

# CERTIFICATE

Standard: **ISO 13485:2003, JIS Q 13485:2005**  
Certification Registr. No. **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: This certificate is valid from 2015-08-01 until 2018-07-31.  
First certification: 2009  
www.tuv.com ID: 0910589004



Yokohama, 2015-07-30

*Y. Semino*

TÜV Rheinland Japan Ltd.

3-19-5 Shin-Yokohama, Yokohama 222-0033, Japan

www.tuv.com



**TÜVRheinland®**  
Precisely Right.



Lloyd's Register  
LRQA

## 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: February 8, 2007  
Current Certificate: January 1, 2014  
Certificate Expiry: December 31, 2016

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



001

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

Macro Revision 1.0

# CERTIFICATE



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



Akkreditiert durch  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
ZLG-ZQ-987.99.07-46

### DQS Medizinprodukte GmbH

Frank Graichen  
Managing Director

Dr. Thomas Feldmann  
Head of Certification Body