Người đại diện hợp pháp của cơ sở
KT. Tổng Giám Đốc
CÔNG TY TNHH SIEMENS HEALTHCARE
Phạm Thị Thu Hà
Trưởng phòng quản lý Chất lượng, Tuân thủ và Đối ngoại

Digitally signed by PHẠM THỊ THU HÀ
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CN=PHẠM THỊ THU HÀ; L=HÀ NỘI; C=VN
Date: 2022.03.07 11:40:56 +07'00'

TÜVRheinland®

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1290554-1

Organization:
Siemens Healthcare Diagnostics Inc.
511 Benedict Ave
Tarrytown NY 10591
USA

Scope:
Design and development, manufacture and distribution of in vitro diagnostic medical devices (reagents, controls, instruments and software) used in the diagnosis, detection and management of cancer, genetic testing, prenatal screening, immune status, disease status, autoimmune status, drugs of abuse, cardiac markers, coagulation, protein metabolism, endocrine disorders, blood analytes and blood components, donor screening, transmissible agents, sexually transmissible agents, fertility testing, pregnancy testing, immunological typing and therapeutic drug monitoring, including near-patient in vitro diagnostic medical 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.: 1093003-40
Effective date: 2022-03-04
Expiry date: 2024-12-31
Issue date: 2022-03-04

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

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1290554-1

Organization: Siemens Healthcare Diagnostics Inc.
511 Benedict Ave
Tarrytown NY 10591
USA

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Siemens Healthcare Diagnostics Inc. 511 Benedict Ave Tarrytown NY 10591 USA	Design and development of in vitro diagnostic medical devices (reagents, controls, instruments and software).
/02	c/o Siemens Healthcare Diagnostics Inc. 5210 Pacific Concourse Drive Los Angeles CA 90045 USA	Manufacture of in vitro diagnostic reagent components.
/05	c/o Siemens Healthcare Diagnostics Inc. 62 Flanders-Bartley Road Flanders NJ 07836 USA	Design, development and manufacture of in vitro diagnostic analyzers/software.
/06	c/o Siemens Healthcare Diagnostics Inc. 333 Coney Street East Walpole MA 02032 USA	Manufacture, warehousing and distribution of in vitro diagnostic reagents.

Report No.: 1093003-40
Effective date: 2022-03-04
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Tillystraße 2 · 90431 Nürnberg · Germany

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

Certificate

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Quality Management System
EN ISO 13485:2016

Registration No.: SX 1290554-1

Organization:
Siemens Healthcare Diagnostics Inc.
511 Benedict Ave
Tarrytown NY 10591
USA

The scope of certification also covers the following:

/07	c/o Siemens Healthcare Diagnostics Inc. 02 Edgewater Drive Norwood MA 02062 USA	Design and development of in vitro diagnostic medical devices (reagents, controls, instruments and software).
/08	c/o Siemens Healthcare Diagnostics Inc. 3400 MIDDLEBURY ST ELKHART IN 46516 USA	Manufacture of in vitro diagnostic reagent components.
/09	c/o Siemens Healthcare Diagnostics Inc. 430 South Beiger Street Mishawaka IN 46544 USA	Manufacture of in vitro diagnostic reagents.
/10	c/o Siemens Healthcare Diagnostics Products Limited Glyn Rhonwy Llanberis, Gwynedd LL55 4EL United Kingdom	Design, development and manufacture of in vitro diagnostic medical devices (reagents, controls and software).

Report No.: 1093003-40
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Quality Management System
EN ISO 13485:2016

Registration No.: SX 1290554-1

Organization:
Siemens Healthcare Diagnostics Inc.
511 Benedict Ave
Tarrytown NY 10591
USA

The scope of certification also covers the following:

/11	c/o Siemens Healthcare Diagnostics Manufacturing Ltd Northern Road Chilton Industrial Estate Sudbury Suffolk CO10 2XQ United Kingdom	Manufacture, warehousing and distribution of in vitro diagnostic reagents and analyzers.
/12	c/o Siemens Healthcare Diagnostics Manufacturing Ltd Chapel Lane Swords Co Dublin Ireland	Manufacture, warehousing and distribution of in vitro diagnostic analyzers/software.
/13	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.
/14	c/o Siemens Healthcare Diagnostics Inc. 660 Pencader Dr Glasgow NY 19702 USA	Warehousing and distribution of in vitro diagnostic reagents and controls.

Report No.: 1093003-40
Effective date: 2022-03-04
Expiry date: 2024-12-31
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Quality Management System
EN ISO 13485:2016

Registration No.: SX 1290554-1

Organization: Siemens Healthcare Diagnostics Inc.
511 Benedict Ave
Tarrytown NY 10591
USA

The scope of certification also covers the following:

/15	c/o Siemens Healthcare Diagnostics Inc. 2150 Stanley Road Plainfield IN 46168 USA	Warehousing and distribution of in vitro diagnostic reagents and instruments

Report No.: 1093003-40
Effective date: 2022-03-04
Expiry date: 2024-12-31
Issue date: 2022-03-04

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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

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