ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 16 07 93875 003

Manufacturer:

AusDiagnostics Pty Ltd
205 Victoria Street
Beaconsfield NSW 2015
AUSTRALIA

EC-Representative:

AusDiagnostics UK Ltd
Unit 3 (Ground Floor)
Angio 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_CA2_2016

Valid from: 2016-10-28
Valid until: 2021-10-27

Date, 2016-10-26

Stefan Preiß

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

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Product Service

EC Certificate
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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 16 07 93875 003

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
205 Victoria Street, Beaconsfield NSW 2015, AUSTRALIA

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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