



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 18 02 03496 002

Manufacturer: **AusDiagnostics Pty Ltd**

290 - 292 Coward Street
Mascot NSW 2020
AUSTRALIA



EC-Representative: **AusDiagnostics UK Ltd**

Unit 3
Anglo Business Park
Asheridge Road
Chesham
Buckinghamshire HP5 2QA
UNITED KINGDOM

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. See also notes overleaf.

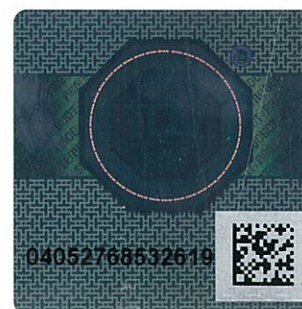
Report No.: SIN_5010329172_CC2_2018

Valid from: 2018-04-24

Valid until: 2021-10-27

Date, 2018-04-24

Stefan Preiß



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

Page 1 of 2



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 18 02 03496 002

Model(s):

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

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