Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2186929-1

Organization: Core Technology Co., Ltd.
Room 100, C Building, No.29 Life Park Road, Changping District,
102206 Beijing, P.R. China

Scope: Design and Development, Manufacture and Distribution of In-vitro Diagnostic Test Kits used in the Detection of Fertility Testing, Pregnancy Testing, Drug of Abuse and Cancer, Cardiac Markers, Protein Metabolism and used in Diagnostic of Disease Status, Sexually Transmissible Agents, Transmissible Agents, Infectious Diseases including Home Use, Near Patient In-vitro Diagnostic Devices

Digitally signed by Guțan Ghenadie
Date: 2022.10.31 09:12:15 EET
Reason: MoldSign Signature
Location: Moldova

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.:	190141668 110
Effective date:	2022-10-31
Expiry date:	2025-10-30
Issue date:	2022-10-25

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2186929-1

Organization: Core Technology Co., Ltd.
Room 100, C Building, No.29 Life Park Road, Changping District,
102206 Beijing, P.R. China

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Core Technology Co., Ltd. No.30, Area 9, Douda Avenue, Fangshan District, 102433 Beijing, P.R. China	Design and Development, Manufacture and Distribution of In-vitro Diagnostic Test Kits used in the Detection of Fertility Testing, Pregnancy Testing, Drug of Abuse and Cancer, Cardiac Markers, Protein Metabolism and used in Diagnostic of Disease Status, Sexually Transmissible Agents, Transmissible Agents, Infectious Diseases including Home Use, Near Patient In-vitro Diagnostic Devices

Report No.: 190141668 110
Effective date: 2022-10-31
Expiry date: 2025-10-30
Issue date: 2022-10-25

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02