



Product Service

Certificate

No. Q5 085830 0010 Rev. 00

Holder of Certificate: **Access Bio, Inc.**
65 Clyde road
Somerset NJ 08873
USA

Facility(ies): Access Bio, Inc.
65 Clyde road, Somerset NJ 08873, USA

Access Bio, Inc. (Ethiopian Branch)
Yeka Sub-city, Woreda 9, Kebele 16, House No-New, Addis
Ababa, ETHIOPIA

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of in-vitro diagnostic medical devices for infectious diseases and genetic disorders based on immunological and biochemical technologies**

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.: 74955423

Valid from: 2019-12-19

Valid until: 2022-12-18

Date, 2019-11-28

Christoph Dicks
Head of Certification/Notified Body