

# Certificate

## Quality Management System

**EN ISO 13485:2016**

**EN ISO 13485:2016/AC:2018**

**EN ISO 13485:2016/A11:2021**

Registration No.: SX 2085126-1

Certificate Holder: Grand Dynasty Industrial  
Co., Ltd. (Doctor Plant)  
No. 2, Sec. 2, Bao'an St., Shulin District,  
New Taipei City 23876  
Taiwan

Scope: Contract Manufacture of Plastic Biochip Frame of IVD  
Instrument used in the Diagnosis of Biological Samples of  
Infectious Diseases

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.: 48250757-050

Effective date: 2025-03-13

Expiry date: 2028-03-12

Issue date: 2025-03-13

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

  
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