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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

C E R T I F I C A T E

No. QS6 076205 0016 Rev. 00

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

Certification Mark:

Scope of Certificate: **Design and Development and Manufacture of In-Vitro Diagnostic Reagents and In-Vitro Diagnostic Test Kits used in the Diagnosis and Detection of Disease Status, Sexually Transmissible Agents and Transmissible Agents**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Health Canada. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: **37-050-3977**

Effective Date: **2020-06-12**

Expiry Date: **2023-06-11**

Date of Issue: 2020-07-02

(Tina Israel)
Manager, US Certification Body,
Medical and Health Services

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Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002 - Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Canada
- Medical Device Regulations – Part 1- SOR 98/282

Facility(ies): Fast Track Diagnostics Luxembourg S.à.r.l.
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Facility Scopes: Design and Development and Manufacture of In-Vitro Diagnostic Reagents and In-Vitro Diagnostic Test Kits used in the Diagnosis and Detection of Disease Status, Sexually Transmissible Agents and Transmissible Agents
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