

# 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



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EN ISO 13485:2016**

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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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Tarrytown NY 10591  
USA

The scope of certification also covers the following:

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

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511 Benedict Ave  
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USA

The scope of certification also covers the following:

- |     |   |   |
|-----|---|---|
| /11 | c/o Siemens Healthcare Diagnostics<br>Manufacturing Ltd<br>Northern Road<br>Chilton Industrial Estate<br>Sudbury<br>Suffolk<br>CO10 2XQ<br>United Kingdom | Manufacture, warehousing and distribution of<br>in vitro diagnostic reagents and analyzers.                         |
| /12 | c/o Siemens Healthcare Diagnostics<br>Manufacturing Ltd<br>Chapel Lane<br>Swords<br>Co Dublin<br>Ireland  | Manufacture, warehousing and distribution of<br>in vitro diagnostic analyzers/software.                             |
| /13 | c/o Siemens Healthcare Diagnostics Inc.<br>500 GBC Drive, P.O. Box 6101<br>Newark DE 19714<br>USA   | Design, development and manufacture of in<br>vitro diagnostic medical devices, including<br>analyzers and software. |
| /14 | c/o Siemens Healthcare Diagnostics Inc.<br>660 Pencader Dr<br>Glasgow NY 19702<br>USA   | Warehousing and distribution of in vitro<br>diagnostic reagents and controls.                                       |

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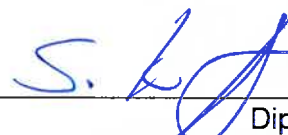

Organization: Siemens Healthcare Diagnostics Inc.  
511 Benedict Ave  
Tarrytown NY 10591  
USA

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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