



Certificate

No. Q5 070202 0006 Rev. 00

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:



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.: 713144629

Valid from: 2019-03-01

Valid until: 2022-02-28

Date, 2019-02-12

Stefan Preiß