

MED/CERT Certificate

The Certification Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith confirms that the company

Roche PVT GmbH
Maybachstraße 30 – 71332 Waiblingen
Germany

with its facility:

Roche PVT GmbH
Bernhardsläicher Weg 10 – 71686 Remseck
Germany

has introduced and applies a Quality Management System in the area of

**Development, manufacture and sales of
automatized laboratory systems and auxiliary equipment for
handling, aliquoting and treating of samples in laboratories**

A Quality Audit demonstrated compliance of the Quality Management System with

EN ISO 13485:2012 + AC:2012

The certification assumes that the company is applying and maintaining its
Quality Management System according to the above given standard.

The license of certification is subject to surveillance by MEDCERT.

This certificate is valid until: 18 September 2018

Hamburg, 10 January 2014

Process No.: QS - 4953
Certificate No.: 4953GB438140110

MEDCERT Certification Body
(Markus Bianchi)



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-983.99.02-46



Rodney James Ward

Tổng Giám Đốc

CERTIFICATE

SAO Y BẢN CHÍNH

Ngày.....Tháng.....Năm.....



Standard: **JIS Q 13485:2005, ISO 13485:2003,
EN ISO 13485:2012, EN ISO 13485:2012 /AC:2012**

Certification Registr. No. **81 105 4757**

TÜV Rheinland Japan Ltd. Certifies:

Certification Holder: **Hitachi High-Technologies Corporation
Naka Division**
882, Ichige, Hitachinaka-shi, Ibaraki-ken 312-8504, Japan
including the locations according to annex

Scope: **Development, design and manufacturing and various
services of Active Medical Devices and In-Vitro
Diagnostic Medical Devices**

**Products: Magnetocardiographs, Clinical Chemistry
Analyzers, Urine Analyzers, Immunoassay
Analyzers, Clinical Laboratory Automation
Systems, DNA Sequencer**

An audit was performed, Report No. 4757.
Proof has been furnished that the requirements are fulfilled
according to JIS Q 13485:2005, ISO 13485:2003, EN ISO
13485:2012, EN ISO 13485:2012 /AC:2012.
The due date for future audits is 04-01 (mm-dd).

Validity: This certificate is valid from 2015-05-01 until 2018-04-30.
First certification: 2009
www.tuv.com ID: 0091054757



Yokohama, 2015-05-01

J. Semino
TÜV Rheinland Japan Ltd.
3-1-5 Shin-Yokohama, Yokohama 222-0033, Japan

Annex to Certificate

Standard: **JIS Q 13485:2005, ISO 13485:2003,
EN ISO 13485:2012, EN ISO 13485:2012 /AC:2012**
Certification Registr. No. **81 105 4757**

Location: **Hitachi High-Technologies Corporation Naka Division
882, Ichige, Hitachinaka-shi, Ibaraki-ken 312-8504, Japan**

Scope: **Development, Design and Manufacturing of Active
Medical Devices and In-Vitro Diagnostic Medical Devices**

**Products: Magnetocardiographs, Clinical Chemistry
Analyzers, Urine Analyzers, Immunoassay
Analyzers, Clinical Laboratory Automation
Systems, DNA Sequencer**

Certification Registr. No. **81 105 4757/01**

Location: **Hitachi High-Technologies Corporation Omuta Center
1892-1 Tegama, Omuta-shi, Fukuoka-ken 836-0004, Japan**

Scope: **Manufacturing of Immunoassay Analyzers, Parts for
Immunoassay Analyzers, Capillary array for DNA
Sequencer and Parts for Clinical Chemistry Analyzers**

Certification Registr. No. **81 105 4757/02**



Yokohama, 2015-05-01

TÜV Rheinland Japan Ltd.
3-1-5 Shin-Yokohama, Yokohama 222-0033, Japan



Annex to Certificate

Standard: **JIS Q 13485:2005, ISO 13485:2003,
EN ISO 13485:2012, EN ISO 13485:2012 /AC:2012**
Certification Registr. No. **81 105 4757**

Location: **Hitachi High-Tech Manufacturing & Service Corporation
1040 Ichige, Hitachinaka-shi, Ibaraki-ken 312-0033, Japan**

Scope: **Manufacturing of Assembly Units for IVD (In Vitro
Diagnostic Medical Device)
IVD : Medical Analytical Instruments, Immunoassay
System, Laboratory Automation System, DNA
Sequencer**

**Manufacturing of Molded Plastic Parts, Service Parts
(including Rinsing Agents and others) and Assembling of
Printed Circuit Board for IVD**

Certification Registr. No. **Business Support Services (Correction control of
Measuring Instruments, EMC Testing, Parts inspection
and parts logistics for IVD)
81 105 4757/03**

Location: **Hitachi High-Tech Manufacturing & Service Corporation
5th Works
1892-1 Tegama, Omuta-shi, Fukuoka-ken 836-0004, Japan**

Scope: **Manufacturing of Immunoassay Analyzers, Parts for
Immunoassay Analyzers, Capillary array for DNA
Sequencer and Parts for Clinical Chemistry Analyzers**

Certification Registr. No. **81 105 4757/04**



Yokohama, 2015-05-01

Y. Sumino
TÜV Rheinland Japan Ltd.
3-1-5 Shin-Yokohama, Yokohama 222-0033, Japan

Annex to Certificate

Standard: **JIS Q 13485:2005, ISO 13485:2003,
EN ISO 13485:2012, EN ISO 13485:2012 /AC:2012**
Certification Registr. No. **81 105 4757**

Location: **Hitachi High-Technologies Corporation
Tokyo Technical Center
2-4-1, Shibakoen, Minato-ku, Tokyo-to 105-0011, Japan**

Scope: **Demonstration and training of Clinical Chemistry
Analyzers, Clinical Laboratory Automation Systems**
Certification Registr. No. **81 105 4757/05**



Y. Sumino
TÜV Rheinland Japan Ltd.
3-1-15 Shin-Yokohama, Yokohama 222-0033, Japan



Yokohama, 2015-05-01



Product Service

CERTIFICATE

No. Q1N 16 02 95005 001

Holder of Certificate: Hitachi, Ltd.
 2-16-1, Higashi-Ueno, Taito-ku
 Tokyo
 110-0015 JAPAN

SAO Y BẢN CHÍNH
 Ngày..... Tháng..... Năm.....

Certification Mark:



Scope of Certificate: Design and Development, Production, Distribution and Servicing of Instruments, Systems and Accessories for the following Applications:
 Diagnostic Ultrasound, Nuclear Medicine Diagnostic, Bone Densitometry, Therapeutic and Surgical, Clinical Laboratory Test, Automated Pipetting, Luminometry, Photometry, and Sterilized puncture adaptor

Tổng Giám Đốc

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: JAQ235023786

Valid from: 2016-04-01
Valid until: 2018-03-31



Date, 2016-03-29

S. Preiß
 Stefan Preiß

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Product Service

CERTIFICATE

No. Q1N 16 02 95005 001

Applied Standard(s):

EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

Facility(ies):

Hitachi, Ltd. Healthcare Business Unit
2-16-1, Higashi-Ueno, Taito-ku, Tokyo, 110-0015 JAPAN

Hitachi, Ltd. Healthcare Tokyo Works
3-7-19, Imai, Ome-shi, Tokyo, 198-8577 JAPAN

Hitachi, Ltd. Healthcare Ultrasound R&D Center
3-1-1, Higashikoigakubo, Kokubunji-shi, Tokyo, 185-0014
JAPAN

Hitachi Healthcare Manufacturing, Ltd. Tokyo Works
3-7-19, Imai, Ome-shi, Tokyo, 198-8577 JAPAN

Hitachi Healthcare Manufacturing, Ltd. Kokubunji Factory
3-1-1, Higashikoigakubo, Kokubunji-shi, Tokyo, 185-0014
JAPAN



ZERTIFIKAT ♦ CERTIFICATE ♦ 認証証書 ♦ CERTIFICADO ♦ CERTIFICAT