

CERTIFICATE

No. QS6 005387 0001 Rev. 00

Regulatory Requirements: Audit/Certification Criteria

Australia

- Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

Brazil

- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada

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

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

Japan

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

Facility(ies):

Thai Nippon Rubber Industry Public Company Limited.
1 Charoenrat Road, Thungwatdon, Sathon, Bangkok 10120,
THAILAND

Thai Nippon Rubber Industry Public Company Limited.
49-49/1, Factory Standard Building Export Zone 1, Laemchabang
Industrial Estate, Moo 5, Thungsukhla, Sriracha, Chonburi 20230,
THAILAND

Thai Nippon Rubber Industry Public Company Limited.
789/139, Pinthong Industrial Estate Building, Moo 1, Nongkham,
Sriracha, Chonburi 20110, THAILAND

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Date of Issue: 2019-02-07



(Arie Henkin)

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Facility Scopes:

Thai Nippon Rubber Industry Public Company Limited.
1 Charoenrat Road, Thungwatdon, Sathon, Bangkok 10120,
THAILAND

Marketing and Sales of Non-Sterile Natural Rubber Latex
Male Condoms and Lubricant Gel for Condoms
DUNS No: 66-129-1530

Thai Nippon Rubber Industry Public Company Limited.
49-49/1, Factory Standard Building Export Zone 1,
Laemchabang Industrial Estate, Moo 5, Thungsukhla, Sriracha,
Chonburi 20230, THAILAND

Manufacturing of Non-Sterile Natural Rubber Latex
Non-Medicated Male Condoms
DUNS No: 67-204-4751

Thai Nippon Rubber Industry Public Company Limited.
789/139, Pinthong Industrial Estate Building, Moo 1, Nongkham,
Sriracha, Chonburi 20110, THAILAND

Design and Manufacturing of Non-Sterile Natural Rubber
Latex Non-Medicated and Medicated Male Condoms and
Lubricant Gel for Condoms
DUNS No: 67-204-5068



(Arie Henkin)

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