



# Certificate

No. Q5 082138 0005 Rev. 01

**Holder of Certificate:** **ACEA Bio (Hangzhou) CO., Ltd.**

Building 5, 2# Xiyuan Wu Road  
Xihu District  
310030 Hangzhou, Zhejiang Province  
PEOPLE'S REPUBLIC OF CHINA

**Facility(ies):**

ACEA Bio (Hangzhou) CO., Ltd.  
Building 5, 2# Xiyuan Wu Road, Xihu District, 310030 Hangzhou,  
Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:**

**Design and Development, Production and Distribution of Real Time Cell Analysis(RTCA) systems and Flow Cytometry products, including Instruments and Consumables(RTCA Plates, Reagents, Cells/Cell Lines, Antibodies)**

**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.:** TAM/SH1875207

**Valid from:** 2018-12-05

**Valid until:** 2021-12-04

**Date,** 2018-11-05

Stefan Preiß

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT