

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 1290554-1
Certificate Holder: 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, 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, and therapeutic drug monitoring, including near-patient in vitro diagnostic medical devices. Design, development and manufacture of software products for Point of Care (POC) Data Management.

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.: 1162122-100
Effective date: 2025-01-01
Expiry date: 2027-12-31
Issue date: 2024-12-19
Replaces certificate SX 1290554-1 issued 2022-03-04



Dr. Matthias Fischer
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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USA

The scope of certification also covers the following sites:

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 and instruments).
/05	c/o Siemens Healthcare Diagnostics Inc. 62 Flanders-Bartley Road Flanders NJ 07836 USA	Design, development and manufacture of in vitro diagnostic analyzers.
/06	c/o Siemens Healthcare Diagnostics Inc. 333 Coney Street East Walpole MA 02032 USA	Manufacture, warehousing and distribution of in vitro diagnostic reagents.
/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 and instruments).
/08	c/o Siemens Healthcare Diagnostics Inc. 3400 Middlebury Street 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.

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The scope of certification also covers the following sites:

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|-----|--|---|
| /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). |
| /12 | c/o Siemens Healthcare Diagnostics Manufacturing Ltd
Chapel Lane
Swords
Co Dublin
Ireland | Manufacture, warehousing and distribution of in vitro diagnostic analyzers. |
| /13 | c/o Siemens Healthcare Diagnostics Inc.
500 GBC Drive, P.O. Box 6101
Newark DE 19714
USA | Design, development, manufacture of in vitro diagnostic medical devices (reagents, controls and instruments) |
| /14 | c/o Siemens Healthcare Diagnostics Inc.
660 Pencader Dr
Glasgow DE 19702
USA | Warehousing and distribution of in vitro diagnostic reagents and controls. |
| /15 | c/o Siemens Healthcare Diagnostics Inc.
2150 Stanley Road
Plainfield IN 46168
USA | Warehousing and distribution of in vitro diagnostic reagents and instruments. |
| /16 | c/o Siemens Healthineers AG
Am Studio 1
12489 Berlin
Germany | Design, development and manufacture of software products for Point of Care (POC) Data Management. |

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USA

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|-----|---|---|
| /17 | c/o Siemens Healthcare
Diagnostics
Manufacturing Ltd
Northern Road
Chilton Industrial Estate
Sudbury
Suffolk
CO10 2XQ
United Kingdom | Manufacture of in vitro diagnostic reagents. |
| /18 | c/o Siemens Healthcare
Diagnostics
Manufacturing Ltd.
Windham Road
Chilton Industrial Estate,
Sudbury
Suffolk
CO10 2XD
United Kingdom | Manufacture of in vitro diagnostic analyzers. |
| /19 | c/o Siemens Healthcare
Diagnostics
Manufacturing Ltd.
Byford Road
Chilton Industrial Estate,
Sudbury
Suffolk
CO10 2YG
United Kingdom | Warehousing and distribution of in vitro diagnostic analyzers and reagents. |

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