

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: The design, development, control of manufacture, control of service and control of distribution of in vitro diagnostic medical devices, in vitro diagnostic test kits, in vitro diagnostic reagents, in vitro diagnostic analyzers/software used in the diagnosis, management of cancer, genetic testing, prenatal screening, immune status, disease status, autoimmune status, drugs of abuse, cardiac markers, 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. Control of manufacture of medical devices used for blood sample collection.

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.: 3325435-90
Effective date: 2020-07-14
Expiry date: 2021-12-31
Issue date: 2020-07-14



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

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

No.	Facility	Scope
/01	Siemens Healthcare Diagnostics Inc. 511 Benedict Ave Tarrytown NY 10591 USA	Design, development and servicing of in vitro diagnostic medical devices, in vitro diagnostic test kits, in vitro diagnostic reagents, in vitro diagnostic analysers/software used in the diagnosis, management of cancer, genetic testing, prenatal screening, immune status, disease status, autoimmune status, drugs of abuse, cardiac markers, 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. Oversight of medical devices original equipment manufacturers (OEM) activities.

Report No.: 3325435-90
Effective date: 2020-07-14
Expiry date: 2021-12-31
Issue date: 2020-07-14



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

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

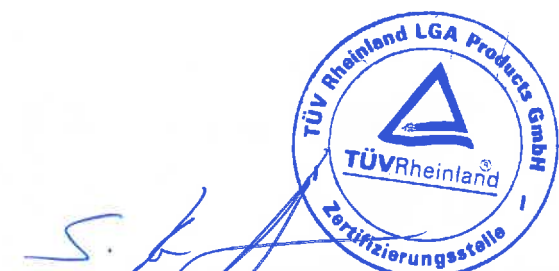
/02	Siemens Healthcare Diagnostics Inc. 5210 Pacific Concourse Drive Los Angeles CA 90045 USA	Manufacture of intermediate components and antisera for use in immunoassay reagents for in vitro diagnostic detection and management of disease status, metabolic disorders, immune status, fertility and therapeutic drug monitoring.
/03	Siemens Healthcare Diagnostics Inc. 45764 Copco Avenue Gorman CA 93243 USA	Development and production of Antisera.
/04	Siemens Healthcare Diagnostics Inc. 725 Potter Street Berkeley CA 94710 USA	Design of in vitro diagnostic reagents, instruments, software and accessories. Oversight over the manufacturing of HCV genotyping assay.
/05	Siemens Healthcare Diagnostics Inc. 62 Flanders-Bartley Road Flanders NJ 07836 USA	Design and manufacture of in vitro diagnostic analytical equipment and associated software design and development.

Report No.: 3325435-90

Effective date: 2020-07-14

Expiry date: 2021-12-31

Issue date: 2020-07-14



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

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

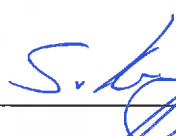
/06	Siemens Healthcare Diagnostics Inc. 333 Coney Street East Walpole MA 02032 USA	Manufacture of In-Vitro Diagnostic and Near Patient In Vitro Devices Used in the Diagnosis and Management of Disease Status including Determination of Blood Analytes and Blood Gases, Infectious Disease Testing of Blood Components, Pregnancy Testing, Immunological Typing, and Therapeutic Drug Monitoring.
/07	Siemens Healthcare Diagnostics Inc. 02 Edgewater Drive Norwood MA 02062 USA	Design and development and servicing of in vitro diagnostic reagents, instruments and accessories. Manufacture of medical device for blood gas sample collection.
/08	Siemens Healthcare Diagnostics Inc. 3400 MIDDLEBURY ST ELKHART IN 46516 USA	Manufacture of in vitro diagnostic urinalysis reagents, urinalysis accessories and in vitro diagnostic reagent components.
/09	Siemens Healthcare Diagnostics Inc. 430 South Beiger Street Mishawaka IN 46544 USA	Manufacture of in vitro diagnostic reagents for urinalysis and diabetes testing.

Report No.: 3325435-90

Effective date: 2020-07-14

Expiry date: 2021-12-31

Issue date: 2020-07-14



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

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

/10 Siemens Healthcare Diagnostics
Products Limited
Glyn Rhonwy
Llanberis, Gwynedd
LL55 EL
United Kingdom

Manufacture and design of in vitro diagnostic reagents and in vitro diagnostic test kits used in the diagnosis, management and detection of autoimmune status, blood components, cancer, cardiac markers, disease status, drugs of abuse, endocrine disorders, fertility testing, immune status, pregnancy testing, prenatal screening, protein metabolism, transmissible agents and therapeutic drug monitoring.

/11 Siemens Healthcare Diagnostics Inc.
Northern Road
Chiltern Industrial Estate
Sudbury
Suffolk
CO10 2XQ
United Kingdom

The manufacture of in vitro diagnostic urinalysis and blood gas diagnostic instruments, associated consumables and reagents.

/12 Siemens Healthcare Diagnostics
Manufacturing Ltd
Chapel Lane
Swords
Co Dublin
Ireland

Manufacture of in vitro diagnostic instruments and accessories.

Report No.: 3325435-90

Effective date: 2020-07-14

Expiry date: 2021-12-31

Issue date: 2020-07-14