

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Azure Biotech Inc.
5250 Gulfton St,
Houston TX 77081
USA

has established and applies a quality management system for medical devices
for the following scope:

**Manufacture and Distribution of In Vitro Diagnosis Test kits
of Rapid Test of Fertility, Tumor Markers, Cardiac Markers,
Drug of Abuse and Infectious Disease**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2019-09-03
Certificate Registration No.: SX 60139135 0001
An audit was performed. Report No.: 15096372 002
This Certificate is valid until: 2022-07-02

Certification Body



Date 2019-09-03



Herbert Zhong

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com http://www.tuv.com/safety