

Certificate



Quality Management System
EN ISO 13485:2016

Registration No.: SX 2156044-1

Organization: Phalanx Biotech Group
6F, No.6, Technology 5th Rd., Hsinchu Science Park,
Hsinchu City 30078
Taiwan

Scope: Design and Development, Manufacture and Distribution of Microarray
diagnostic kits used in the detection of inherited disease testing for clinical
laboratory use

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 238492498-025
Effective date: 2021-03-21
Expiry date: 2024-03-20
Issue date: 2021-03-10



Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany