CERTIFICATE

Standard: Certification Registr. No. ISO 13485:2003, JIS Q 13485:2005 81 105 89004

TÜV Rheinland Japan Ltd. Certifies:

Certification Holder:

SYSMEX CORPORATION

1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan

including the locations according to annex

Scope:

Development, Design, Production, Sales and Servicing of Blood Analyzer, Urine Analyzer, Related Reagents and Accessories

Product Categories:

Analyzers and Reagents for Hematological Test, Blood Coagulation Test, Immune Serum Test, Biochemical Test,

Genetic Test, Bacteriological Test and Urine Test

An audit was performed, Report No. 89004. Proof has been furnished that the requirements are fulfilled

according to ISO 13485:2003, JIS Q 13485:2005. The due date for future audits is 07-11 (mm-dd).

Validity:

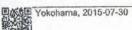
TUEV and TUV are registered trademarks.

4.09 E A4

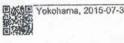
This certificate is valid from 2015-08-01 until 2018-07-31.

First certification: 2009

www.tuv.com ID: 0910589004











CERTIFICATE OF APPROVAL

This is to certify that the Quality 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 Quality Management System Standards:

ISO 13485:2003

The Quality Management System is applicable to:

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

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: Current Certificate:

February 8, 2007

January 1, 2014

Certificate Expiry:

Martha Wingsie

December 31, 2016

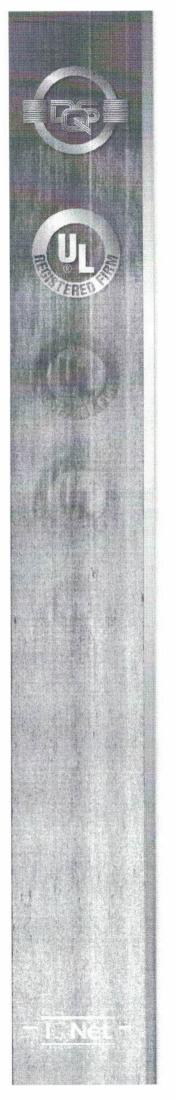
Issued by: Lloyd's Register Quality Assurance, Inc. for and on behalf of Lloyd's Register Quality Assurance Limited



This document is subject to the provision on the reverse 1330 Enclave Parkway, Suite 200, Houston, Texas 77077, USA For and on behalf of 71 Fenchurch Street, London EC3M 4BS, United Kingdom

This approval is carried out in accordance with the LRQA assessment and certification procedures and monitored by LRQA.

The use of the UKAS Accreditation Mark indicates Accreditation in respect of those activities covered by the Accreditation Certificate Number 001



CERTIFICATE



Akkreditiert durch

ZLG-ZQ-987.99.07-46

This is to certify that the company

Thermo Electron LED GmbH

Zweigniederlassung Osterode

Am Kalkberg 37520 Osterode am Harz Germany

has implemented and maintains a Quality Management System.

Scope:

Design, development, manufacturing, sales and service of laboratory centrifuges for in-vitro diagnostic

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

EN ISO 13485 : 2003 + AC : 2009

Certificate registration No.

000651 MP29

Certificate unique ID

170549755

Effective date

2012-10-16

Expiry date

2017-10-15

Frankfurt am Main

2012-09-17

DQS Medizinprodukte GmbH

Frank Graichen Managing Director Dr. Thomas Feldmann Head of Certification Body