

# Certificate



**Quality Management System  
EN ISO 13485:2016**

Registration No.: SX 7091841-1

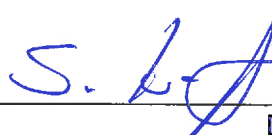

Organization: Siemens Healthcare Diagnostics Inc.  
500 GBC Drive, P.O. Box 6101  
Newark, DE 19714  
USA

The scope of certification also covers the following:

No.	Facility	Scope
/01	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.
/02	c/o Siemens Healthcare Diagnostics Inc. 660 Pencader Dr Glasgow DE 19702 USA	Warehousing and distribution of in vitro diagnostic reagents and controls.

Report No.: 1093283-40  
Effective date: 2021-12-14  
Expiry date: 2024-12-13  
Issue date: 2021-12-13



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

# Certificate



## Quality Management System EN ISO 13485:2016


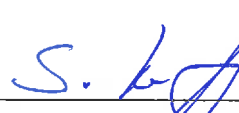
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Organization: Siemens Healthcare Diagnostics Inc.  
500 GBC Drive, P.O. Box 6101  
Newark, DE 19714  
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Scope: Design, development and manufacture of in vitro diagnostic medical devices (reagents, controls, instruments and software) used in the diagnosis, management and detection of autoimmune status, blood analytes, blood components, cancer, cardiac markers, coagulation, drugs of abuse, endocrine disorders, fertility testing, immune status, pregnancy testing, prenatal screening, protein metabolism, immunological typing and therapeutic drug monitoring.

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.

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