



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 104507 0002 Rev. 01

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

Product Category(ies): Lancets, Safety Lancets

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: SH1974310

Valid from: 2019-10-24

Valid until: 2023-09-06

Date, 2019-10-24

Stefan Preiß
Head of Certification/Notified Body

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



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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

AZURE Institute, Inc.
 10125 Mesa Rim Road, San Diego CA 92121, USA

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