



America

CERTIFICATE

No. QS6 124500 0001 Rev. 00

Certificate Holder:

Eco Medi Glove Sdn Bhd
Lot 23826, Jalan Tembaga Kuning
Kamunting Raya Industrial Estate
34600 Kamunting, Taiping, Perak
MALAYSIA

Certification Mark:



Scope of Certificate:

Production of Non-Sterile Nitrile Examination Gloves for Medical Use

Standard(s):

ISO 13485:2016

Regulatory Authority(ies):

Australia TGA, Health Canada, Japan MHLW / PMDA, USA FDA. See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:

[www.tuvsud.com/ps-cert?q=cert:QS6 124500 0001 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:QS6_124500_0001_Rev_00)

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID:

F007317

Report No.:

721433827

Effective Date:

2024-09-03

Expiry Date:

2027-09-02

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Date of Issue: 2024-09-06

(Renee Walker)
Director, US Certification Body, MHS

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Regulatory Requirements: Audit/Certification Criteria

Australia

- Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure
- Schedule 3, Part 4 – Production Quality Assurance Procedure

Canada

- Medical Device Regulations – Part 1- SOR 98/282

Japan

- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
- Japan PMD Act (as applicable)

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies):

Eco Medi Glove Sdn Bhd

Lot 23826, Jalan Tembaga Kuning, Kamunting Raya Industrial Estate, 34600 Kamunting, Taiping, Perak, MALAYSIA

Eco Medi Glove Sdn Bhd

Lot 26910, Lorong Perusahaan 3/3, Kamunting Raya Industrial Estate, 34600 Taiping, Perak, MALAYSIA



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