



Product Service

# Certificate

No. Q5 076205 0014 Rev. 01

**Holder of Certificate:** **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

**Certification Mark:**



**Scope of Certificate:** **Design and development, production and  
distribution of nucleic acid based in vitro  
diagnostics**

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** 713157879

**Valid from:** 2019-09-10

**Valid until:** 2022-09-09

**Date,** 2019-09-10

Stefan Preiß  
Head of Certification/Notified Body

TÜV SÜD  
ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFIKAT