Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 7091841-1

Organization: Siemens Healthcare Diagnostics Inc.
500 GBC Drive, P.O. Box 6101
Newark, DE 19714
USA

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Siemens Healthcare Diagnostics Inc. 500 GBC Drive, P.O. Box 6101 Newark, DE 19714 USA	Design, development and manufacture of in vitro diagnostic medical devices, including analyzers and software.
/02	c/o Siemens Healthcare Diagnostics Inc. 660 Pencader Dr Glasgow DE 19702 USA	Warehousing and distribution of in vitro diagnostic reagents and controls.

SAO Y BẢN CHÍNH

CÔNG TY TNHH THƯƠNG MẠI-DỊCH VỤ KỸ THUẬT LỤC TỈNH

PHÓ GIÁM ĐỐC
TỐNG THỊ BÍCH TUYỀN

Report No.: 1093283-40
Effective date: 2021-12-14
Expiry date: 2024-12-13
Issue date: 2021-12-13

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Dipl.-Ing. Sven Hoffmann
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

Certificate

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EN ISO 13485:2016

Registration No.: SX 7091841-1

Organization: Siemens Healthcare Diagnostics Inc.
500 GBC Drive, P.O. Box 6101
Newark, DE 19714
USA

Scope: Design, development and manufacture of in vitro diagnostic medical devices (reagents, controls, instruments and software) used in the diagnosis, management and detection of autoimmune status, blood analytes, blood components, cancer, cardiac markers, coagulation, drugs of abuse, endocrine disorders, fertility testing, immune status, pregnancy testing, prenatal screening, protein metabolism, immunological typing and therapeutic drug monitoring.

Name CERT-01220-GLA Version 2.0

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.

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