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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 003496 0007 Rev. 00

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

Product Category(ies): **Products for determination of infection markers**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. 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:V1 003496 0007 Rev. 00

Report no.: SIN_5010329172_EXT_2021

Valid from: 2021-10-28
Valid until: 2024-05-26

Date, 2021-10-26

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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

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No. V1 003496 0007 Rev. 00

Model(s):

In-Vitro Diagnostic Medical Devices for Detection of Nucleic Acid Sequences including those of Chlamydia and/or Cytomegalovirus

Facility(ies):

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

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

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