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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 070202 0006 Rev. 01

Holder of Certificate: **AmplexDiagnostics GmbH Gesellschaft für molekularbiologische Diagnostik**
Werkstr. 2
83555 Gars-Bahnhof
GERMANY

Facility(ies): AmplexDiagnostics GmbH Gesellschaft für molekularbiologische Diagnostik
Werkstr. 2, 83555 Gars-Bahnhof, GERMANY

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design and development, production, distribution, installation and servicing of instruments and test kits for nucleic acid based in-vitro diagnostics for determination of infection markers**

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.: 713172242

Valid from: 2020-03-04
Valid until: 2022-02-28

Date, 2020-03-04

Christoph Dicks
Head of Certification/Notified Body

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

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