



# Certificate

No. Q5 002160 0005 Rev. 00

**Holder of Certificate:** **Nitto Denko Asia Technical Centre  
Pte Ltd**  
3 Biopolis Drive  
Synapse Building #03-17/18  
Singapore 138623  
SINGAPORE

**Certification Mark:**



**Scope of Certificate:** **Design & Development, Production,  
Servicing and Distribution of In Vitro  
Diagnostic System (Reagents and  
Instruments) used for quantitative  
determination of albumin, creatinine, and  
albumin/creatinine ratio (UACR) in human  
urine**

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 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:Q5 002160 0005 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:Q5 002160 0005 Rev. 00)

**Report No.:** SIN\_002160\_CA\_2021

**Valid from:** 2022-03-16  
**Valid until:** 2025-03-15

**Date,** 2022-03-16

Christoph Dicks  
Head of Certification/Notified Body

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**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):** Nitto Denko Asia Technical Centre Pte Ltd  
3 Biopolis Drive, Synapse Building #03-17/18, Singapore 138623,  
SINGAPORE

See Scope of Certificate