Cuff-Style	: Beaded
Palm pattern	: Smooth (Finger Textured)
Donning Surface Finishing	: Single Chlorinated
Packaging Type	: Dispenser box
Contents	: 100, 150 or 200 gloves
Country of origin	: Malaysia

### Performance Specifications

Tensile at Break/ Before Aging	: min 14 Mpa
Tensile at Break/ After Aging	: min 14 Mpa
Elongation at Break/ Before Aging	: 500%
Elongation at Break/ After Aging	: 400%

### In compliance with

EN 455-1, -2, -3, -4  
EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN ISO 374-4:2019,  
EN ISO 374-5:2016  
EN 16523-1:2015, EN ISO 21420:2020  
ISO 9001:2015, ISO 13485:2016  
ASTM F1671, ASTM D6978

Resistance against Bacteria and Fungi – PASS

Resistance against Virus – PASS

Chemical Permeation			Level	Mean Degradation
(EN 16523-1:2015+A1:2018)				(EN ISO 374-4:2019)
K	40%	Sodium Hydroxide	6	23.9%
T	37%	Formaldehyde	5	33.9%
P	30%	Hydrogen Peroxide	1	34.6%

### Performance Level

1	2	3	4	5	6
Measured Breakthrough Time (min)					
>10	>30	>60	>120	>240	>480

# Specifications

## Disposable Nitrile Gloves – Non-sterile, Powder-free

Size	XS On request	S	M	L	XL	<b>Variance</b> (mm)
Overall Length (mm)	245	245	245	245	245	+/- 5
Min. Weight (g)	2.30	2.80	3.30	3.80	4.30	
Cuff Thickness (mm)	0.06	0.06	0.06	0.06	0.06	+/- 0.02
Palm Thickness (mm)	0.08	0.08	0.08	0.08	0.08	+/- 0.02
Finger Thickness (mm)	0.10	0.10	0.10	0.10	0.10	+/- 0.02
Cuff Width (mm)	80	84	90	95	97	+/- 5
Palm Width (mm)	75	84	94	105	113	+/- 5
Wrist Width (mm)	73	79	85	92	97	+/- 5
Thumb Length/ Width (mm)	50/ 25	55/ 32	60/ 32	63/ 38	65/ 40	+/- 2
Finger2 Length/ Width (mm)	65/ 23	70/26	75/ 30	75/ 36	77/ 38	+/- 2
Finger3 Length/ Width (mm)	75/ 25	78/ 28	82/ 32	85/ 40	86/ 44	+/- 2
Finger4 Length/ Width (mm)	77/ 24	80/ 26	85/ 30	87/ 34	90/ 36	+/- 2
Finger5 Length/ Width (mm)	50/ 20	55/ 22	58/ 25	63/ 29	65/ 32	+/- 2

# Logistic Data

## Disposable Nitrile Examination Gloves

### Regular Cuff

Size	XS	S	M	L	XL
<b>100-pcs Dispenser Box</b>					
Dimensions Dispenser Box: 22 x 11 x 6.5cm					
<b>Leli Part Number</b>	QUGLOVESXS	QUGLOVESS	QUGLOVESM	QUGLOVESL	QUGLOVESXL
<b>MPN</b>	QUBE-NPF-XS-TP(HK)	QUBE-NPF-XS-TP(HK)	QUBE-NPF-XS-TP(HK)	QUBE-NPF-XS-TP(HK)	QUBE-NPF-XS-TP(HK)
<b>Ref</b>	NBR9PFFTBS1	NBR9PFFTBS2	NBR9PFFTBS3	NBR9PFFTBS4	NBR9PFFTBS5
<b>EAN Box 100pcs</b>	9551012524011	4897088620413	4897088620406	4897088620390	4897088620420
<b>EAN Master Carton</b>	9551012524110	4897088620451	4897088620444	4897088620437	4897088620468
<b>Box/ Master Carton</b>	10	10	10	10	10

<b>150-pcs Dispenser Box</b>					
Dimensions Dispenser Box: 24 x 12.7 x 7.3cm					
<b>Leli Part Number</b>	QUGLOVES150XS	QUGLOVES150S	QUGLOVES150M	QUGLOVES150L	QUGLOVES135XL
<b>Ref</b>	NBR9PFFTBS1	NBR9PFFTBS2	NBR9PFFTBS3	NBR9PFFTBS4	NBR9PFFTBS5
<b>EAN Box 200pcs</b>	9551012524400	9551012524417	9551012524424	9551012524431	9551012524448
<b>EAN Master Carton</b>	9551012524455	9551012524462	9551012524479	9551012524486	9551012524493
<b>Box/ Master Carton</b>	10	10	10	10	10

<b>200-pcs Dispenser Box</b>					
Dimensions Dispenser Box: 24 x 12.7 x 9.5cm					
<b>Leli Part Number</b>	QUGLOVES200XS	QUGLOVES200S	QUGLOVES200M	QUGLOVES200L	QUGLOVES180XL
<b>MPN</b>	QUBE-NPF-XS-DQ(HK)	QUBE-NPF-S-DQ(HK)	QUBE-NPF-M-DQ(HK)	QUBE-NPF-L-DQ(HK)	QUBE-NPF-XL-DQ(HK)
<b>Ref</b>	NBR9PFFTBS1	NBR9PFFTBS2	NBR9PFFTBS3	NBR9PFFTBS4	NBR9PFFTBS5
<b>EAN Box 200pcs</b>	9551012524066	9551012524073	9551012524080	9551012524097	9551012524301
<b>EAN Master Carton</b>	9551012524165	9551012524172	9551012524189	9551012524196	9551012524318
<b>Box/ Master Carton</b>	10	10	10	10	10



# Packaging

## Disposable Nitrile Examination Gloves

### Regular Cuff 100-Box



EN - Nitrile examination gloves, powder-free, non-sterile, single use  
 NL - Nitril-Underszoekhandschoenen, poedervrij, niet-steriel, voor eenmalig gebruik  
 FR - Gants d'examen en nitrile, non poudrés, à usage unique  
 ES - Guantes de examen de nitrilo, sin polvo, no esteriles, de un solo uso  
 IT - Guanti da esame in nitrile, senza polvere, senza sterili, monouso

**Nitrile Examination Gloves**  
 Powder Free - Non Sterile

**Single Use - Ambidextrous**  
 Beaded Cuff - Latex Free

**100x M**

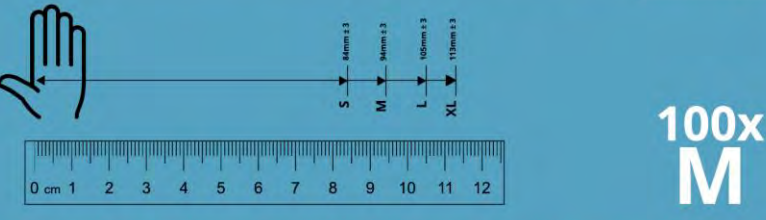


Imported by:  
 Grix B.V.  
 Surweg, 15  
 3720 SC Soest, The Netherlands  
 www.griomedical.com

Manufactured by:  
 Qube Medical Products Sdn Bhd  
 10, Jalan Sultan Ismail, Kawasan Perindustrian Kuningang  
 Kundang Jaya, Rawang  
 41000, Selangor Darul Ehsan  
 Malaysia

Lot No. [ ] [ ] [ ]

EC REP [ ]



**User information:**

- This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals.
- The chemical resistance has been assessed under laboratory conditions from samples taken from the palm only (except in cases where the glove is equal to or over 400mm – where the cuff is tested also) and relates only to the chemical tested. It can be different if the chemical is used in a mixture.
- It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on temperature, abrasion and degradation.
- When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves.
- Before usage, inspect the gloves for any defect or imperfections.

For multi-language instructions, Declaration of Conformity and other relevant information, please visit [www.griomedical.com](http://www.griomedical.com)

**In compliance with:**  
 EN 455-1, -2, -3, -4,  
 EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019,  
 EN ISO 374-4:2019, EN ISO 374-5:2016  
 EN 16523-1:2015, EN ISO 21420:2020  
 ISO 9001:2015, ISO 13485:2016

Resistance against Bacteria and Fungi – PASS  
 Resistance against Virus – PASS

**Storage:** Store in a cool, dry, well ventilated location, out of direct sunlight.  
**Precaution:** In case the usage of gloves causes irritation and/or allergic reactions, please discontinue using the product and seek appropriate medical advice immediately.

Performance Level	
1	2
3	4
5	6
Measured Breakthrough Time (min)	
>10	>60
>120	>240
>480	

Chemical Permeation (EN 16523-1:2015+A1:2018)	Level	Mean Degradation (EN ISO 374-4:2019)
K 40% Sodium Hydroxide	6	23.9%
T 37% Formaldehyde	5	33.9%
P 30% Hydrogen Peroxide	1	34.6%

Degradation levels indicate the change in Puncture Resistance of the glove after exposure to the challenge chemical

Part number: QUBE-NPF-M-TP(HK)

4 897088 620406

REF NBR9PFFTBSC

CE 2797

EU Type Examination Certificate is issued by Notified Body (CE 2777) SATRA Technology Europe Ltd Bicester Business Park, Clonee, O15 Y1Q9, Ireland

EU Type Conformity by Notified Body (CE 2797) BSI, Bay Building, John M. Keynesplein 9 1056 EP Amsterdam, The Netherlands



# Packaging

## Disposable Nitrile Examination Gloves

### Regular Cuff 200-Box

200x  
M/7-8

qube®

Nitrile Examination Gloves  
Powder Free - Non Sterile

Single Use - Ambidextrous  
Beaded Cuff - Latex Free



200x  
M/7-8

200x  
M/7-8

**HU** Nitril kinnigine leక్కరి ఇచ్చిన కుప్పానిలు. కన్నకొర పనిని చేయడానికి మరియు ఉపయోగించడానికి ఉత్తమ పరిష్కారం. ఇది ఒకసారి మాత్రమే ఉపయోగించబడినప్పుడు మాత్రమే ఉపయోగించబడుతుంది. నెలకొన్న వ్యాధి కలుగజేయకుండా అన్ని వ్యాధి సోపానాలకు ముందుగా ముందుగా ఉపయోగించండి. మాత్రమే ఒకసారి ఉపయోగించండి.

**IT** Questo da guaina in nitrile per uso singolo. Non sterile. Si utilizza una sola volta. È il miglior modo di proteggersi in tutti i lavori che richiedono un'azione difensiva. È progettato per essere usato una sola volta e deve essere gettato nel cestino dei rifiuti. Assicurarsi di indossare sempre la guaina prima di toccare qualsiasi oggetto.

**LT** Vienkartis naudojimas bekepus, bekepus, bekepus, bekepus. Nitriliniai kinnigiai, skirti vienam naudojimui. Tinka apsaugoti rankas nuo pavojingų cheminių medžiagų, mikroorganizmų, infekcijos ir kitų pavojų. Nereikalauja sterility. Nėra sterilūs. Nėra sterili.

**LV** Šis nitrilinis kinnigis ir vienreizējais lietošanai. Taisnā veidā ir piemērots aizsargāties pret kaitīgām vielām, mikroorganismiem, infekcijas un citiem apdraudumiem. Kinnigis ir paredzēts vienreizējai lietošanai un jāsliko izmet atkritumos pēc lietošanas. Pirms lietošanas kinnigim jābūt nepārtūvētam, nedrīkst lietot, ja kinnigis ir bojāts.

**NL** Dit is een eenmalig gebruikte nitril handschoen. Het is best gebruikt om u te beschermen tegen schade van giftige stoffen, bacteriën en schimmels. De handschoen is niet steril en kan alleen maar een keer worden gebruikt. Gebruik de handschoen vóór dat u iets aanraakt.

**NO** Dette er engangsbrukt nitril hansker. De brukes til å beskytte mot skadelige kjemiske stoffer, mikroorganismer og infeksjoner. Handskene er ikke sterile og kan kun brukes én gang.

**PL** Nitrilowa rękawiczka jednorazowego użytku. Jest przeznaczona do użytku jednorazowego. Służy do ochrony przed substancjami szkodliwymi, mikroorganizmami, infekcją i innymi zagrożeniami. Rękawiczki nie są sterylne i mogą być użyte tylko raz.

**PT** Luvas de nitrilo de uso único. Não são estéril. São utilizadas para proteção pessoal contra produtos químicos nocivos, microorganismos, infecção e outros perigos. São de uso único e devem ser descartadas após o uso.

**SE** Detta är en nitrilhandske av ett enda bruk. Den är inte steril. Den används för personlig skydd mot skadliga kemiska ämnen, mikroorganismer, infektioner och andra faror. Handskarna är avsett för ett enda bruk och ska kastas i avfall efter användning.

**TR** Bu nitril eldivermecekleri sadece bir kullanim icin tasarlanmistir. Steril degildir. Kimyasal, mikroorganizma, enfeksiyon ve diger tehlikelerden koruma saglamak icin kullanilir. Eldiverler sadece bir kullanim icin tasarlanmistir ve kullanildikten sonra atilmali.

**User information:**

- This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals.
- The chemical resistance has been assessed under laboratory conditions from samples taken from the palm only (except in cases where the glove is equal to or over 400mm – where the cuff is tested also) and relates only to the chemical tested. It can be different if the chemical is used in a mixture.
- It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on temperature, abrasion and degradation.
- When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc., may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves.

For Declaration of Conformity and other relevant information, please visit [www.qubegloves.com](http://www.qubegloves.com)

**In compliance with:**  
EN 455-1, -2, -3, -4  
EN ISO 374-1:2016+1:2018, EN ISO 374-2:2019, EN ISO 374-3:2019, EN ISO 374-4:2019  
EN 16523-1:2015, EN ISO 21420:2020  
ISO 9001:2015, ISO 13485:2016  
ASTM F1671, ASTM D6978

**Performance Level**

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

Chemical Permeation Level (EN 16523-1:2015+A1:2018)	Level	Mean Degradation (%) (EN ISO 374-4:2019)
N 40% Sodium Hydroxide	6	23.9%
T 37% Formaldehyde	5	33.9%
F 30% Hydrogen Peroxide	1	34.6%

Part number: QUBE-NPF-M-DQ(HK)



REF: NB9PFFTBSC  
CE 2797

EU Type Examination Certificate is issued by Nitrifield Body:  
(CE 2797) SAFRA Technology Europe Ltd  
Buckaroo Business Park, Clonsilla, 01573 P209, Ireland  
EU Type Conformity by Nitrifield Body:  
(CE 2797) BSL Say-Balancing, John M. Keynespark 9  
1066 EP Amsterdam, The Netherlands

\*) Degradation levels indicate the change in puncture resistance of the glove after exposure to the challenge substance.

**EN** This nitrile examination glove is a non-sterile, disposable, single-use glove. It is designed for personal protection against chemical, biological, infectious and other hazards. The glove is not intended for use in situations where the user is exposed to high concentrations of chemicals or biological agents. The glove is not intended for use in situations where the user is exposed to high concentrations of biological agents. The glove is not intended for use in situations where the user is exposed to high concentrations of infectious agents. The glove is not intended for use in situations where the user is exposed to high concentrations of other hazards. The glove is not intended for use in situations where the user is exposed to high concentrations of other hazards.

**EN** Diese Nitriluntersuchungshandschuh ist ein nicht-steriles, wegwerfbare, Einmalhandschuh. Er ist für den persönlichen Schutz vor chemischen, biologischen, infektiösen und anderen Gefahren konzipiert. Der Handschuh ist nicht für Situationen geeignet, in denen der Benutzer hohen Konzentrationen von Chemikalien oder biologischen Agenten ausgesetzt ist. Der Handschuh ist nicht für Situationen geeignet, in denen der Benutzer hohen Konzentrationen von biologischen Agenten ausgesetzt ist. Der Handschuh ist nicht für Situationen geeignet, in denen der Benutzer hohen Konzentrationen von infektiösen Agenten ausgesetzt ist. Der Handschuh ist nicht für Situationen geeignet, in denen der Benutzer hohen Konzentrationen von anderen Gefahren ausgesetzt ist. Der Handschuh ist nicht für Situationen geeignet, in denen der Benutzer hohen Konzentrationen von anderen Gefahren ausgesetzt ist.

Imported by: QUBE B.V.  
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E: info@qubegloves.com

Manufactured by:  
Qube Medical Products Sdn. Bhd.  
100, Jalan Sultan, Seremban  
70300 Seremban, Negeri Sembilan,  
Malaysia

200 X M/7-8

Lot No.

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