





CE 2777 Certificate

Production ouality Assurance System Directive 93/42/EEC on Medical Devices (MDD), Annex V (Devices in Class IIa, IIb or III)

No. G2 0493 Rev. 03

Manufacturer: Route 1, Long Thanh Industrial Zone

Long Thanh District, Dong Nai Province

76211, Vietnam

Trade Mark: Superieur Gloves.

Product Latex and Nitrile Surgical Powder

Category(ies): free Glove, Sterile

The Certification Body of TUV SUD Product Service GmbH declares that the aforementioned manufacturer has implemented aquality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class lib and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: MYQMH0319070Rev2-721358413

Valid from: 2020-02-19 2024-07-28 Valid until:

Date, 2020-02-19

> Christoph Dicks Head of Certification/Notified Body











Certificate

No. P2 075269 0011 Rev. 003

Holder of Certificate: Route 1, Long thanh Industrial zone

Long thanh District, Dong Nai Province

76211, Vietman.

Facility(ies):

Route 1, Long Thanh Industrial Zone
Long Thanh District, Dong Nai Province

76211, Vietnam.

Report Certification: EN 388: 2 PROTECTIVE GLOVES AGAINST CHEMICAL RISKS

EN 455: 1 Medical Gloves for Single use, Requirements and testing

for freedom from holes.

EN 455: 2 Medical Gloves for Single use, Requirements and testing

for physical properties.

EN 455





Scope of Certificate: 1. Non-S

1. Non-Sterile Natural Rubber Nitrile Gloves.

2. Non-Sterile Synthetic Rubber Latex Examination

Glove

3. Sterile Natural Rubber Nitrile Surgical Glove

4. Sterile Synthetic Rubber Latex Surgical Glove

Applied Standard(s): EN ISO 13485:2016

Medical devices - Quality management systems -

Requirements for regulatory purposes

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

The Certification Body of TUV SUD 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). See also notesoverleaf.

Report No.: MYQMH1218060-79359813

Valid from: 2019-05-05 Valid until: 2020-06-30

Date, 2019-05-05

Stefan Prei£

1. Purmit