



# Certificate

No. Q5 003496 0005 Rev. 00

**Holder of Certificate:** **AusDiagnostics Pty Ltd**  
290 - 292 Coward Street  
Mascot NSW 2020  
AUSTRALIA

**Certification Mark:**



**Scope of Certificate:** **Design and development, production, distribution and service of in-vitro diagnostics medical devices (reagents) for detection of clinically relevant nucleic acid sequences for the area of human infections and genetic disorders**

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\\_003496\\_0005\\_Rev.\\_00](http://www.tuvsud.com/ps-cert?q=cert:Q5_003496_0005_Rev._00)

**Report No.:** SIN\_5010329172\_SA1\_CC1\_2020

**Valid from:** 2021-01-11  
**Valid until:** 2022-10-27

**Date,** 2021-01-11



Christoph Dicks  
Head of Certification/Notified Body



Product Service

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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):** AusDiagnostics Pty Ltd  
 290 - 292 Coward Street, Mascot NSW 2020, AUSTRALIA

Design and development, production, distribution and service of in-vitro diagnostics medical devices (reagents) for detection of clinically relevant nucleic acid sequences for the area of human infections and genetic disorders

AusDiagnostics UK Ltd  
 Unit 3, Anglo Business Park, Asheridge Road, Chesham,  
 Buckinghamshire HP5 2QA, UNITED KINGDOM

Production, distribution of in-vitro diagnostics medical devices (reagents) for detection of clinically relevant nucleic acid sequences for the area of human infections and genetic disorders