

Certificate



Quality Management System EN ISO 13485:2016

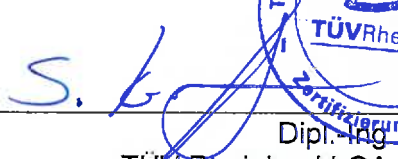

Registration No.: SX 1290554-1

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



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



Certificate

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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.

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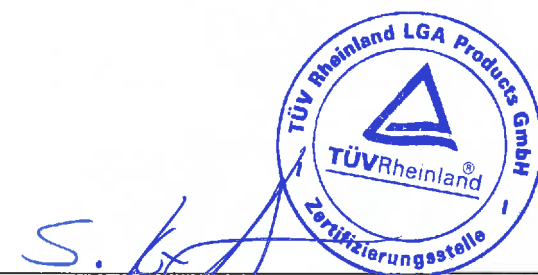
Registration No.: SX 1290554-1

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). |

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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. |

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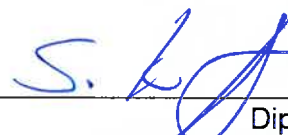

Organization: Siemens Healthcare Diagnostics Inc.
511 Benedict Ave
Tarrytown NY 10591
USA

The scope of certification also covers the following:

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

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