



# Product Specifications



## PHYSICAL SPECIFICATION

<b>Type</b>	Polymer Coated Powder free Examination Gloves 4 mil.		
<b>Material</b>	Acrylonitrile Butadiene Copolymer (NBR)	<b>Classification</b>	Class I (FDA)
<b>Design</b>	Ambidextrous; beaded cuff	<b>Usage</b>	Disposable, Single Use Only
<b>Packing Size</b>	11cm x 6.7cm x 21.6cm	<b>Content</b>	100 gloves per box (by weight)
<b>Carton Size</b>	23cm x 35cm x 23cm	<b>Content</b>	10 boxes per carton
<b>Colors</b>	Blue (ASTM D573-04:2019)	<b>Texture</b>	Smooth/ Textured
<b>Shelf Life</b>	3 Years	<b>Storage</b>	Store in a cool, dry place, between 10° – 40°C (50° – 104°F)
<b>Standard</b>	ASTM D6319-19   EN 455-1,2,3   EN 1186   ASTM D6124   ASTM D412-16   ASTM D573-04:2019		

## PHYSICAL PROPERTIES

Values	S Small	M Medium	L Large	XL Extra Large	Meet Standard
<b>Glove Length (mm)</b>	≥ 240				ASTM D6319-19; Clause 7.4, ASTM D3767-3:2020 & EN 455-2:2015
<b>Palm Width (mm)</b>	83-85	92-95	103-106	112-115	
<b>Finger Thickness (mm)</b>	0.12 ± 0.03	0.12 ± 0.03	0.12 ± 0.03	0.12 ± 0.03	
<b>Palm Thickness (mm)</b>	≥ 0.1				
<b>Weight (g/glove)</b>	3.8 ± 0.3	4.3 ± 0.3	4.7 ± 0.3	5.0 ± 0.3	
<b>Powder Residue (mg)</b>	Requirement 2.0	Test Result 1.7			ASTM D6319-19; Clause 7.6 & ASTM D6124-06:2017
<b>Freedom from Holes</b>	Requirement AQL 4.0	Test Result AQL 1.5			EN 455-1:2000
<b>Proteins extraction</b>	MDL 3 µg/g	Test Result Not Detected			EN 455-3:2015
<b>Determination of pH Value, pH Value</b>	Requirement >3.5 & <9.5	Test Result 8.5			BS EN ISO 21420:2020

# Product Specifications

<b>Sizing, minimum length of glove (mm), Size M</b>	Requirement 240	Test Result 240 ± 5	BS EN ISO 21420:2020
<b>Values</b>	<b>Standard &amp; Result</b>		<b>Meet Standard</b>
<b>Dexterity, level of performance</b>	Level of performance	Smallest pin diameter fulfilling test conditions	BS EN ISO 21420:2020
	1	11 mm	Test Result 5
	2	9.5 mm	
	3	8 mm	
	4	6.5 mm	
	5	5 mm	
	<b>Before Aging (N)</b>	<b>After Accelerated Aging (N)</b> (70°C for 166 hours)	
<b>Tensile Strength (MPa)</b>	40.5	35.0	ASTM D6319-19; Clause 7.5 & ASTM D573-04:2019
<b>Elongation at Break (%)</b>	630	620	
<b>Median Force at Brake</b>	8.57	8.72	EN 455-2:2015
<b>Values</b>	<b>Standard &amp; Result</b>		<b>Meet Standard</b>
<b>Food Grade</b>	US (United State of America) & EU (Europe)		
<b>For use in contact with aqueous foods:</b>			
<b>Extractants: Distilled Water</b>	<b>RL</b> (Denote Reporting Limit)	<b>Result</b>	<b>Permissible Limit</b>
Reflux Temperature for 7 hours	0.1mg/inch <sup>2</sup>	0.7mg/inch <sup>2</sup>	20mg/inch <sup>2</sup>
Succeeding 2 hours of extraction	0.1mg/inch <sup>2</sup>	Not Detected	1mg/inch <sup>2</sup>
<b>For use in contact with fatty foods:</b>			
<b>Extractants: n-Hexane</b>	<b>RL</b> (Denote Reporting Limit)	<b>Result</b>	<b>Permissible Limit</b>
Reflux Temperature for 7 hours	0.1mg/inch <sup>2</sup>	0.3mg/inch <sup>2</sup>	175mg/inch <sup>2</sup>
Succeeding 2 hours of extraction	0.1mg/inch <sup>2</sup>	Not Detected	4mg/inch <sup>2</sup>
<b>Food Grade</b>	EU (Europe)		
<b>Global Migration from Rubber</b>	The migratory behaviour is examined in accordance with Directive 82/711/EEC and Council Directive 85/572/EEC and its corresponding regulations. Deviatine to the regulations the following tests were performed as orientating single test.		EN 1186

## QUALITY STANDARD

CE 0197

For PPE cat III  
Personal Protective  
Equipment,  
Regulation(EU) 2016/425

EN 455  
1,2,3

EN 455-1,2,3

FDA

US FDA

EN 1186

EN 1186



Food Contact

ASTM  
D 6319-19

ASTM D6319-19

ASTM  
D 6124

ASTM D6124

ASTM  
D 412-16

ASTM D412-16

ASTM  
D 573-04

ASTM D573-04:2019



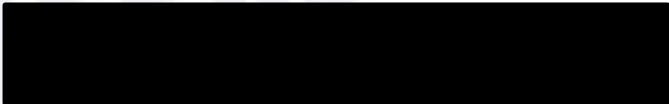
Products



Report No.: 242123187-01

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Client:



Identification/ Model No(s): Nitrile Exam 091020

Model No(s):

Sample Receiving date: 2020-10-15

Testing Period: 2020-10-15 to 2020-10-21

Delivery condition: Apparent good, Samples tested as

Test Specification:

Test result:

Test parameter was selected by client

1. US FDA 21 CFR 177.2600 (Rubber Articles) Amount of Extractives PASS

Other Information:

Material type: Examination Glove

Manufacturer:

Origin: USA, EUROPE

For and on behalf of  
TÜV Rheinland Thailand Ltd.



2020-10-21

Wilawan Sriprom / Manager

Date

Name/Position

Test result is drawn according to the kind and extent of tests performed.

This test report relates to the above mentioned test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any safety mark on this or similar products.

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**Material list**

Item: ██████████ Nitrile Exam 091020

Material No.	Material	Color	Location
M001	Nitrile glove	Blue	Refer to photo

**1. US FDA 21 CFR 177.2600 (Rubber Articles) – Determination of Aqueous Extractables**

Test Method: With reference to US FDA 21 CFR 177.2600

For use in contact with aqueous foods:

Extractants	Test Condition	RL (mg/inch <sup>2</sup> )	Result (mg/inch <sup>2</sup> )	Permissible Limit (mg/inch <sup>2</sup> )
			M001	
Distilled Water	Reflux temperature for 7 hours	0.1	0.7	20
	Succeeding 2 hours of extraction	0.1	n.d.	1
Comment	--	--	Pass	--

For use in contact with fatty foods:

Extractants	Test Condition	RL (mg/inch <sup>2</sup> )	Result (mg/inch <sup>2</sup> )	Permissible Limit (mg/inch <sup>2</sup> )
			M001	
n-Hexane	Reflux temperature for 7 hours	0.1	0.3	175
	Succeeding 2 hours of extraction	0.1	n.d.	4
Comment	--	--	Pass	--

Abbreviation: n.d. denotes Not Detected (<RL)  
 RL denotes Reporting Limit  
 mg/inch<sup>2</sup> denotes Milligram per square inch



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Sample photo:





Products

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Client:



Identification/

Nitrile Exam 091020

Model No(s):

Sample Receiving date: 2020-10-15

Testing Period: 2020-10-15 to 2020-10-21

Delivery condition: Apparent good, Samples tested as received

Test Specification:

Test result:

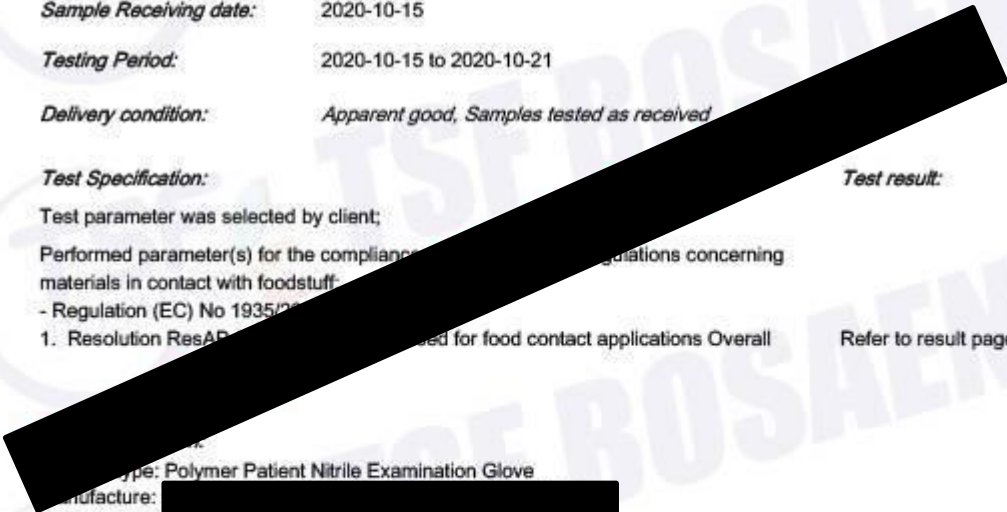
Test parameter was selected by client;

Performed parameter(s) for the compliance with the regulations concerning materials in contact with foodstuff:

- Regulation (EC) No 1935/2004

1. Resolution ResAP/018000/2011 for food contact applications Overall

Refer to result page.



Type: Polymer Patient Nitrile Examination Glove

Manufacturer:

Country of Origin:

Country of Destination: USA, EUROPE

For and on behalf of  
TÜV Rheinland Thailand Ltd.



2020-10-21

Wilawan Sriprom / Manager

Date

Name/Position

Test result is drawn according to the kind and extent of tests performed.

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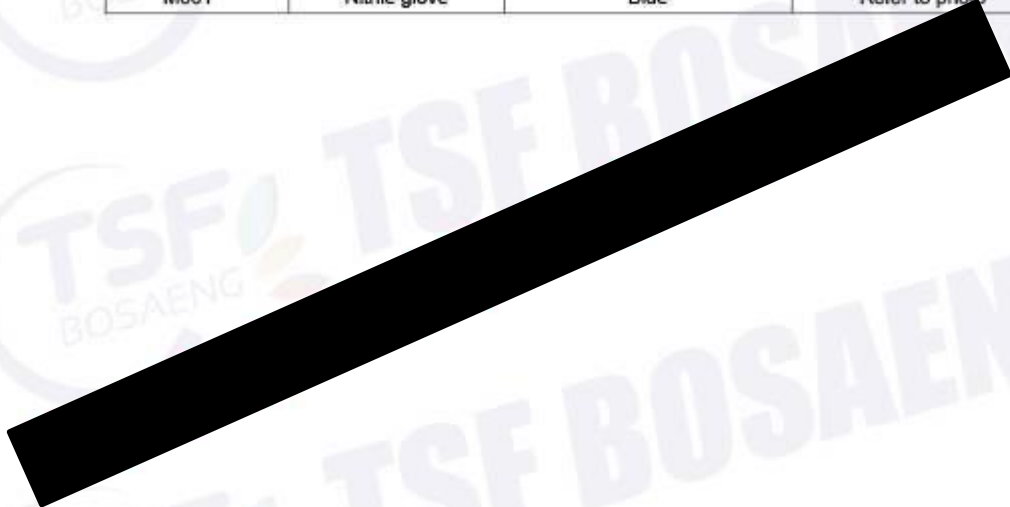


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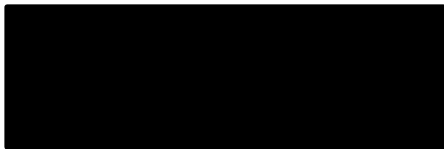
Material list

Item :  Nitrile Exam 091020

Material No.	Material	Color	Location
M001	Nitrile glove	Blue	Refer to photo







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Global Migration from Rubber

Test method: The migratory behaviour is examined in accordance with Directive 82/711/EEC and Council Directive 85/572/EEC and its corresponding regulations. Deviating to the regulations the following tests were performed as orientating single tests.

Limit: Resolution AP (2004) 4 on rubber used for food contact applications

The following food simulants and conditions were applied:

Food simulant	Test duration / Temperature
Acetic acid 3 %	2 hours / 40 °C
Ethanol 10 %	2 hours / 40 °C
Ethanol 20 %	2 hours / 40 °C
Olive oil	2 hour(s) / 40 °C

Test Method	T001		
	Unit	Result	Limit
Acetic acid 3 %	mg/kg	78 <sup>(*)</sup>	60
Ethanol 10 %	mg/kg	< 3	60
Ethanol 20 %	mg/kg	< 3	60
Olive oil	mg/kg	< 2	60

Abbreviations:

mg/dm<sup>2</sup> = Milligram per square decimetre

< = Less than

Remark:

\*1 Acc. to DIN EN 1186-1 the following analytical tolerances have been observed:

- 18 mg/kg in migration tests using rectified olive oil or substitutes,
- 12 mg/kg in migration tests using aqueous simulants

A material or article that exceeds the overall migration limit by an amount not greater than the analytical tolerance mentioned above should therefore be deemed to be in compliance with the overall migration limit.

\*2 The examined item does not meet the requirement



Products

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Sample Photo:





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**Report No.:** 242123187-03

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**Client:**



**Identification/**

Nitrile Exam 091020

**Model No(s):**

**Sample Receiving date:** 2020-10-15

**Testing Period:** 2020-10-15 to 2020-10-29

**Delivery condition:** Apparent good, Samples tested as received

**Test Specification:**

1. EN 455-1: 2000: Requirements for freedom from holes
2. EN 455-2: 2015: Physical properties test;
  - Dimension test
  - Force at break test
3. EN 455-3: 2015 (E), Annex A : Proteins extraction

**Test result:**

PASS  
PASS

Refer to result page

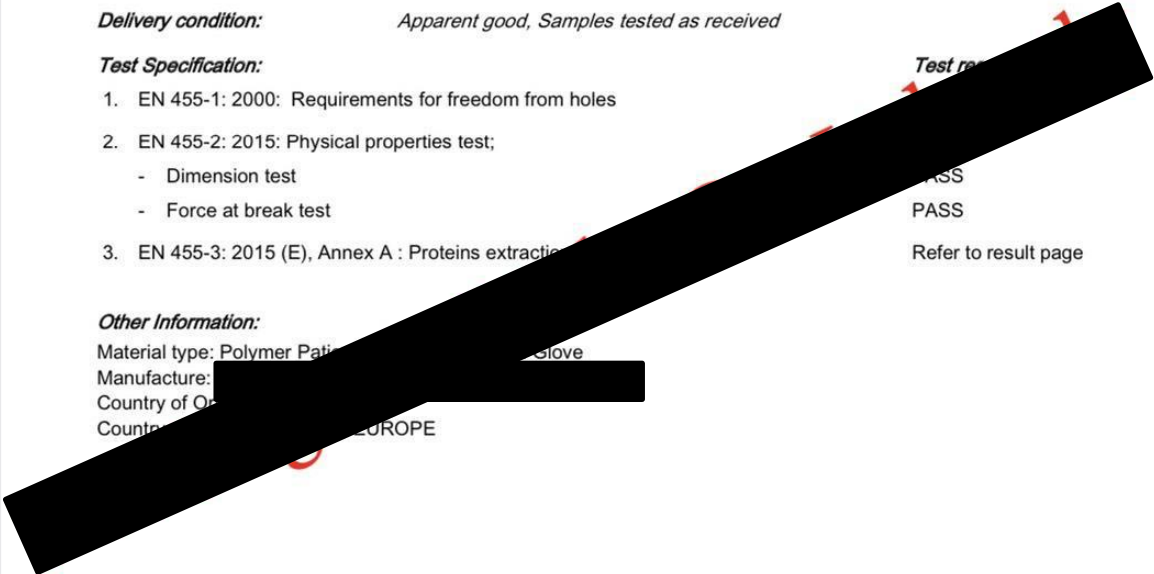
**Other Information:**

Material type: Polymer Patient Examination Glove

Manufacturer:

Country of Origin:

Country of Origin: EUROPE



For and on behalf of  
TÜV Rheinland Thailand Ltd.



2020-10-29

Wilawan Sriprom / Manager

**Date**

**Name/Position**

*Test result is drawn according to the kind and extent of tests performed.*

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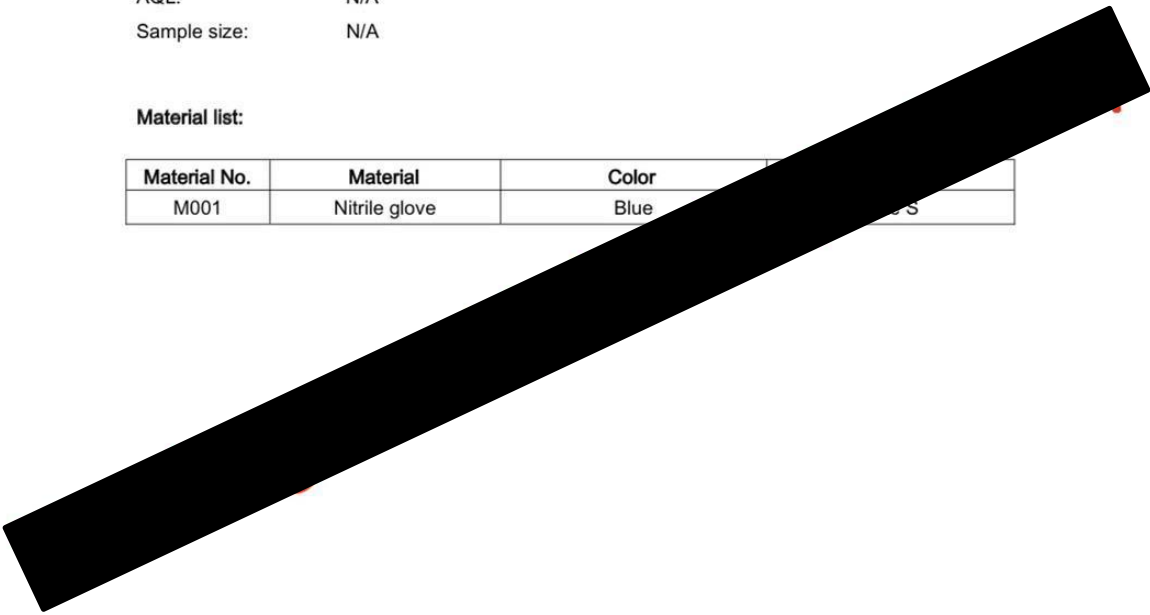
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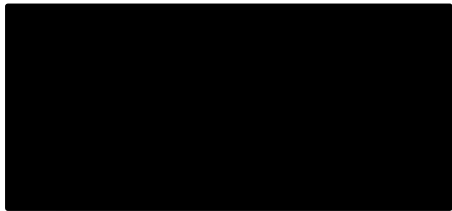
**Sampling Information:**

Inspection Method: No inspection, submitted sample by client  
Inspection level: N/A  
AQL: N/A  
Sample size: N/A

**Material list:**

Material No.	Material	Color
M001	Nitrile glove	Blue





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**Freedom from holes**

Test method: With reference to EN 455-1: 2000

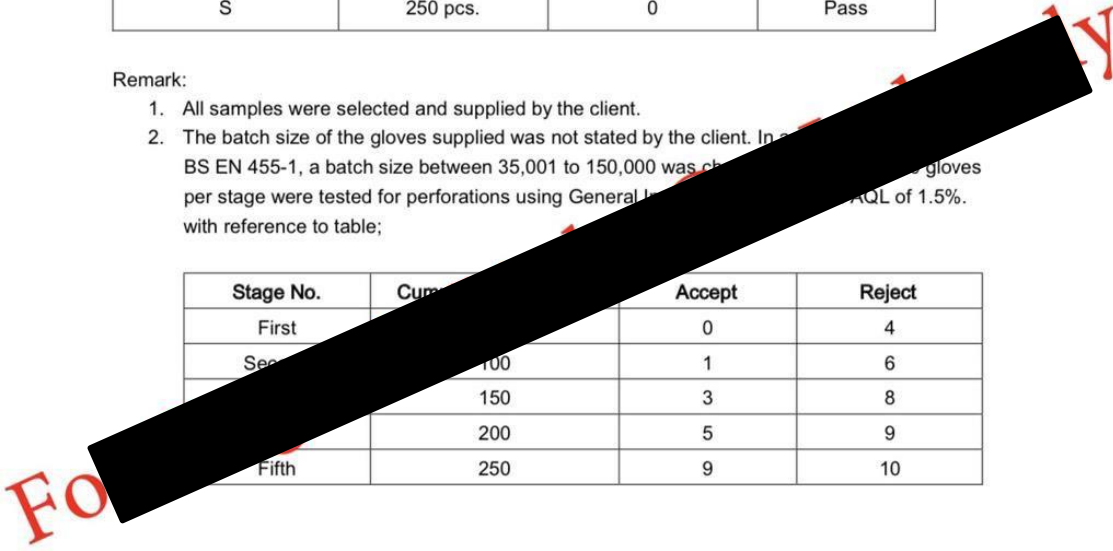
**Test result:**

Gloves Size	Tested samples	No. of samples for Non-compliance	Conclusion
S	250 pcs.	0	Pass

**Remark:**

- All samples were selected and supplied by the client.
- The batch size of the gloves supplied was not stated by the client. In accordance with BS EN 455-1, a batch size between 35,001 to 150,000 was chosen. In this test, 250 gloves per stage were tested for perforations using General Inspection Method with AQL of 1.5% with reference to table;

Stage No.	Cumulative	Accept	Reject
First		0	4
Second	100	1	6
Third	150	3	8
Fourth	200	5	9
Fifth	250	9	10



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**Dimension test**

Test method: EN 455-2: 2015

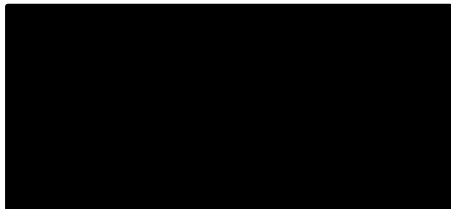
**Test results:**

Test No.:	T001	
Material No.:	M001	
Tested no.	Length (mm)	Width (mm)
1	244	82
2	241	83
3	243	83
4	245	83
5	244	81
6	241	81
7	243	83
8	241	82
9	244	82
10	242	82
11	242	82
Result	242	82
Conclusion	Pass	Pass

Abbreviation: mm = millimeter

Remark: Dimension limit reference to table

Size	Median length (mm)	Median width (mm)
Extra small	≥ 240	≤ 80
Small		80±10
Medium		95±10
Large		110±10
Extra large		≥ 110



Products



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Force at break

Test method: EN 455-2: 2015

Test results:

Test No.	T001	
Material No.	M001	
Tested no.	Force at break Before ageing (N)	Force at break After ageing (N)
1	7.99	8.21
2	8.63	8.34
3	8.59	9.13
4	8.60	7.45
5	7.31	
6	8.08	
7		7.09
8		10.27
9		10.33
10	9.00	7.46
11	7.51	7.91
12	9.41	9.31
13	8.82	8.84
Median result	8.57	8.72
Conclusion	Pass	Pass

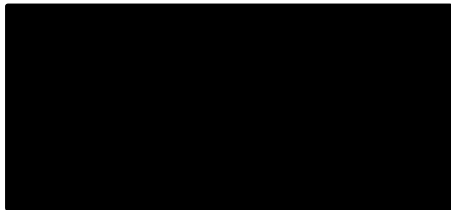
Abbreviation: N = Newton

Remark:

- Median values of force at break

Force at Break (newton)		
a)	b)	c)
≥ 9.0	≥ 6.0	≥ 3.0

- Requirements for all surgical gloves
- Requirements for all examination gloves, except gloves made from thermoplastic materials (e.g. Polyvinylchloride, Polyethylene)
- Requirements for gloves made from thermoplastic materials (e.g. Polyvinylchloride, Polyethylene)



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**Proteins extraction**

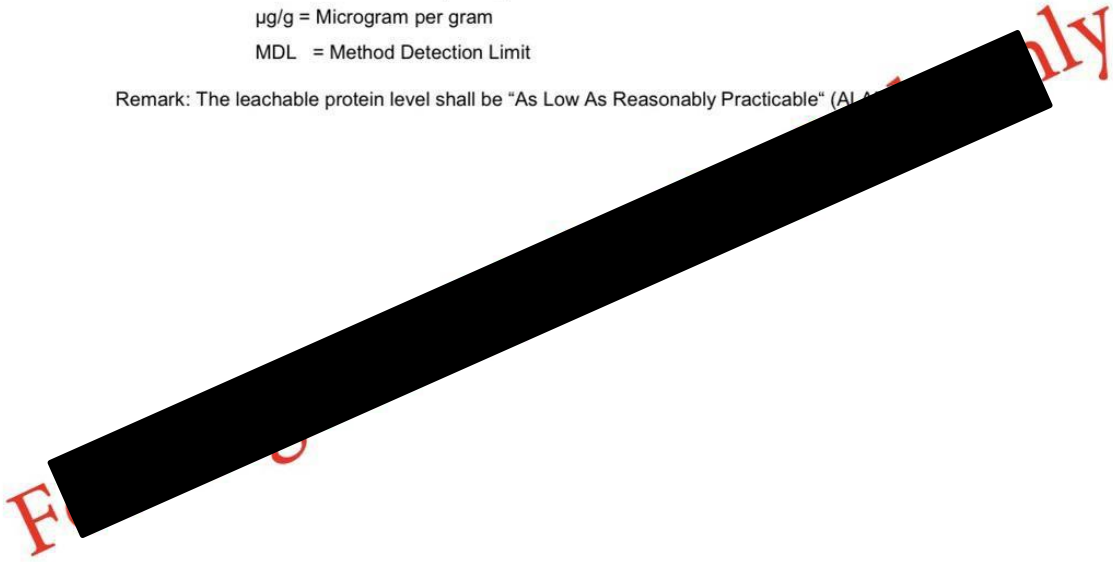
Test method: With reference to EN 455-3: 2015 (E), Annex A.

**Test result:**

Test No.	Material No.	Test parameter	Unit	MDL	Test result
T001	M001	Proteins	µg/g	3	n.d.

Abbreviation: n.d. = Not Detected (<MDL)  
 µg/g = Microgram per gram  
 MDL = Method Detection Limit

Remark: The leachable protein level shall be "As Low As Reasonably Practicable" (ALARP)







Products



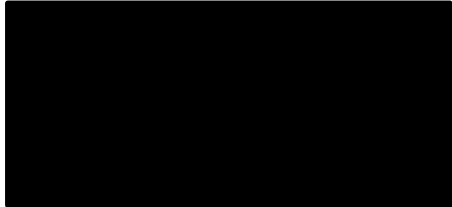
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Sample photo:





◆ CERTIFICAT

◆ CERTIFICADO

◆ СЕРТИФИКАТ

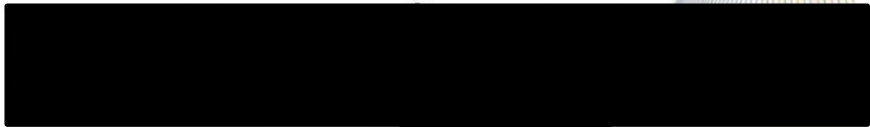
◆ CERTIFICATE

◆ ZERTIFIKAT

# CERTIFICATE OF REGISTRATION



This is to Certify that the  
Medical Devices- Quality Management System



has been independently audited and is compliant  
with the requirements of

## ISO 13485:2016

This Certificate is applicable to the following product or service ranges:

- 1) Manufacture of non-sterile powder free nitrile examination gloves
- 2) Manufacture of non-sterile powder free latex examination gloves
- 3) Manufacture of Industrial , household and multi-purpose gloves
- 4) Distribution of synthetic examination, natural latex, Industrial , household and multi purpose gloves

:: Certificate No :: **THIS IS REDACTED**

Date of initial registration: 27 November 2020

Date of last surveillance audit: 27 November 2020

Date of next surveillance audit on or before: 26 November 2021

Certificate Due / Certificate expiry: 26 November 2023

This Certificate remains valid subject to satisfactory surveillance audits.



*Emmanuel*  
**Emmanuel ADEMOSU**  
Director

### STAUNCHLY MANAGEMENT AND SYSTEM SERVICES LIMITED

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For Bright Glove Brand

SMS/FM/001/REV06

