

TECHNICAL SHEET

Product: SERIX Latex Powdered Examination Gloves

Manufacturer: Maxter Glove Manufacturing Sdn Bhd

EC-REP: Supermax Healthcare (Europe) Limited

UK-REP: Supermax Healthcare Limited



Latex Powdered 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	4.6 ±0.2	0,08 mm	0,09 mm	0,10 mm
S		80-89	5.0 ±0.2			
M		90-99	5.4 ±0.2			
L		100-109	5.8 ±0.2			
XL		110-119	6.3 ±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)



MAXTER
GLOVE MANUFACTURING SDN BHD
(221942-04)

LOT 6070
Jalan Haji Abdul Manan, 6th Miles Off Jalan Meru, 41050 Klang, Selangor, Malaysia
Tel: 03-39029888 (9 lines) Fax: 03-39023333
E-MAIL: info@maxter.com.my

Date: 06th 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, 6th 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 Supermax Healthcare (Europe) Limited, 38 Main Street, Swords Co. Dublin, Ireland K67 E0A2.

Klang, Selangor
Malaysia



Yap Peak Geeh
QA & Regulatory Affairs Manager

SGS

Certificate MY19/1811030073

The management system of

Maxter Glove Manufacturing Sdn. Bhd.

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

has been assessed and certified as meeting the requirements of

Regulation (EU) 2016/425 Module D

For the following activities

Natural Latex, Nitrile Rubber Gloves, Chemical Protective Gloves
Note: All products marked CE0598 must have a valid EU type-examination certificate issued under Module B or a valid EC type-examination certificate issued under Article 10 of the PPE Directive 89/686/EEC.

This certificate is valid from 04 May 2021 until 04 May 2024 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 04 March 2024
Issue 3. Certified since 01 July 2019

Authorized by

Tom Tom

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Tukimieki 8, FI-00380 Helsinki, Finland
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FINAS
Finnish Accreditation Service
S803 (EN ISO/IEC 17065)



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Certificate MY00/51618

The management system of

Maxter Glove Manufacturing Sdn. Bhd.

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

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

Manufacture and Distribution of Non Sterile Natural Latex
and Nitrile Rubber Examination Gloves

This certificate is valid from 10 May 2021 until 04 May 2024 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 04 March 2024
Issue 14. Certified since 04 May 2000

The audit leading to this certificate commenced on 01 March 2021
Previous issue certificate validity date was until 04 May 2021

Authorized by

AR

SGS United Kingdom Ltd
Rosemore Business Park, Ebbw Vale, Carmarthenshire, NP23 5SN, UK
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HC 5045 13485 2016 0118

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Certificate MY0051619

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The management system of

Maxter Glove Manufacturing Sdn. Bhd.

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

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

Manufacture and Distribution of Non Sterile Natural Latex and Nitrile
Rubber Examination Gloves

This certificate is valid from 04 May 2021 until 04 May 2024 and
remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date.
Issue 11, Certified since 04 May 2000

Authorized by

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HC: SGS 9001 2015 0816

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SATRA
TECHNOLOGY

Issued in

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

Notified Body: 2777

SATRA customer number: P19025

EU Type-Examination Certificate

Certificate number: 2777/12636-01/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.

Product reference:

SSLPLP

Description:

Powdered latex gloves in creamy white colour

Sizes:

Extra Small – 6
Small – 7
Medium – 8
Large – 9
Extra Large – 10

Classification:

EN ISO 374-1:2016 Type C	Level	EN 374-4:2013
Sodium hydroxide 40% (K)	3	-15.0%
Sulphuric acid 96% (L)	1	95.2%
Hydrogen peroxide 30% (P)	1	-8.0%
Formaldehyde 37% (T)	2	-19.2%

EN ISO 374-5:2016

Protection against bacteria and fungi – Pass
Protection against Virus – Pass

Standards/Technical specifications applied:

EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016; EN 420:2003+A1:2009

Technical reports/Approval documents:

SATRA: CHM0277509/1844/JH/A/Final, CHM0277509/1844/JH/B/Final, CHM0277509/1844/JH/C/Final, CHM0277509/1844/SPT/1
CENTEXBEL: 17.00806.01

Signed on behalf of SATRA:

Tara Holly

Geoff Graham

Date first issued: 26/04/2019

Date of issue: 26/04/2019

Expiry date: 26/04/2024

Page 1 of 2

SATRA Technology Europe Limited, Riverside Business Park, Clonsilla, D15V1GP, Republic of Ireland

Test Report No. : CPSA/210562863-CA64055
 Company : Maxter Glove Manufacturing Sdn Bhd
 Lot 6070, Jalan Haji Abdul Manan,
 6th Miles Off Jalan Meru,
 41050 Klang, Selangor, Malaysia

TEST REPORT

Sample Description : Latex Examination Gloves (Powdered)
 Lot No. : 6110206188
 Manufacturer : Maxter Glove Manufacturing Sdn Bhd
 Size : Medium
 Quantity Tested : 200 pieces
 Test Conducted : Freedom from holes
 Test Method : EN455 Part 1:2020
 Testing Period : 07 May 2021 - 28 May 2021

Based on submitted samples, the following results obtained :-

Acceptable Quality Limit (AQL) : 1.5 : Accept : 7 : Found : 6

Result : Within AQL

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



CHEE TUCK CHOON
 SECTION HEAD
 IKM No. M3983/6401/12/14

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Test Report No. : CPSA/210562863-CA64055
 Company : Maxter Glove Manufacturing Sdn Bhd
 Lot 6070, Jalan Haji Abdul Manan,
 6th Miles Off Jalan Meru,
 41050 Klang, Selangor, Malaysia

TEST REPORT

Sample Description : Latex Examination Gloves (Powdered)
 Lot No. : 6110206188
 Manufacturer : Maxter Glove Manufacturing Sdn Bhd
 Size : Medium
 Quantity Tested : 13 pieces
 Test Conducted : Dimensions
 Test Method : EN 455 Part 2:2015
 Testing Period : 07 May 2021 - 28 May 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	95	95	95	95	95	95	95	95	95	95	95	96	95	
Median: 95+10mm														
Length	259	251	250	256	256	257	257	249	255	250	258	250	255	
Median: ≥ 240mm														

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Test Report No. : CPSA/210562863-CA64055
 Company : Master Glove Manufacturing Sdn Bhd
 Lot 6070, Jalan Haji Abdul Manan,
 6th Miles Off Jalan Meru,
 41050 Klang, Selangor, Malaysia

TEST REPORT

Sample Description : Latex Examination Gloves (Powdered)
 Lot No. : 6110206188
 Manufacturer : Master Glove Manufacturing Sdn Bhd
 Size : Medium
 Sample Quantity : 13 pieces per test
 Test Conducted : Force at Break During Shelf Life and After Challenge
 Test Method : EN455 Part 3:2015
 Ageing : 70 ± 2 Deg.C for 168 hrs
 Testing Period : 07 May 2021 - 28 May 2021

SIZE	SAMPLE NO.	Force at Break, N	
		BEFORE AGING	AFTER AGING
M	1	8.2	9.1
	2	8.7	9.0
	3	10.0	8.8
	4	8.8	7.9
	5	8.4	8.3
	6	9.1	8.6
	7	8.3	8.1
	8	9.2	8.9
	9	8.1	9.1
	10	9.1	8.3
	11	9.9	8.5
	12	8.5	9.1
	13	9.1	10.0
Median		8.8	8.8
Requirement		≥ 6.9	≥ 6.8

Test Report No. : CPSA/210562863-CA64055
 Company : Master Glove Manufacturing Sdn Bhd
 Lot 6070, Jalan Haji Abdul Manan,
 6th Miles Off Jalan Meru,
 41050 Klang, Selangor, Malaysia

TEST REPORT

Sample Description : Latex Examination Gloves (Powdered)
 Lot No. : 6110206188
 Manufacturer : Master Glove Manufacturing Sdn Bhd
 Size : Medium
 Quantity Tested : 2 pieces
 Test Conducted : Powder Content
 Test Method : EN455 Part 3:2015
 Testing Period : 07 May 2021 - 28 May 2021

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

SIZE	Average Powder Mass per Glove
M	6.70 mg

Test Report No. : CPSA/210562863-CA64055
 Company : Master Glove Manufacturing Sdn Bhd
 Lot 6070, Jalan Haji Abdul Manan,
 6th Miles Off Jalan Meru,
 41050 Klang, Selangor, Malaysia

TEST REPORT

Sample Description : Latex Examination Gloves (Powdered)
 Lot No. : 6110206188
 Manufacturer : Master Glove Manufacturing Sdn Bhd
 Size : Medium
 Quantity Tested : 8 pieces
 Test Conducted : Aqueous Extractable Protein Content
 Test Method : EN455 Part 3:2015
 Testing Period : 07 May 2021 - 28 May 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
M	52

Note: Detection limit = 10 µg/g

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Customer details: Maxter Glove Manufacturing Sdn Bhd
Lot 6070
Jalan Haji Abdul Manan
6th Miles off Jalan Meru
41050 Klang
Selangor
Malaysia

SATRA reference: CHM0277509/1844/JH
/B/Final

Your reference:

Date of report: 19th December 2018

Samples received: 12th November 2018

Date(s) work carried out: 25th to 26th November 2018

TECHNICAL REPORT

Subject: EN 374-4:2013 determination of resistance to degradation by chemicals on gloves described as Latex Powdered Glove SSLPLP

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.

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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

(Page 1 of 6)

SATRA Technology Centre Ltd (a subsidiary of SATRA). Registered in England No. 3892296 at the above address.

WORK REQUESTED:

Samples of gloves described as Latex Powdered Glove SSLPLP colour beige were received on the 12th November 2018 for testing in accordance with EN 374-4:2013.

SAMPLES SUBMITTED:



Samples described as Latex Powdered Glove SSLPLP colour beige

CONCLUSION:

When assessed in accordance with EN 374-4:2013 the samples of gloves described as Latex Powdered Glove SSLPLP colour beige achieved the following degradation results:

Chemical	Mean degradation / %
n-Heptane (CAS: 142-82-5)	66.2
25% Ammonium hydroxide (CAS: 1336-21-6)	-78.8
96% Sulphuric acid (CAS: 7664-93-9)	95.2
30% Hydrogen peroxide (CAS: 7722-84-1)	-6.0
37% Formaldehyde (CAS: 50-00-0)	-19.2

TESTING REQUIRED:

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

Maxter Glove Manufacturing Sdn Bhd
SATRA Reference: CHM0277509/1844/JH/B/Final
Date: 19th December 2018 (Page 2 of 6)

Signed:

RESULTS:

Sample description:	Latex Powdered Glove SSLPLP		
Challenge chemical:	n-Heptane (CAS: 142-82-5)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	87.7	46.1	64.8
Mean degradation (DR) / %:	66.2		
Standard deviation (σ_{DR}) / %:	20.9		
UoM / ± %:	50.3		
Appearance of samples after testing:	Discoloured		

Sample description:	Latex Powdered Glove SSLPLP		
Challenge chemical:	25% Ammonium hydroxide (CAS: 1336-21-6)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	-98.9	-76.2	-61.2
Mean degradation (DR) / %:	-78.8		
Standard deviation (σ_{DR}) / %:	19.0		
UoM / ± %:	23.7		
Appearance of samples after testing:	Swollen		

Sample description:	Latex Powdered Glove SSLPLP		
Challenge chemical:	96% Sulphuric acid (CAS: 7664-93-9)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	96.5	95.6	93.4
Mean degradation (DR) / %:	95.2		
Standard deviation (σ_{DR}) / %:	1.6		
UoM / ± %:	<5		
Appearance of samples after testing:	Shrunk, disintegrated and discoloured		

Maxter Glove Manufacturing Sdn Bhd
 SATRA Reference: CHM0277509/1844/JH/B/Final
 Date: 19th December 2018 (Page 3 of 6)

Signed:



Sample description:	Latex Powdered Glove SSLPLP		
Challenge chemical:	30% Hydrogen peroxide (CAS: 7722-84-1)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	-33.7	-6.0	21.7
Mean degradation (DR) / %:	-6.0		
Standard deviation (σ_{DR}) / %:	27.7		
UoM / ± %:	26.5		
Appearance of samples after testing:	Slightly swollen		

Sample description:	Latex Powdered Glove SSLPLP		
Challenge chemical:	37% Formaldehyde (CAS: 50-00-0)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	-26.5	-8.3	-22.9
Mean degradation (DR) / %:	-19.2		
Standard deviation (σ_{DR}) / %:	9.7		
UoM / ± %:	25.6		
Appearance of samples after testing:	Slightly swollen		

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

Maxter Glove Manufacturing Sdn Bhd
 SATRA Reference: CHM0277509/1844/JH/B/Final
 Date: 19th December 2018 (Page 4 of 6)

Signed:



Customer details: Master Glove Manufacturing Sdn Bhd
Lot 6070
Jalan Haji Abdul Manan
6th Miles off Jalan Menu
41050 Klang
Selangor
Malaysia

SATRA reference: CHM0277509 /1844
/SPT /1

Your reference:

Date of report: 22 November 2018

Samples received: 12 November 2018

For the attention of: Yap Peak Geeh

Date(s) work carried out: 21 November 2018

TECHNICAL REPORT

Subject: Testing of gloves identified as Latex (powder free) glove MTCLPF 57 in accordance with EN 420:2003+A1:2009 clause 5 Sizing and Dexterity and EN 374-2:2014

Conditions of issue:

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

Report signed by: Sue Clayton
Position: Technologist
Department: Safety Product Testing

(Page 1 of 6)

SATRA Technology Centre Ltd (a subsidiary of SATRA) Registered in England No. 5854296 at the above address.

Work Requested

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

Table 1 - Samples received

Sample description as stated by the client	Sizes submitted for testing	Colour of samples submitted	Approximate weight of one glove
Latex (powder free) glove MTCLPF 57	XS - XL	Cream	Size: XS Weight: 4.8 g



Latex (powder free) glove MTCLPF 57

Conclusion

Standard	Clause / Property	Result
EN 420:2003+A1:2009	5.1 Sizing	PASS
	5.2 Dexterity	Level 5
EN 374-2:2014	7.2 Air leak test	See Note *
	7.3 Water leak test	PASS

Note * - As per clause 4.3 of EN 374-2:2014, the gloves submitted for testing were found to be unsuitable for the Air leak test. Therefore, as per EN 374-2, only the Water leak test has been performed.

Master Glove Manufacturing Sdn Bhd
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Signed:

Testing

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

Requirements

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

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

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

Table 3 - Requirements for EN 374-2: 2014

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

Test Results

Table 4 - EN 420:2003 + A1:2009 Test results for gloves identified as Latex (powder free) glove MTCLPF 57

Clause / Test	Test Results		UoM	Result
5.1 Sizing	Size	Length / mm		
		Left	Right	
	XS / 6	255	257	
	Comments on fit: Satisfactory			
	S / 7	258	261	
	Comments on fit: Satisfactory			
	M / 8	255	253	
	Comments on fit: Satisfactory			
	L / 9	263	255	
	Comments on fit: Satisfactory			
	XL / 10	266	267	
	Comments on fit: Satisfactory			
5.2 Dexterity	Size	Minimum pin diameter / mm		
	XS / 6	5.0		
	S / 7	5.0		
	M / 8	5.0		
	L / 9	5.0		
	XL / 10	5.0		
			N/A	Level 5

Table 5 - EN 374-2:2014 Test results for gloves identified as Latex (powder free) glove MTCLPF 57

Clause / Test	Test Results		UoM	Result
7.2 Air leak test	Total air pressure used:	2.50 kPa		
	Sample size	Leaks		
	XS / 6			
	S / 7			
	M / 8	See Note •		
	L / 9			
	XL / 10			
7.3 Water leak test	Sample size	Leaks		
	XS / 6	No leaks detected		
	S / 7	No leaks detected		
	M / 8	No leaks detected		
	L / 9	No leaks detected		
	XL / 10	No leaks detected		
			N/A	PASS

Thank you!



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