



VERIDIA

Certification Pack.

Latex Gloves Powder Free.



This pack contains
TGA Certificate
Test Report

Date Released

September 2021



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

| | | |
|--------------------------------|---|--|
| Summary for ARTG Entry: | 138392 | Medical Industries Australia Hold Co Pty Ltd- Glove, <specify> |
| ARTG entry for | Medical Device Included Class 1 | |
| Sponsor | Medical Industries Australia Hold Co Pty Ltd | |
| Postal Address | 2 Imperata Close, Kemps Creek, NSW, 2178 Australia | |
| ARTG Start Date | 10/05/2007 | |
| Product Category | Medical Device Class 1 | |
| Status | Active | |
| Approval Area | Medical Devices | |

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

| Name | Address |
|--------------------------------------|---|
| Supermax Glove Manufacturing Sdn Bhd | Lot 38 Putra Industrial Park Bukit Rahman Putra 47000 Sungai Buloh Selangor, Darul Ensan, Malaysia |

Products

| 1 . Glove, <specify> | | | |
|-------------------------|---|----------------|--|
| Product Type | | Effective Date | |
| Single Device Product | | 10/05/2007 | |
| GMDN | 11879 Glove, <specify> | | |
| Intended Purpose | A device acting as a protective barrier between the user's hand or hands and the external environment. This will typically be, e.g. an infection barrier between patient and healthcare provider or as an overall protection of the skin of the hand and fingers. The device may also provide therapeutic protection. | | |

Specific Conditions
No Specific Conditions included on Record

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Public Summary

Report No : **CRSSA/07452/17**
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 : Non Sterile Powder Free Latex Examination Gloves
Lot No. : Size S-67201 98996, Size M-67202 98997, Size L-67203 98998
Size : Small, Medium, Large
Quantity Tested : 200 pieces
Test Conducted : Freedom from holes
Test Method : EN455 Part 1:2000
Testing Period : 08 June 2017 – 15 June 2017

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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TECHNICAL MANAGER

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Report No : **CRSSA/07453/17**
 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 : Non Sterile Powder Free Latex Examination Gloves
 Lot No. : Size S-67201 98996, Size M-67202 98997, Size L-67203 98998
 Size : Small, Medium, Large
 Quantity Tested : 13 pieces
 Test Conducted : Dimensions
 Test Method : EN 455 Part 2:2015
 Testing Period : 08 June 2017 – 15 June 2017

Based on submitted samples, the following results obtained :-

| Size | S | S | M | M | M | M | M | M | M | M | L | L | L |
|-----------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Width | | | | | | | | | | | | | |
| Median: | | | | | | | | | | | | | |
| S: 80±10mm | 83 | 83 | 93 | 92 | 92 | 92 | 92 | 93 | 93 | 92 | 103 | 103 | 103 |
| M: 95±10mm | | | | | | | | | | | | | |
| L: 110±10mm | | | | | | | | | | | | | |
| Length | | | | | | | | | | | | | |
| Median: ≥ 240mm | 245 | 241 | 245 | 240 | 240 | 240 | 240 | 245 | 240 | 241 | 245 | 246 | 246 |

Acceptable Quality Limit (AQL) : 4.0 Accept : 1 Found : 0

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Report No : **CRSSA/07454/17**
 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 : Non Sterile Powder Free Latex Examination Gloves
 Lot No. : Size S-67201 98996, Size M-67202 98997, Size L-67203 98998
 Size : Small, Medium, Large
 Test Conducted : Force at Break before aging and after aging
 Test Method : EN 455 Part 2:2015
 Ageing : 70 ± 2 Deg C for 168 hrs
 Testing Period : 08 June 2017 – 21 June 2017

| SIZE | SAMPLE NO. | Force at Break, N | |
|--------------------|------------|----------------------|---------------------|
| | | <u>BEFORE AGEING</u> | <u>AFTER AGEING</u> |
| S | 1 | 10.5 | 9.9 |
| | 2 | 10.0 | 11.1 |
| M | 3 | 9.8 | 8.7 |
| | 4 | 10.8 | 9.0 |
| | 5 | 10.9 | 10.6 |
| | 6 | 10.0 | 7.8 |
| | 7 | 10.7 | 7.7 |
| | 8 | 10.1 | 9.7 |
| L | 9 | 10.2 | 9.5 |
| | 10 | 12.4 | 10.2 |
| | 11 | 10.9 | 13.2 |
| | 12 | 14.2 | 11.8 |
| | 13 | 12.8 | 11.7 |
| Median Requirement | | 10.7 ≥ 6.0 | 9.9 ≥ 6.0 |

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Report No : **CRSSA/07455/17**
 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 : Non Sterile Powder Free Latex Examination Glove |
 Lot No. : Size S-67201 98996, Size M-67202 98997, Size L-67203 98998
 Size : Small, Medium, Large
 Quantity Tested : 8 pieces
 Test Conducted : Aqueous Extractable Protein Content
 Test Method : EN455 Part 3:2015
 Testing Period : 08 June 2017 – 23 June 2017

EXTRACTABLE PROTEIN CONTENT

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

| SIZE | AQUEOUS EXTRACTABLE PROTEIN CONTENT, µg/g |
|------|---|
| S | NOT DETECTED |
| M | NOT DETECTED |
| L | 10 |

Note: Detection limit = 10µg/g

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Report No : **CRSSA/07456/17**
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 : Non Sterile Powder Free Latex Examination Gloves
Lot No. : Size S-67201 98996, Size M-67202 98997, Size L-67203 98998
Size : Small, Medium, Large
Quantity Tested : 5 pieces
Test Conducted : Powder Content
Test Method : EN455 Part 3:2015
Testing Period : 08 June 2017 – 23 June 2017

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

| <u>SIZE</u> | <u>Average Powder Mass per Glove</u> |
|-------------|--------------------------------------|
| S | 0.26 mg |
| M | 0.32 mg |
| L | 0.46 mg |

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