



Certificate

No. Q5 003496 0005 Rev. 01

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

Certification Mark:



Scope of Certificate: **Design and development, production, distribution, installation and servicing of in-vitro diagnostics medical devices, including instruments for detection of clinically relevant nucleic acid sequences for the area of human infections and genetic disorders and the distribution of in-vitro diagnostics medical devices for detection of antigens indicative of infection**

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._01

Report No.: SIN_5010329172_RA_CC1_2022
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Valid from: 2022-10-28
Valid until: 2025-10-27

Date, 2022-10-25



Christoph Dicks
Head of Certification/Notified Body

Certificate

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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, installation and servicing of in-vitro diagnostics medical devices, including instruments for detection of clinically relevant nucleic acid sequences for the area of human infections and genetic disorders and the distribution of in-vitro diagnostics medical devices for detection of antigens indicative of infection

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

Production, distribution, installation and servicing of in-vitro diagnostics medical devices, including instruments for detection of clinically relevant nucleic acid sequences for the area of human infections and genetic disorders and the distribution of in-vitro diagnostics medical devices for detection of antigens indicative of infection

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