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 17 10 02532 003

Manufacturer:

DIAsource ImmunoAssays S.A.
In der Au 29
61440 Oberursel
GERMANY

Facility(ies):

DIAsource ImmunoAssays S.A.
In der Au 29, 61440 Oberursel, GERMANY

Product Category(ies):

Products for determination of infection markers Chlamydia, Rubella, Toxoplasma, Cytomegalovirus

Model(s):

ELISA and IFA for the determination of antibodies against Chlamydia, Rubella, Toxoplasma and Cytomegalovirus

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.: 713119029 / 713113406

Valid from: 2017-10-20
Valid until: 2019-02-10

Date, 2017-10-20

Stefan Preiß

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

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

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