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

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:**

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

**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

Digitally signed by Monastîrschii Viorica
Date: 2020.09.25 10:56:55 MSK
Reason: MoldSign Signature
Location: Moldova


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

TÜV®

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

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## No. Q5 104507 0001 Rev. 01

**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

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

A4 / 07.17


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