

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 2156044-1
Certificate Holder: Phalanx Biotech Group
4F., No. 66, Shengyi 5th Rd., Zhubei City,
Hsinchu County 302041
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.: 48222674-040
Effective date: 2024-03-21
Expiry date: 2027-03-20
Issue date: 2024-02-29
Replaces certificate SX 2156044-1 issued 2022-09-23

This certificate can be validated on <https://www.certipedia.com>


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