

Certificate

Quality Management System EN ISO 13485:2016

Registration No.	SX 2073725-1
Certificate Holder	Shijiazhuang Hipro Biotechnology Co., Ltd. No. 3 Building, Block C, Fangyi Science Park, No. 365 Huai'an East Road, Hi-tech Zone, Shijiazhuang, 050000 Hebei P.R. China
Scope	Design and Development, Manufacture and Distribution of Nephelometric Immunoassay Analyzer, Reagents and Sampling and Sample Injector Units used in the Detection of Blood Analytes, Cardiac Markers, Disease Status, Protein Metabolism, Autoimmune Status, Immune Status including Point of Care In-vitro Diagnostic Devices

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.	190146672-110
Effective date	2023-07-17
Expiry date	2026-07-16
Issue date	2023-06-29
Replaces certificate SX 2073725-1 issued 2023-05-11	

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


Wenxiang Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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