



# 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 0006 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\\_0006\\_Rev.00](http://www.tuvsud.com/ps-cert?q=cert:V1_003496_0006_Rev.00)

**Report no.:** SIN\_5010329172\_CC2\_2020

**Valid from:** 2020-12-16

**Valid until:** 2021-10-27

**Date,** 2020-12-16

Christoph Dicks  
Head of Certification/Notified Body



# 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 0006 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