

TUV SUD  
ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT



Product Service

# Certificate

No. Q5 003496 0003 Rev. 00

**Holder of Certificate:** AusDiagnostics Pty Ltd

290 - 292 Coward Street  
Mascot NSW 2020  
AUSTRALIA

**Facility(ies):**

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

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

**Certification Mark:**



**Scope of Certificate:** Design and Development, Production, Distribution and Service of In-Vitro Diagnostic Medical Devices for Detection of Nucleic Acids Sequences specific to Pathogens including Chlamydia and/or Cytomegalovirus

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)  
DIN EN ISO 13485:2016

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). See also notes overleaf.

**Report No.:** SIN\_5010329172\_CC1\_2018

**Valid from:** 2019-01-21  
**Valid until:** 2019-10-27

**Date,** 2019-01-21 Stefan Preiß