



America

CERTIFICATE

No. QS6 109080 0001 Rev. 02

Certificate Holder: Professional Latex Sdn. Bhd.
Lot 20734 & 20735
Lengkungan Perusahaan Kamunting 3/1
Kawasan Perusahaan Kamunting Raya
34600 Kamunting, Perak Darul Ridzuan
MALAYSIA

Certification Mark:



Scope of Certificate: Manufacture of Non-Sterile Latex and
Nitrile Examination Gloves

Standard(s): ISO 13485:2016

Regulatory Authority(ies): 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_109080_0001_Rev.02

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

REPs Facility ID: F005598
Report No.: 721433833
Effective Date: 2024-05-11
Expiry Date: 2027-05-10

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Date of Issue: 2024-06-07

(Renee Walker)
Director, US Certification Body, MHS



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Regulatory Requirements: **Audit/Certification Criteria**

United States

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

Facility(ies):

Professional Latex Sdn. Bhd.

Lot 20734 & 20735, Lengkungan Perusahaan Kamunting 3/1,
Kawasan Perusahaan Kamunting Raya, 34600 Kamunting,
Perak Darul Ridzuan, MALAYSIA

Facility Scopes:

Manufacture of Non-Sterile Latex and Nitrile Examination
Gloves
REPs Facility ID: F005598

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(Renee Walker)
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