



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:**



**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](http://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



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**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