

Certificate

**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 2084107-1

Organization: Tianjin MNCHIP Technologies Co., Ltd.
A-3, 4F, 122 Dongting Rd, Binhai New Area,
300457 Tianjin
P.R. China

Scope: Design and Development, Manufacture and Distribution of In-vitro Diagnostic Chemistry Analyzers, In-vitro Diagnostic Test Kits used in the Detection of Cardiac Markers, Disease Status, Protein Metabolism and Electrolytes including Home 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.: 190142604-110
Effective date: 2023-02-28
Expiry date: 2023-09-02
Issue date: 2023-02-28



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



Certificate

**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 2084107-1

Organization: Tianjin MNCHIP Technologies Co., Ltd
A-3, 4F, 122 Dongting Rd, Binhai New Area,
300457 Tianjin
P.R. China

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Tianjin MNCHIP Technologies Co., Ltd A-3, 4F, 122 Dongting Rd, Binhai New Area, 300457 Tianjin P.R. China	Design and Development, Manufacture and Distribution of In-vitro Diagnostic Chemistry Analyzers and Design, Development and Distribution of In-vitro Diagnostic Test Kits used in the Detection of Cardiac Markers, Disease Status, Protein Metabolism and Electrolytes including Home Use
/02	c/o Tianjin MNCHIP Technologies Co., Ltd. 2102, 2202, Building 2, No.19 Xinhuan Rd. West, TEDA, 300457 Tianjin P.R. China	Manufacture of In-vitro Diagnostic Test Kits used in the Detection of Cardiac Markers, Disease Status, Protein Metabolism and Electrolytes including Home Use

Report No.: 190142604-110
Effective date: 2023-02-28
Expiry date: 2023-09-02
Issue date: 2023-02-28



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

