

# TECHNICAL SHEET

**Denumire Produs:** SERIX Latex Powder-Free Examination Gloves

**Producator:** Maxter Glove Manufacturing Sdn Bhd

**EC-REP:** Supermax Healthcare (Europe) Limited

**UK-REP:** Supermax Healthcare Limited



# Latex Powder-Free Examination Gloves SERIX

Characteristics	BEFORE AGING	AFTER AGING
	ASTM D 3578	
Tensile Strength (Mpa)	18 Min	14 Min
Elongation (%)	650 Min	500 Min
Force at Break (N)	6 Min	6 Min

All sizes	Length (mm)	Palm Width (mm)	Weight (g)	Thickness Cuff	Thickness Palm	Thickness Finger
XS	240	70-79	4.9 ±0.2	0,07 mm	0,10 mm	0,13 mm
S		80-89	5.2 ±0.2			
M		90-99	5.7 ±0.2			
L		100-109	6.1 ±0.2			
XL		110-119	6.7 ±0.2			

Characteristics	Watertight Test	Dimensions	Physical Properties	Major Defects	Minor Defects
Inspection ISO 2859	G1	S2	S2	G1	G1
AQL	1.5	4.0	4.0	2.5	4.0

Packaging	Pcs
Box	100 Pcs
BAX	10 boxes (1.000 pcs)



LOT 6070  
Jalan Haji Abdul Manan, 6<sup>th</sup> Miles Off Jalan Meru, 41050 Klang, Selangor, Malaysia  
Tel: 03-33000000 (9 lines), Fax: 03-33023222  
E-MAIL: info@maxter.com.my

Date: 06<sup>th</sup> October 2021

To Whom It May Concern

### EC DECLARATION OF CONFORMITY

We, MAXTER GLOVE MANUFACTURING SDN. BHD, located at Lot 6070, Jalan Haji Abdul Manan, 6<sup>th</sup> Miles Off Jalan Meru, 41050 Klang, Selangor, Malaysia, declares under our sole responsibility that the medical devices described hereafter as :-

- Non Sterile Latex Examination Gloves
- Non Sterile Nitrile Examination Gloves

- Are in conformity with the general safety and performance requirements of Annex I Medical Device Regulation (EU) 2017/745 for Class I medical devices.
- Classification: Class I based on Rule 5 transient use, Annex VIII of Medical Device Regulation (EU) 2017/745.
- Are in conformity with the national standard transposing harmonized standard EN 455.
- The gloves are manufactured according to ISO 9001:2015 and EN ISO 13485:2016 Quality Management Systems and certified by Notified Body, SGS United Kingdom Ltd Systems & Services Certification.
- Our Authorized Representative is Supenmax Healthcare (Europe) Limited, 38 Mann Street, Swords Co. Dublin, Ireland K67 E0A2.



Klang, Selangor  
Malaysia

Yap Peak Goh  
QA & Regulatory Affairs Manager

# Latex Powder-Free Examination Gloves SERIX



# Latex Powder-Free Examination Gloves SERIX



Issued to:

Maxter Glove Manufacturing Sdn Bhd  
Lot 6070  
Jalan Haji Abdul Manan  
6th Mile off Jalan Meru  
41050 Klang  
Selangor  
Malaysia

Halled Body: 2777

SATRA customer number: P18025

EU Type-Examination Certificate

**Certificate number: 2777/12719-01/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.

<b>Product reference:</b>	<b>Description:</b>		
MTCLPF	Non sterile powder free latex examination gloves		
<b>Sizes:</b>	<b>Classification:</b>	<b>Level</b>	<b>EN 374-4: 2013</b>
Extra Small – 6	<b>EN ISO 374-1:2016 Type C</b>	3	-21.7%
Small – 7	Sodium hydroxide 40% (K)	1	95.8%
Medium – 8	Sulphuric acid 96% (L)	5	-21.4%
Large – 9	Formaldehyde 37% (T)		
Extra Large – 10			
	<b>EN ISO 374-5: 2016</b>	<b>Level</b>	
	Protection against bacteria & fungi	Pass	
	Protection against viruses	Pass	

**Standards/Technical specifications applied:**  
EN ISO 374-1:2016, EN 420: 2003+A1: 2009, EN ISO 374-5:2016

**Technical reports/Approval documents:**  
SATRA: CHM0277509/1844/JHD, CHM0277509/1844/SPT/1, CHM0277509/1844/UeG/Final, CHM0277509/1844/JHE, CHM0277509/1844/JHF, CENTEXBL: 17 00806.01

Signed on behalf of SATRA: 

Date first issued: 20/05/2019  
Date of issue: 20/05/2019

Tara Holly 

Expiry date: 20/05/2024

Quincy Brown

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SATRA Technology Europe Limited, Treatment Business Park, Clonsilla, DUBLIN 15, Republic of Ireland



Certificat MY0051618

Sistem de management al

**Maxter Glove Manufacturing Sdn. Bhd.**

Lot 6070, Jalan Haji Abdul Manan  
6th Mile Off Jalan Meru, 41050 Klang, Selangor Darul Ehsan  
MALAYSIA

Este valabil pe certificații în întregime din

**ISO 13485:2016**  
**EN ISO 13485:2016**

Pentru următoarele activități:

Fabricarea și distribuția mănușilor de examinare nesterile din latex natural și cauciuc nitrilic

Acest certificat este valabil de la 10 mai 2021 până la 4 mai 2024 și rămâne valabil sub rezerva unor audituri de supraveghere satisfăcătoare. Auditul de recertificare trebuie efectuat înainte de 04 martie 2024  
Emisia nr. 14, Certificat din 4 mai 2000

Auditul care a condus la eliberarea acestui certificat a început la 01 martie 2021. Date de expirare a certificatului este anterior a fost până la 04 mai 2021  
Autorizat la

**SGS**



**UKAS**



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HC 5025 13485:2016 01B  
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# Latex Powder-Free Examination Gloves SERIX



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6th Miles off Jalan Meru  
41050 Klang  
Selangor  
Malaysia

SATRA reference: CHM0277509/1844/JH/E

Your reference:

Date of report: 19<sup>th</sup> December 2018

Samples received: 12<sup>th</sup> November 2018

Date(s) work carried out: 23<sup>rd</sup> November to 3<sup>rd</sup> December 2018

## TECHNICAL REPORT

Subject: EN 374-4:2013 determination of resistance to degradation by chemicals on gloves described as Latex Powder Free Glove MTCLPF 57

### 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 if 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: Jade Hurley  
Position: Technologist  
Department: Chemical & Analytical Technology

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## TECHNICAL REPORT



### WORK REQUESTED:

Samples of gloves described as Latex Powder Free Glove MTCLPF 57 were received on the 12<sup>th</sup> November 2018 for testing in accordance with EN 374-4:2013.

### SAMPLES SUBMITTED:



Samples described as Latex Powder Free Glove MTCLPF 57

### CONCLUSION:

When assessed in accordance with EN 374-4:2013 the samples of gloves described as Latex Powder Free Glove MTCLPF 57 achieved the following degradation results:

Chemical	Mean degradation / %
n-Heptane (CAS: 142-82-5)	69.4
40% Sodium hydroxide (CAS: 1310-73-2)	-21.7
25% Ammonium hydroxide (CAS: 1336-21-6)	-60.9
96% Sulphuric acid (CAS: 7664-93-9)	95.8
30% Hydrogen peroxide (CAS: 7722-84-1)	41.2
37% Formaldehyde (CAS: 50-00-0)	-21.4

### TESTING REQUIRED:

- EN 374-4:2013. Protective gloves against chemicals and micro-organisms. Part 4: Determination of resistance to degradation by chemicals.

Maxler Glove Manufacturing Sdn Bhd  
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Date: 19<sup>th</sup> December 2018

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Signed:

# Latex Powder-Free Examination Gloves SERIX



## TECHNICAL REPORT



### RESULTS:

Sample description:	Latex Powder Free Glove MTCLPF 57		
Challenge chemical:	n-Heptane (CAS: 142-82-5)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	81.1	67.1	60.1
Mean degradation (DR) / %:	69.4		
Standard deviation ( $\sigma_{DR}$ ) / %:	10.7		
UoM / ± %:	37.5		
Appearance of samples after testing:	Swollen		

Sample description:	Latex Powder Free Glove MTCLPF 57		
Challenge chemical:	40% Sodium hydroxide (CAS: 1310-73-2)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	8.3	-49.3	-24.1
Mean degradation (DR) / %:	-21.7		
Standard deviation ( $\sigma_{DR}$ ) / %:	28.9		
UoM / ± %:	16.9		
Appearance of samples after testing:	Swollen		

Sample description:	Latex Powder Free Glove MTCLPF 57		
Challenge chemical:	25% Ammonium hydroxide (CAS: 1336-21-6)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	-61.2	-59.2	-62.2
Mean degradation (DR) / %:	-60.9		
Standard deviation ( $\sigma_{DR}$ ) / %:	1.5		
UoM / ± %:	15.9		
Appearance of samples after testing:	Swollen		

Maxler Glove Manufacturing Sdn Bhd  
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Signed:



## TECHNICAL REPORT



Sample description:	Latex Powder Free Glove MTCLPF 57		
Challenge chemical:	96% Sulphuric acid (CAS: 7664-93-9)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	95.9	97.2	94.3
Mean degradation (DR) / %:	95.8		
Standard deviation ( $\sigma_{DR}$ ) / %:	1.5		
UoM / ± %:	<5		
Appearance of samples after testing:	Swollen, brittle, disintegrated and discoloured		

Sample description:	Latex Powder Free Glove MTCLPF 57		
Challenge chemical:	30% Hydrogen peroxide (CAS: 7722-84-1)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	42.7	39.8	41.0
Mean degradation (DR) / %:	41.2		
Standard deviation ( $\sigma_{DR}$ ) / %:	1.4		
UoM / ± %:	22.8		
Appearance of samples after testing:	Swollen		

Sample description:	Latex Powder Free Glove MTCLPF 57		
Challenge chemical:	37% Formaldehyde (CAS: 50-00-0)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	-28.9	-17.2	-18.1
Mean degradation (DR) / %:	-21.4		
Standard deviation ( $\sigma_{DR}$ ) / %:	6.5		
UoM / ± %:	16.9		
Appearance of samples after testing:	Discoloured		

NOTE: Where the test specimens gave an increased puncture force after chemical exposure, the result is reported as a negative degradation.

Maxler Glove Manufacturing Sdn Bhd  
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 Date: 19<sup>th</sup> December 2018 (Page 4 of 6)

Signed:

# Thank you!



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