





NITRILE EXMINATION GLOVES





Gloves act as a protective barrier between the environment and our hands.

- Disposable
- No dust
- Not sterile
- Sizes: S, M, L y XL
- Dual Use Gloves
- Medical device Class I (declaration of conformity)
- EPI Category III (CE 0598)

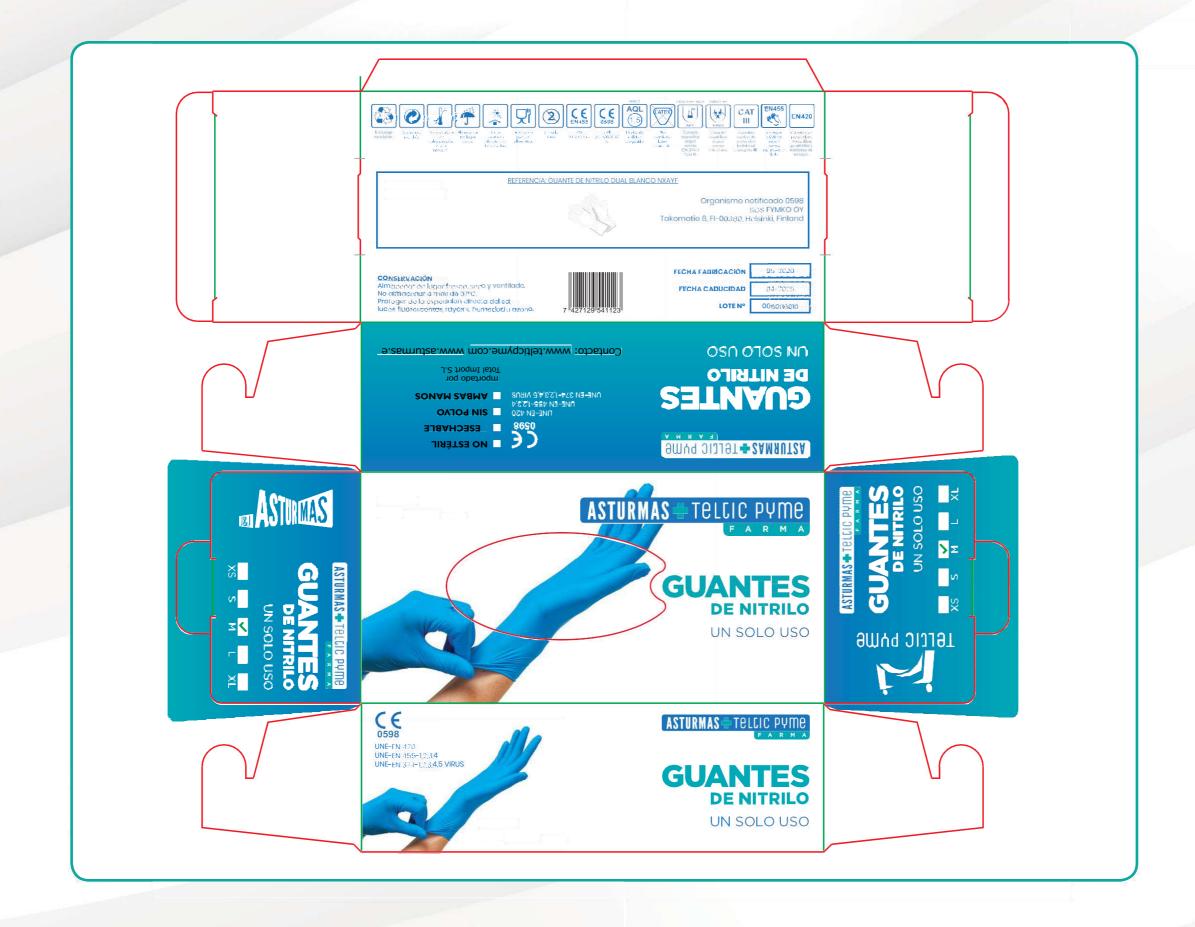




NITRILE GLOVES PACKAGING







NITRILE GLOVES CERTIFICATES

FDA Registration for Asther Import Export and Production SDN BHD

10/28/2020

FDA U.S. Food and Drug Administration

Registration Confirmation

Facility: Asther Import Export and Production SDN BHD, Kuala Lumpu, Selangor, MALAYSIA

 $You\ have\ successfully\ entered\ your\ facility\ registration\ and\ device\ listing\ information.\ You\ should\ print\ a\ copy\ of\ this\ page\ for\ your\ print\ print$ records. Listing numbers appear below for the products manufactured, developed, or processed at this facility.

As a manufacturer, specification developer, or single-use device reprocessor, you are required to pay an annual fee for medical device facility registration.

You will receive another e-mail providing you with your registration number in approximately 30 to 90 days. Until your registration number is assigned, reference your Owner/Operator number in any correspondence with the Center for

Your registration will be valid through Dec 31, 2021. An e-mail will be sent to the Owner/Operator and the Official Correspondent 90 days before the facility is required to re-register for Fiscal Year 2021 with instructions on how and when

Note: Registering your device facility and listing your devices does not, in any way, constitute FDA approval of your facility or your devices.

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The Owner/Operator Number for this Registration is: 10078572

Facility Information	
Initial Importer:	
Facility Name:	
Address:	
Foreign Trade Zone:	

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GARGOLA HEALTHCARE
Hospital supplies and services

'2020 FD	DA Registration for Asther Import Export and Production SDN BHD
Owner/Operator Information	
Owner/Operator Number:	
Contact Name:	
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NITRILE GLOVES CERTIFICATES









FDA Registration for Asther Import Export and Production SDN BHD

Davica	Lictinac
Device	Listings

isting lumber	Premarket Submission Number/Type	Product Code(s)	Device Name(s)	Activities	Importers
D423614	Enforcement Discretion	LZA	Polymer patient examination glove	Manufacturer Specification Developer Contract Manufacturer Repackager/Relabeler Remanufacturer Foreign Exporter Complaint File Establishment Foreign Private Label Distributor	

Date of Initial Registration: Wed Oct 28 09:29:51 EDT 2020

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Test Report No. 7191245904-EEC20-LDY dated 28 Oct 2020

GARGOLA HEALTHCARE
Hospital supplies and services

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

SUBJECT:

Testing of Gloves submitted on 13 Oct 2020.

TESTED FOR:



Add value. Inspire trust.

TEST DATE:

16 Oct 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Brand/ Model	Size	Colour	Lot No.	Expiry date	Sample received (pieces)	Manufacturer
1	Nitrile Examination Powder Free Gloves	ASTHER	М	Blue	A20200008	2023-09	507	Asther Production, Trading, Import and Export Limited Company

METHOD OF TEST:

The tests were conducted in accordance with the following test standards:

BS EN ISO 21420: 2020 Protective gloves - General requirements and test methods

- Clause 4.2c pH value
- Clause 5.1 Sizing and measurement of gloves
- Clause 5.2 Dexterity



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CERTIFICATES

Test Report No. 7191245904-EEC20-LDY dated 28 Oct 2020



RESULTS

Sample: Nitrile Examination Powder Free Gloves, ASTHER, Blue, Lot No. A20200008

Test	BS EN ISO 21420:	2020 Requirements	Results	Inferred Results
I. Determination of pH Value, pH value	> 3.5 ar	nd < 9.5	7.5	Passed
II. Sizing, minimum length of glove (mm)		-	240	(see remark 1)
	Level of performance	Smallest pin diameter fulfilling test conditions (mm)		
III. Dexterity, level of performance	1 2 3 4 5	11 9.5 8 6.5 5	5	(see remark 2)

REMARKS:

- Sizes of gloves are defined with respect to the sizes of the hands they are to fit. If required for specific use (for example, gloves for welders and firefighters), the minimum glove length shall be defined in the relevant specific standards.
- 2. For Dexterity test, a glove should allow as much dexterity as possible given its purpose.



Wong Bee Hui Product Manager Medical Health Services (NAM)

APPENDIX:



Photo: Nitrile Examination Powder Free Gloves, ASTHER, Blue, Lot No. A20200008

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GARGOLA HEALTHCARE

Hospital supplies and services





Test Report No. 7191245904-EEC20-LDY

dated 28 Oct 2020



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Effective 01 September 2020



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Test Report No. 7191245908-EEC20-WBH dated 30 Oct 2020

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Testing of Gloves submitted on 13 Oct 2020.

TESTED FOR:

TEST DATE

13 Oct 2020 to 29 Oct 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Brand/ Model	Size	Colour	Lot No.	Expiry Date	Sample Received (pieces)	Manufacturer
1	Nitrile Examination Powder Free Gloves	ASTHER	М	Blue	A20200008	2023-09	507	Asther Production, Trading, Import and Export Limited Company

Lot size as specified by client: 35,001 to 150,000 pieces

METHOD OF TEST:

- EN 455-1:2020 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
- 3. EN 455-3:2015 Medical glove for single use Part 3: Requirements and testing for biological evaluation



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PSB Singapore

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GARGOLA HEALTHCARE

Hospital supplies and services





Test Report No. 7191245908-EEC20-WBH

dated 30 Oct 2020



RESULTS:

Sample: Nitrile Examination Powder Free Gloves, ASTHER, Blue, Size M, Lot No. A20200008

Table 1: Results for EN 455-1:2020

Clause	Tests	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4 5	Freedom from holes	Shall not leak	7	200	6	Passed

Table 2: Results for EN 455-2:2015 Clauses 4-5

Clause	Tests	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	Dimensions a) Length (mm)	≥ 240	13	241	Passed
4	b) Width (mm)	For Size M: 95 ± 10	13	92	Passed
	Strength a) Force at break (N)	For nitrile examination gloves: ≥ 6.0	13	6.3	Passed
5	b) Force at break after challenge testing (N) 7 days at (70±2)°C	For nitrile examination gloves: ≥ 6.0	13	6.1	Passed

Table 3: Results for EN 455-2:2015 Clause 7

Clause	Tests	Requirements	Results	Inferred results
7	Labelling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2008+A1:2013. Date of manufacture is defined as the packaging date.	Comply	Passed

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CERTIFICATES

Test Report No. 7191245908-EEC20-WBH dated 30 Oct 2020



RESULTS (cont'd):

Sample: Nitrile Examination Powder Free Gloves, ASTHER, Blue, Size M, Lot No. A20200008

Table 4: Results for EN 455-3:2015 Clauses 4.2-4.5

Clause	Tests	Requirements	Results / Remarks	Inferred results
4.2 Chemicals		Gloves shall not be dressed with talcum powder (magnesium silicate).	Glove is talcum powder-free glove, based on client's declaration letter	Passed
4.2	Chemicals	Other chemicals	Manufacturer shall disclose upon request a list of chemical ingredients	NA
4.3 5.1	Endotoxins	< 20 EU/pair for gloves labelled with 'low endotoxin content'.	Not labelled with 'low endotoxin content'	NA
4.4 5.2	Powder- free gloves	For powder-free gloves: The total quantity of powder residues shall not exceed 2 mg per glove.	1.08 mg per glove	Passed
4.5 5.3	Proteins, leachable	The manufacturer shall strive to minimize the leachable protein level for gloves containing natural rubber latex.	Not natural rubber latex glove	NA

Table 5: Results for EN 455-3:2015 Clause 4.6

Clause	Tests	Requirements	Results
		In addition to the labelling specified in EN 1041:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply:	
		 a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1:2012 symbol for latex; 	NA
		The labelling shall include the following or equivalent warning statement together with the symbol: '(Product) contains natural rubber latex which may cause allergic reactions, including anaphylactic responses';	NA
4.6	Labelling	 b) the labelling shall include a prominent indication of whether the glove is powdered or powder-free; 	Comply
	, ,	c) sterile powdered gloves shall be labelled with the following or equivalent: 'CAUTION: Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions';	NA
		d) for any medical glove containing natural rubber latex the product labelling shall not include: - any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein; - any unjustified indication of the presence of allergens;	NA
		 e) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 5.3 shall be given. 	NA
		Inferred results	Passed

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Test Report No. 7191245908-EEC20-WBH dated 30 Oct 2020



- 1. Labelling requirements are assessed based on the submitted packaging by client.
- 2. NA: Not applicable for the submitted sample.



Product Manager Medical Health Services (NAM)

APPENDIX:



Photo 1: Nitrile Examination Powder Free Gloves, ASTHER, Blue, Size M, Lot No. A20200008

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GARGOLA HEALTHCARE

Hospital supplies and services







TEST REPORT: 7191245911-CHM20-03-RC

27 OCT 2020 Date:

Client's Ref:

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

SUBJECT

Bacteriophage Penetration Test

CLIENT



PSB Singapore

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SAMPLE SUBMISSION DATE / TEST DATE

13 Oct 2020 / 22 Oct 2020

DESCRIPTION OF SAMPLE

One sample of gloves was received.

S/N	Product Description	Brand/ Model	Size	Colour	Lot No.	Expiry date	Sample received (pieces)	Manufacturer
1	Nitrile Examination Powder Free Gloves	ASTHER	M	Blue	A20200008	2023-09	507	Asther Production, Trading, Import and Export Limited Company

Lot size as specified by client: 35,001 to 150,000 pieces



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CERTIFICATES

TEST REPORT: 7191245911-CHM20-03-RC

27 OCT 2020



DESCRIPTION OF SAMPLE (cont'd)



Figure 1: Photograph of Nitrile Examination Powder Free Gloves (Lot No.: A20200008)

METHOD OF TEST

ISO 16604 : 2004, "Clothing for protection against contact with blood and body fluids - Determination of resistance of protective clothing materials to penetration by blood-borne pathogens – Test method using Phi-

Time and Pressure Protocols: Procedure B

Retaining Screen: Metal square mesh screen

- Dimensions of 75 mm square were cut from the palm and back area of the gloves for the tests.
- Average thickness of test specimen: 0.03 mm
- Average mass per unit area of test specimen: 69.33 grams per square metre

Tests were performed in triplicates.

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GARGOLA HEALTHCARE

Hospital supplies and services







TEST REPORT: 7191245911-CHM20-03-RC

27 OCT 2020



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	1.34

Test Specimens

Product Name

Nitrile Examination Powder Free Gloves

Lot No.

Test Specimens (Triplicates)	Starting Bacteriophage challenge Titer (PFU/ml)	Ending Bacteriophage challenge Titer (PFU/mI)	Detection of Phi-X174 Bacteriophage in assay fluid from the surface of sample (PFU/mI)	Specification	Pass / Fail
#1		200 000 000	Less than 1		Pass
#2	200 000 000	190 000 000	Less than 1	< 1 PFU/ml	Pass
#3		190 000 000	Less than 1		Pass

PFU: Plaque Forming Unit

Remarks

The above test results relate to the samples as received.

MS GERMAINE KHONG ZHI YU TECHNICAL EXECUTIVE

MR RANDY CHIN KOK FEI PRODUCT MANAGER MICROBIOLOGY CHEMICAL & MATERIALS

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TEST REPORT: 7191245911-CHM20-03-RC

27 OCT 2020



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SUBJECT:

Testing of Gloves submitted on 13 Oct 2020.

TESTED FOR:

TEST DATE:

16 Oct 2020 and 22 Oct 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Brand/ Model	Size	Colour	Lot No.	Expiry date	Sample received (pieces)	Manufacturer
1	Nitrile Examination Powder Free Gloves	ASTHER	М	Blue	A20200008	2023-09	507	Asther Production, Trading, Import and Export Limited Company



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Test Report No. 7191245911-EEC20/02-LDY dated 28 Oct 2020



METHOD OF TEST:

The tests were conducted in accordance with the following test standards:

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

- Clause 5.1 General requirements (Test method described in EN 420:2003+A1:2009 Protective gloves – General requirements and test methods)
- Clause 5.2 Penetration
 (Test method described in EN 374-2:2014 Protective gloves against dangerous chemicals and microorganisms Part 2: Determination of resistance to penetration)
- Clause 5.3 Protection against viruses
 (Test method described in ISO 16604:2004, Clothing for protection against contact with blood and body fluids Determination of resistance of protective clothing materials to penetration by blood-borne Pathogens Test method using Phi-X 174 Bacteriophage, Method B)

RESULTS:

Sample: Nitrile Examination Powder Free Gloves, ASTHER, Blue, Lot No. A20200008

Table 1: Results for tests according to BS EN ISO 374-5:2016 Clause 5.1-5.3

Clause	Tests	Specification	Results	Inferred Result
	General	Protective gloves against dangerous chemicals shall	Refer to Table 2 for results of EN 420, Clause 4 and Clause 5 for applicable tests.	Passed
5.1	Requirement	comply with the requirements given in EN 420:2009, Clause 4, Clause 5 and Clause 7.	The submitted glove and packaging not tested to EN 420 Clause 7 Marking and information as requested by client.	Not tested
5.2	Penetration	Protective gloves shall not leak when tested according to EN 374-2:2014, 7.2 and 7.3. 7.2 Air leak test 7.3 Water leak test	No leakage for both tests	Passed
5.3	Protection against viruses	Shall exhibit no detectable transfer (<1 PFU/ml) of the Phi-X174 bacteriophage in the assay titre	Refer to 7191245911-CHM20-03-RC for detailed results.	Passed

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GARGOLA HEALTHCARE

Hospital supplies and services





Test Report No. 7191245911-EEC20/02-LDY dated 28 Oct 2020



RESULTS (cont'd):

Sample: Nitrile Examination Powder Free Gloves, ASTHER, Blue, Lot No. A20200008

Table 2: Results for EN 420:2003+A1:2009

Test	EN 420:2003+/	Results	Inferred Results	
I. Determination of pH Value, pH value	> 3.	7.5	Passed	
II. Sizing,	Size	Minimum length of glove (mm)		
minimum length of glove (mm)	M (8)	240	240	Passed
	Level of performance	Smallest pin diameter fulfilling test conditions (mm)		
III. Dexterity,	1	11		(see
level of	2	9.5	5	Remark
performance	3	8		1)
	4	6.5		
	5	5		1 1

REMARKS:

- A glove should allow as much dexterity as possible given its purpose. Four gloves were tested and smallest performance level was reported.
- For Clause 5.2 Penetration, the test sample will be four gloves of each size, with an overall minimum of 4 gloves per performed test (Air leak test and Water leak test). If one sample fails the penetration test, the test shall be reported as having failed.

Lee Dai Yi Engineer

Wong Bee Hui Product Manager Medical Health Services (NAM)

APPENDIX:



Photo: Nitrile Examination Powder Free Gloves, ASTHER, Blue, Lot No. A20200008

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TEST REPORT: 7191246549-CHM20-TSL

23 OCT 2020 Date:

Client's Ref:

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SUBJECT

Overall Migration for "Nitrile Examination Powder Free Gloves" Sample

CLIENT



Add value. Inspire trust.

SAMPLE SUBMISSION

12 Oct 2020

DESCRIPTION OF SAMPLE

One packet of glove sample labelled as follows was received

S/N	Product Description	Brand/ Model	Size	Colour	Lot No.	Expiry date	Sample received (pieces)	Manufacturer
1	Nitrile Examination Powder Free Gloves	Asther	М	Blue	A20200008	2023-09	507	Asther Production, Trading, Import and Export Limited Company



DATE OF ANALYSIS

14 Oct 2020 - 23 Oct 2020



TÜV SÜD PSB Pte. Ltd.

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CERTIFICATES

TEST REPORT: 7191246549-CHM20-TSL

23 OCT 2020



METHOD OF TEST

1. Preparation of Test Specimen

Only the exterior of the glove sample was performed for the test.

 Overall Migration Content with Aqueous Food Simulant (10% Ethanol, 3% Acetic Acid, 20% Ethanol & 50% Ethanol)

According to BS EN 1186-9:2002 – Test Methods for overall migration into aqueous food simulants by article filling.

3. Overall Migration Content with Fatty Food Simulant (Olive Oil)

According to BS EN 1186-8:2002 - Test Methods for overall migration into olive oil by article filling.

RESULTS

Table 1 : Overall Migration Content with Food Simulant for "Nitrile Examination Powder Free Gloves, Lot No: A20200008" Sample

Type of Simulant	Testing Condition*	Surface Area (dm²)	Volume of Extractant (ml)	Overall Migration (mg/dm²)	Commission Regulation (EU) No 10/2011 Requirement for Overall Migration Content (mg/dm²)
1. 10% Ethanol	100 °C, 1 hour	4.02	200	1.6	<10
2. 3% Acetic Acid	100 °C, 1 hour	4.08	200	11.2	<10
3. 20% Ethanol	100 °C, 1 hour	4.07	200	1.7	<10
4. 50% Ethanol	100 °C, 1 hour	3.97	200	6.3	<10
5. Vegetable Oil (Olive Oil)	100 °C, 1 hour	4.12	200	<1.0	<10

^{*}The OM4 test condition as specified by client.

Based on the above results, the "Nitrile Examination Powder Free Gloves, Lot No.: A20200008" sample met the overall migration requirement under Commission Regulation (EU) No 10/2011 – "Plastic materials and articles shall not transfer their constituents to foodstuffs in quantities exceeding 10 milligrams of total constituents released per dm² of food contact surface (mg/dm²) (overall migration limit)", except for 3% Acetic Acid.

MS TAN SER LING
TECHNICAL EXECUTIVE

DR XIAO ZHOU
PRODUCT MANAGER
MICROCONTAMINATION DIAGNOSIS
CHEMICAL & MATERIALS

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GARGOLA HEALTHCARE

Hospital supplies and services







TEST REPORT: 7191246549-CHM20-TSL

23 OCT 2020



Please note that this Report is issued under the following terms

- 1. This report applies to the sample of the specific product/equipment given at the time of its testing/calibration. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that TÜV SÜD PSB approves, recommends or endorses the manufacturer, supplier or user of such product/equipment, or that TÜV SÜD PSB in any way "guarantees" the later performance of the product/equipment. Unless otherwise stated in this report, no tests were conducted to determine long term effects of using the specific product/equipment.
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- The tests carried out by TÜV SÜD PSB and this report are subject to TÜV SÜD PSB's General Terms and Conditions of Business and the Testing and Certification Regulations of the TÜV SÜD Group.

Effective 01 September 2020



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CERTIFICATESS









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EU Declaration of Conformity

We, Asther Trading Pte Ltd, located at 3013 Bedok Industrial Park E, #02–2104, Singapore 489979 being the manufacturer for the medical devices as described hereafter:

Product: Nitrile Examination Gloves Type: Powder Free, Non-sterile Model number: A0398245P

This declaration of conformity is issued under the sole responsibility of the manufacturer and we hereby declare that the above product in **Class I** is manufactured in conformity with the relevant Union harmonisation legislation:

Regulation (EU) 2016/425 Of The European Parliament And Of The Council on personal protective equipment

the procedure relating to the EC declaration of conformity set out in Annex VII, and meet the requirements of the following EN standard:

Standard No.	Standard Description
EN 455-1	Requirements and testing for freedom from holes
EN 455-2	Requirements and testing for physical properties
EN 455-3	Requirements and tests for biological evaluation

Should you have any questions or to check the authenticity of this declaration please contact:

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Signed for and on behalf of:

(UEN: 201809277N)

Please of issue: On the 2nd of November, 2020

w

Shawn Zhang

Managing Director

HU

Luxon Pua

QA Director

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OFFER FOR SHIPPING BY PLANE IN 7 DAYS

Nitrile examination gloves, powder-free, Malaysian Origin, with Spanish brand, from the manufacturer Hartalega.

Delivery by air in 7 days, after receipt of the payment instrument LC MT700.

Process:

- 1º- Contract and invoice are sent
- 2°- The client sends the LC to our bank
- 3°- In 7 days the gloves are delivered to the carrier (Air Company) and we send to the buyer's bank the documents that prove the shipment, which include:
- a) SGS inspection certificate
- b) BL
- d) Certificate of origin

And all the usual shipping documents.

- 3°- The buyer's bank upon receipt of the documents verifies them and releases the payment.
- 4°- When the seller's bank receives the SWIFT MT103, to release the payment, it releases the load for the carrier to transport it to the destination airport.

VISIT TO THE SUPPLIER IN SPAIN TO VERIFY STOCKS AND CLOSE PURCHASE AGREEMENTS IS POSSIBLE BY APPOINTMENT