ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 089752 0007 Rev. 06

Holder of Certificate: **Hartalega NGC Sdn. Bhd.**
No.1, Persiaran Tanjung
Kawasan Perindustrian Tanjung
43900 Sepang, Selangor Darul Ehsan
MALAYSIA

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design and Development, Production, and Distribution of Non-Sterile Powdered and Powder-Free Natural Latex and Nitrile Examination Gloves, Sterile Powder-Free Natural Latex and Nitrile Examination Gloves, Non-Sterile Powder-Free Polychloroprene Examination Gloves and Sterile Surgical Gloves**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 089752 0007 Rev. 06

Report No.: 721436013

Valid from: 2026-01-12
Valid until: 2029-01-11

Date, 2026-01-12

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Heruntergeladen von Gast (IP 216.73.217.10) am 25.11.2026 um 00:22 Uhr · sana.swiss

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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TÜV SÜD Product Service

Certificate

No. Q5 089752 0007 Rev. 06

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

Hartalega NGC Sdn. Bhd.
No.1, Persiaran Tanjung, Kawasan Perindustrian Tanjung, 43900 Sepang, Selangor Darul Ehsan, MALAYSIA

Design and Development, Production, and Distribution of Non-Sterile Powdered and Powder-Free Natural Latex and Nitrile Examination Gloves, Sterile Powder-Free Natural Latex and Nitrile Examination Gloves, Non-Sterile Powder-Free Polychloroprene Examination Gloves and Sterile Surgical Gloves

Hartalega NGC Sdn. Bhd.
No. 2 (Lot 39496), Persiaran Tanjung, Kawasan Perindustrian Tanjung, Jalan B20, 43900 Sepang, Selangor Darul Ehsan, MALAYSIA

Design and Development, Production, and Distribution of Non-Sterile Powdered and Powder-Free Natural Latex and Nitrile Examination Gloves, Sterile Powder-Free Natural Latex and Nitrile Examination Gloves, and Non-Sterile Powder-Free Polychloroprene Examination Gloves

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