ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ 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 09 76205 010

Manufacturer:

Fast Track Diagnostics Luxembourg S.à.r.l.
29, rue Henri Koch
4354 Esch-sur-Alzette
LUXEMBOURG

Facility(ies):

Fast Track Diagnostics Luxembourg S.à.r.l.
29, rue Henri Koch, 4354 Esch-sur-Alzette, LUXEMBOURG

Product Category(ies):

Products for determination of infection markers

Model(s):

Products for the determination of the infection markers Chlamydia 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.

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Valid from: 2016-11-20
Valid until: 2021-11-19

Date, 2016-10-18

Stefan Preiß

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

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