Certificate of Approval

This is to certify that the Management System of:

Siemens Healthcare Diagnostics Inc.

511 Benedict Avenue, Tarrytown, NY, 10591, United States

has been approved by LRQA to the following standards:

ISO 13485:2016

David Derrick - Area Operations Manager UK & Ireland

Issued by: Lloyd's Register Quality Assurance

for and on behalf of: Lloyd's Register Quality Assurance Limited

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

Current issue date: 1 January 2019
Expiry date: 31 December 2021
Certificate identity number: 10160935

Original approval(s):

ISO 13485 – 8 February 2007

Approval number(s): ISO 13485 – 0011806

The scope of this approval is applicable to:

Design, Development, Manufacture, Servicing and 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. Manufacture of Medical Devices used for Blood and Tissue Sample Collection.

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Certificate Schedule

Certificate identity number: 10160935

Location	Activities
511 Benedict Avenue, Tarrytown, NY, 10591, United States	ISO 13485:2016 Design, development and servicing of in vitro diagnositc 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 statuds, 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 origianl equipment manufactures (OEM) Activities.
Siemens Healthcare Diagnostics Products Limited Glyn Rhonwy, Llanberis, Gwynedd, LL55 4EL, United Kingdom	ISO 13485:2016 Manufacture and design of in vitro diagnostic reagents and in vitro diagnositc test kits used in the diagnosis, management and detection of autoimmune status, blood componenets, cancer, cardiac markers, disease status, drugs of abuse, enocrine disorders, fertility testing, immune status, pregnancy testing, prenatal screening, protein metabolism, transmissible agents and therapeuic drug monitoring.
Siemens Healthcare Diagnostics Manufacturing Ltd. Northern Road, Chilton Industrial Estate, Sudbury, Suffolk, CO10 2XQ, United Kingdom	ISO 13485:2016 The manufacture of in vitro diagnositc urinalysis and blood gas diagnostic instruments, associated consumables and reagents.
Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane, Swords Co. Dublin, Ireland	ISO 13485:2016 Manufacture of in vitro diagnostic instruments and accessories.

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Location	Activities
Siemens Healthcare Diagnostics Inc. 2 Edgewater Drive, Norwood, MA, 02062, United States	ISO 13485:2016 Design and development of in vitro diagnositc reagents, instruments and accessories. Manufacture of medical device for blood gas sample collection.
Siemens Healthcare Diagnostics Inc. 333 Coney Street, East Walpole, MA, 02032, United States	ISO 13485:2016 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.
Siemens Healthcare Diagnostics Inc. 3400 Middlebury Street, Elkhart, IN, 46516, United States	ISO 13485:2016 Manufacture of in vitro diagnostic reagent components
430 S. Beiger Street, Mishawaka, IN, 46544, United States	ISO 13485:2016 Manufacture of in vitro diagnositc reagents for urinalysis and diabetes testing.
Siemens Healthcare Diagnostics Inc. 45764 Copco Avenue, Gorman, CA, 93243, United States	ISO 13485:2016 Manufacture of intermediatecomponents and antisera for use as immunoassay reagents for in vitro diagnostic detection and management of disease status, metabolic disorders, immune status, fertiltiy and therapeutic drug monitoring.
Siemens Healthcare Diagnostics Inc. 5210 Pacific Concourse Drive, Los Angeles, CA, 90045, United States	ISO 13485:2016 Manufacture of intermediatecomponents and antisera for use as immunoassay reagents for in vitro diagnostic detection and management of disease status, metabolic disorders, immune status, fertiltiy and therapeutic drug monitoring.

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Location	Activities
Siemens Healthcare Diagnostics Inc. 62 Flanders-Bartley Road, Flanders, NJ, 07836, United States	ISO 13485:2016 Design of in vitro diagnostic analytical instruments and associated software.
Siemens Healthcare Diagnostics Inc. 725 Potter Street, Berkeley, CA, 94710, United States	ISO 13485:2016 Design of in vitro diagnostic reagents, instruments, software and accessories. Oversight over the manufacturing of HCV genotyping assay.

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