

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



Product Service

Certificate

No. Q5 104507 0001 Rev. 01

Holder of Certificate: **ACON Laboratories, Inc.**
 5850 Oberlin Drive, #340
 San Diego CA 92121
 USA

Certification Mark:



Scope of Certificate: **Design and Development, Manufacture and distribution of In Vitro Diagnostic Test Kits and Reagents for the Determination of Infectious Diseases, Clinical Chemistry, Drugs of Abuse, Tumor/Cardiac Marker, Fertility/Pregnancy and Blood Glucose Monitoring System, Lancing Devices and Lancets**

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.: SH1974310

Valid from: 2019-10-24
Valid until: 2022-09-06

Date, 2019-10-24

Stefan Preiß
 Head of Certification/Notified Body

Certificate

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

Facility(ies):

- ACON Laboratories, Inc.
5850 Oberlin Drive, #340, San Diego CA 92121, USA
- ACON Laboratories, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA
- ACON Laboratories, Inc.
6865 Flanders Dr., Suite B, San Diego CA 92121, USA
- AZURE Institute, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA