

Certificate

The Certification Body of TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

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

Design and Development, Manufacture and Distribution of Microarray for hereditary disease testing

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:

2018-04-02

Certificate Registration No.:

SX 60127936 0001

An audit was performed. Report No.: 50089963 002

This Certificate is valid until:

2021-03-20

Certification Body



Date 2018-04-02



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