



Lloyd's Register
LRQA

CERTIFICATE OF APPROVAL

This is to certify that the Management System of:

Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, New York 10591, USA

has been approved by Lloyd's Register Quality Assurance
to the following Management System Standards:

ISO 13485:2003
EN ISO 13485:2012

The Management System is applicable to:

**The Design/ Development, Control of Manufacture, Control of Service,
Control of 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.**

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.

This certificate forms part of the approval identified by certificate number UQA 4000486

Approval
Certificate No: UQA 4000486/A

Original Approval: February 8, 2007
Current Certificate: January 1, 2017
Certificate Expiry: March 1, 2019

Issued by: Lloyd's Register Quality Assurance, Inc. for and
on behalf of Lloyd's Register Quality Assurance Limited



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LRQA, Inc. 1330 Enclave Parkway, Suite 200, Houston, Texas 77077, USA
For and on behalf of LRQA Ltd. 1 Trinity Park, Bickenhill Lane, Birmingham, B37 7ES, United Kingdom

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CERTIFICATE SCHEDULE

Siemens Healthcare Diagnostics Inc.

Head Office:

Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, New York 10591, USA

Activities:

Design, Development, and Servicing 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. Oversight of Medical Devices Original Equipment Manufacturers (OEM) activities.

Locations:

Siemens Healthcare Diagnostics Inc.
725 Potter Street
Berkeley, California 94710, USA

Activities:

Design of In Vitro Diagnostic Reagents, Instruments, Software, and Accessories.

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CERTIFICATE SCHEDULE

Siemens Healthcare Diagnostics Inc.

Locations:

Siemens Healthcare Diagnostics
Manufacturing Ltd.
Chapel Lane
Swords, Co. Dublin, Ireland

Siemens Healthcare Diagnostics Inc.
333 Coney Street
East Walpole, Massachusetts 02032, USA

Siemens Healthcare Diagnostics Inc.
3400 Middlebury Street
Elkhart, Indiana 46516, USA

Siemens Healthcare Diagnostics Inc.
62 Flanders-Bartley Road
Flanders, New Jersey 07836, USA

Activities:

Manufacture of In Vitro Diagnostic
Instruments and Accessories.

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.

Manufacture of In Vitro Diagnostic
Urinalysis Reagents, Urinalysis Accessories
and In Vitro Diagnostic Reagent
Components.

Design and Manufacture of In Vitro
Diagnostic Analytical Equipment and
Associated Software Design and
Development.





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CERTIFICATE SCHEDULE

Siemens Healthcare Diagnostics Inc.

Locations:

Siemens Healthcare Diagnostics
Products Limited
Glyn Rhonwy
Llanberis, Gwynedd LL55 4EL
United Kingdom

Siemens Healthcare Diagnostics Inc.
5210 Pacific Concourse Drive
Los Angeles, California 90045, USA

Siemens Healthcare Diagnostics Inc.
45764 Copco Avenue
Gorman, California 93243, USA

Siemens Healthcare Diagnostics Inc.
430 Beiger Street
Mishawaka, Indiana 46544, USA

Activities:

Manufacture and Design of In Vitro
Diagnostic Reagents and In Vitro
Diagnostic Test Kits Used in the
Diagnosis, Management and Detection of
Autoimmune Status, Blood Components,
Cancer, Cardiac Markers, Disease Status,
Drugs of Abuse, Endocrine Disorders,
Fertility Testing, Immune Status,
Pregnancy Testing, Prenatal Screening,
Protein Metabolism, Transmissible Agents
and Therapeutic Drug Monitoring.

Design and Manufacture of In Vitro
Diagnostic Immunoassay Reagents and
Kits for the Detection and Management
of Infectious Diseases, Immune Status,
Metabolic Disorders and Therapeutic
Ranges. Development and Production of
Antisera.

Development and Production of Antisera.

Manufacture of In Vitro Diagnostic
Reagents for Urinalysis.

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CERTIFICATE SCHEDULE

Siemens Healthcare Diagnostics Inc.

Locations:

Siemens Healthcare Diagnostics Inc.
2 Edgewater Drive
Norwood, Massachusetts 02062 USA

Siemens Healthcare Diagnostics
Manufacturing Ltd.
Northern Road
Chilton Industrial Estate
Sudbury, Suffolk CO10 2XQ
United Kingdom

Activities:

Design and Development and Servicing of
In Vitro Diagnostic Reagents, Instruments
and Accessories. Manufacture of Medical
Device for Blood Gas Sample Collection.

Manufacture of In Vitro Diagnostic
Urinalysis and Blood-Gas Diagnostic
Instruments Associated Consumables and
Reagents.

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