ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

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 058438 0013 Rev. 01

Manufacturer: **AB ANALITICA Srl**
Via Svizzera, 16
35127 Padova
ITALY

Facility(ies): AB ANALITICA Srl
Via Svizzera, 16, 35127 Padova, ITALY

Product Category(ies): **Reagents for determination of infection markers and HLA Typing**

Model(s): **Product for identification of Hepatitis C Virus Genotypes as specified in the corresponding Design Examination certificate.
Products according to annex II list B: End-point and Realtime nucleic acid amplification tests for the determination of the infection markers
for Chlamydia, Cytomegalovirus and Toxoplasma (AMPLIQUALITY, REALQUALITY).
Nucleic acid amplification tests for genetic predisposition tests based on HLA tissue typing (GENEQUALITY).**

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 058438 0013 Rev. 01

Report no.: ITA1886889_SCN

Valid from: 2022-04-22
Valid until: 2025-05-26

Date, 2022-04-22

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany