





Product Service

Certificate

No. Q6 042866 0030 Rev. 00

Holder of Certificate: Smart Glove Corporation Sdn. Bhd.

Lot 6487, Batu 5 3/4, Sementa

Jalan Kapar

42100 Klang, Selangor

MALAYSIA

Certification Mark:



Scope of Certificate: Production and Distribution of Examination Gloves

(Sterile & Non-Sterile, Powder & Powder-Free) and Sterile Surgical Gloves (Powder & Powder-Free) of

Natural Rubber Latex and Synthetic Latex

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q6 042866 0030 Rev. 00

Report No.: MYQMH1020017-721424931

MYQMH1120057-721426727

 Valid from:
 2022-01-10

 Valid until:
 2025-01-09

Christoph Dicks

Head of Certification/Notified Body

Date, 2022-01-10





Certificate

No. Q6 042866 0030 Rev. 00

Applied Standard(s): EN ISO 13485:2016

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

Facility(ies): Smart Glove Corporation Sdn. Bhd.

Lot 6487, Batu 5 3/4, Sementa, Jalan Kapar, 42100 Klang, Selangor,

MALAYSIA

See Scope of Certificate

GX CORPORATION SDN. BHD.

Lot 6491, Batu 5 3/4, Sementa, Jalan Kapar, 42100 Klang, Selangor,

MALAYSIA

Production and Distribution of Non Sterile Examination Glove from Natural Rubber Latex & Synthetic Latex (Powder and Powder Free)

Platinum Glove Industries Sdn. Bhd.

Lot 6491-A, Batu 5 3/4, Sementa, Jalan Kapar, 42100 Klang,

Selangor, MALAYSIA

Production and Distribution of Non Sterile Examination Glove from Natural Rubber Latex & Synthetic Latex (Powder and Powder Free)

Sigma Glove Industries Sdn. Bhd.

Lot 6497, Batu 5 3/4, Sementa, Lorong Abdul Manan, 42100 Klang,

Selangor, MALAYSIA

Production and Distribution of Non Sterile Examination Glove from Natural Rubber Latex & Synthetic Latex (Powder and Powder Free)

GX CORPORATION SDN BHD (SPECIALTY PLANT)

Plot 6497-A, Lorong Haji Abdul Manan, 5 3/4 Milestone, Sementa,

Jalan Kapar, 42100 Klang, Selangor, MALAYSIA

Production and Distribution of:

1. Non Sterile Examination Glove from Natural Rubber Latex &

Synthetic Latex (Powder and Powder Free)

2. Sterile Examination Glove From Natural Rubber Latex & Synthetic

Latex (Powder & Powder Free)

PT Smart Glove Indonesia

JL Pelita Raya No. 5-7, Kawasan Industri, Medan Star, Tanjung

Morawa, Deli Serdang, Kode Pos, 20362 Sumatera Utara,

INDONESIA

Production and Distribution of Non Sterile Examination Glove from Natural Rubber Latex & Synthetic Latex (Powder and Powder Free)

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