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

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