TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

QIAGEN N.V.
Spoorstraat 50
5911 KJ Venlo
Netherlands

has established and applies a quality management system
for the following scope:

Design and development, production, marketing and servicing of products for the handling, stabilization, separation, purification, amplification and detection of nucleic acids and proteins (see attachment for additional sites included)

Proof has been furnished that the requirements specified in

EN ISO 9001:2008

are fulfilled. The quality management system is subject to yearly surveillance.

Certificate Registration No.: SY 60039178 0001

An audit was performed. Report No.: 21167338 001

This Certificate is valid until: 19.05.2016

Certification Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date 20.05.2011

Dipl.-Ing. C. Wiora

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc. 1/2, Rev. 1

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: SY 60039178 0001
Report No.: 21167338 003

Organization:
QIAGEN N.V.
Spoorstraat 50
5911 KJ Venlo
Netherlands

Scope:

Additional sites included:

QIAGEN GmbH
QIAGEN Strasse 1
40724 Hilden, Germany
Activities related to design and development, production, marketing and servicing of products for the handling, stabilization, separation, purification, amplification and detection of nucleic acids and proteins

QIAGEN Sciences LLC.
19300 Germantown Road
Germantown, MD 20874, USA
Activities related to manufacture, distribution and service of products for the handling, stabilization, separation, purification, amplification and detection of nucleic acids and proteins

Certification Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date 26.08.2011

Dipl.-Ing. C. Wiora

TÜVRheinland®

Doc. 2/2, Rev. 1

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: SY 60039178 0001
Report No.: 21167338 003

Organization:
QIAGEN N.V.
Spoorstraat 50
5911 KJ Venlo
Netherlands

Scope:

Additional sites included:

QIAGEN Hamburg GmbH
Königstraße 4a
22767 Hamburg, Germany
Activities related to design and development, production and servicing of products for the handling, stabilization, separation, purification, amplification and detection of nucleic acids and proteins

Certification Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Dipl.-Ing. C. Wiora

Date 26.08.2011

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

QIAGEN N.V.
Spoorstraat 50
5911 KJ Venlo
Netherlands

has established and applies a quality management system for medical devices for the following scope:

Design and development, production, marketing and servicing of products for the handling, stabilization, separation, purification, amplification and detection of nucleic acids and proteins for IVD use (see att. for add. sites included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2003 + AC:2009

are fulfilled. The quality management system is subject to yearly surveillance.

Certificate Registration No.: SX 60039177 0001

An audit was performed. Report No.: 21167338 001

This Certificate is valid until: 19.05.2016

Certification Body

Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-995.00.01-46

Date 20.05.2011

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Dipl.-Ing. C. Wiora

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: SX 60039177 0001
Report No.: 21167338 003

Organization:
QIAGEN N.V.
Spoorstraat 50
5911 KJ Venlo
Netherlands

Scope:

Additional sites included:

QIAGEN GmbH
QIAGEN Strasse 1
40724 Hilden, Germany
Activities related to design and development, production, marketing and servicing of products for the handling, stabilization, separation, purification, amplification and detection of nucleic acids and proteins

QIAGEN Sciences LLC.
19300 Germantown Road
Germantown, MD 20874, USA
Activities related to manufacture, distribution and service of products for the handling, stabilization, separation, purification, amplification and detection of nucleic acids and proteins

Akkreditiert durch
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-ZQ-995.00.01-46

Certification Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Dipl.-Ing. C. Wiora

Date 26.08.2011

TÜVRheinland®

Doc. 2/2, Rev. 1

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: SX 60039177 0001
Report No.: 21167338 003

Organization:
QIAGEN N.V.
Spoorstraat 50
5911 KJ Venlo
Netherlands

Scope:

Additional sites included:

QIAGEN Hamburg GmbH
Königstraße 4a
22767 Hamburg, Germany
Activities related to design and development, production and servicing of products for the handling, stabilization, separation, purification, amplification and detection of nucleic acids and proteins

Akkreditiert durch
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-ZQ-995.00.01-46

Date 26.08.2011

Certification Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Dipl.-Ing. C. Wiora

Certificate

TÜVRheinland®

TUV Rheinland of North America, Inc., a CMDCAS recognized registrar, certifies that

QIAGEN GmbH
Qiagen Str. 1
40724 Hilden
Deutschland

has established and maintained a

Quality Management System
according to
ISO 13485:2003

Audit Report No.: 31190856 001
Certificate Registration No.: 74 500 4011
Expiry Date: May 31, 2014

for the Design and development, manufacture and distribution of products for the handling, stabilization, separation, purification, amplification and detection of nucleic acids and proteins for In-Vitro Diagnostic use
(see attachment for additional sites included)

SCC Accredited CB-MS™

Certification Officer: Dipl.-Ing. D. Meier

TUV Rheinland of North America, Inc.
Newtown, Connecticut

Effective Date: June 01, 2011

TÜVRheinland®

Doc. 1/1, Rev. 0

Attachment

Quality Management System according to ISO 13485:2003

for

QIAGEN GmbH
Qiagen Str. 1
40724
Deutschland

The scope of the registration includes the following sites:

QIAGEN Sciences LLC.
19300 Germantown Road
Germantown, MD 20874
USA

Scope:
Activities related to manufacture, distribution and servicing of products for handling, stabilization, separation, purification, amplification and detection of nucleic acids and proteins for In-Vitro Diagnostic use

Audit Report No.:	31190856 001
Certificate Registration No.:	74 500 4011
Expiry Date:	May 31, 2014

SCC Accredited CB-MS™

Certification Officer: Dipl.-Ing. Dieter Meier

TUV Rheinland of North America, Inc.
Newtown, Connecticut

Effective Date: June 01, 2011

TUV Rheinland of North America, Inc., 12 Commerce Road, Newtown, CT 06470, Tel(203) 426-0888 Fax(203)426-4009

TÜVRheinland®

APPROVAL

EC Directive 98/79/EC Annex IV, Article 3
Full Quality Assurance System
In vitro diagnostic medical devices

Registration No.: HL 60039176 0001

Report No.: 21167338 001

Manufacturer:
QIAGEN GmbH
Qiagen Str. 1
40724 Hilden
Deutschland

Scope:
Design/development and production of molecular biological in vitro diagnostic medical devices for detection of nucleic acids

(see attachment for Products included)

Replaces Approval, Registration No.: HL 60018322 0001

Date of Expiry: 19.05.2016

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex IV, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex IV, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierstelle TÜVRheinland®

Date 20.05.2011

Dipl.-Ing. C. Wiora

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. 0197 to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: HL 60039176 0001
Report No.: 21167338 001

Manufacturer:
QIAGEN GmbH
Qiagen Str. 1
40724 Hilden
Deutschland

Scope:

Products included:

- PCR reagents for the detection of Chlamydia trachomatis
- PCR reagents for the detection of Cytomegaloviruses
- PCR reagents for the detection of Hepatitis B viruses
- PCR reagents for the detection of Hepatitis C viruses
- PCR reagents for the detection of HI-viruses

Certification Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 20.05.2011

Dipl.-Ing. C. Wiora

Genehmigung

Richtlinie 98/79/EG Anhang IV, Artikel 3
vollständiges Qualitätsmanagementsystem
In-vitro-Diagnostika

Registrier Nr.: HL 60039176 0001

Bericht Nr.: 21167338 001

Hersteller:
QIAGEN GmbH
Qiagen Str. 1
40724 Hilden
Deutschland

Geltungsbereich: Design/Entwicklung und Produktion von molekularbiologischer In-Vitro-Diagnostika zum Nachweis von Nukleinsäuren

(siehe Anlage für einbezoge Produkte)

Ersetzt Genehmigung, Registrier Nr.: HL 60018322 0001

Gültig bis: 19.05.2016

Hiermit genehmigt die "Benannte Stelle" das vom Hersteller eingeführte und angewandte Qualitätsmanagementsystem. Die Anforderungen des Anhangs IV, Artikel 3 der EG-Richtlinie werden erfüllt. Der Hersteller unterliegt der Überwachung nach Anhang IV, Artikel 5 der Richtlinie. Der Inhaber ist berechtigt, diese Bescheinigung im Rahmen seiner Herstellerkonformitätserklärung zu verwenden.

Zertifizierungsstelle

Datum 20.05.2011

Dipl.-Ing. C. Wiora

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Akkreditiert von der Zentralstelle der Länder für Sicherheitstechnik (ZLS) und der Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notifiziert unter der Nr. 0197 bei der Kommission der Europäischen Gemeinschaft.

CE Die CE-Kennzeichnung darf bei Einhaltung aller zutreffenden EG-Richtlinien angebracht werden. CE

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Anlage zu
Registrier-Nr.: HL 60039176 0001
Bericht-Nr.: 21167338 001

Hersteller:
QIAGEN GmbH
Qiagen Str. 1
40724 Hilden
Deutschland

Geltungsbereich: Einbezogene Produkte:

- PCR-Reagenzien zum Nachweis von Chlamydia trachomatis
- PCR-Reagenzien zum Nachweis von Cytomegaloviren
- PCR-Reagenzien zum Nachweis von Hepatitis-B-Viren
- PCR-Reagenzien zum Nachweis von Hepatitis-C-Viren
- PCR-Reagenzien zum Nachweis von HI-Viren

Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Datum 20.05.2011

Dipl.-Ing. C. Wiora

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Qiagen Gaithersburg Inc.
1201 Clopper Road
Gaithersburg MD 20878
USA

has established and applies a quality management system for medical devices for the following scope:

see attachment

Proof has been furnished that the requirements specified in

EN ISO 13485:2003 + AC:2009

are fulfilled. The quality management system is subject to yearly surveillance.

Certificate Registration No.: SX 60039802 0001

An audit was performed. Report No.: 21167959 002

This Certificate is valid until: 30.06.2016

Certification Body

Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-995.00.01-46

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Date 01.07.2011

Dr. H. Lüdemann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: SX 60039802 0001
Report No.: 21167959 002

Organization:
Qiagen Gaithersburg Inc.
1201 Clopper Road
Gaithersburg MD 20878
USA

Scope:

Design and Manufacture of the Hydrid Capture® Family of in Vitro Diagnostic Kits for the Detection of Infectious Disease

Design and Manufacture of the Cervical Specimen Collection Kits

Design and Manufacture of Laboratory Equipment and Instrumentation for Use with the Hybrid Capture® Family of Tests

Akkreditiert durch
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-ZQ-995.00.01-46

Date 01.07.2011

Certification Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Dr. H. Lüdemann

Certificate

TÜVRheinland®

TUV Rheinland of North America, Inc., a CMDCAS recognized registrar, certifies that

Qiagen Gaithersburg Inc.
1201 Clopper Road
Gaithersburg MD 20878
USA

has established and maintained a

Quality Management System
according to
ISO 13485:2003

Audit Report No.:	31191255 003
Certificate Registration No.:	74 500 4242
Expiry Date:	June 30, 2014

Design and Manufacture of In Vitro Diagnostic Kits for the Detection of Human Papillomavirus, Chlamydia trachomatis, Neisseria gonorrhea, Hepatitis B Virus and of Cervical Specimen Collection Kits

Design and Manufacture of Instruments to Automate in Vitro Diagnostic Devices used in the Detection of Transmissible Agents, Sexually Transmissible Agents and Determination of Disease Status

SCC Accredited CB-MS™

Certification Officer: Dr. H. Lüdemann

TUV Rheinland of North America, Inc.
Newtown, Connecticut

Effective Date: August 30, 2012

TUV Rheinland of North America, Inc., 12 Commerce Road, Newtown, CT 06470, Tel (203) 426-0888 Fax (203) 426-4009

APPROVAL

EC Directive 98/79/EC Annex IV, Article 3
Full Quality Assurance System
In vitro diagnostic medical devices

Registration No.: HL 60039803 0001

Report No.: 21167959 002

Manufacturer:
Qiagen Gaithersburg Inc.
1201 Clopper Road
Gaithersburg MD 20878
USA

Scope:
Design/development and manufacture of assays on "hybrid capture" technique for the detection of Chlamydia trachomatis
(see attachment for products included)

Date of Expiry: 30.06.2016

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex IV, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex IV, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

Notified Body

Date 01.07.2011

Dr. H. Lüdemann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. 0197 to the EC Commission.

CE **The CE marking may be used if all relevant and effective EC Directives are complied with.** CE

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: HL 60039803 0001
Report No.: 21167959 002

Manufacturer: Qiagen Gaithersburg Inc.
1201 Clopper Road
Gaithersburg MD 20878
USA

Scope: included products:
- Hybrid Capture 2 CT/GC DNA Test (Catalogue # 5130-1330)
- Hybrid Capture 2 CT-ID DNA Test (Catalogue # 5135-1330)

Certification Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Dr. H. Lüdemann

Date 01.07.2011

APPROVAL

EC Directive 93/42/EEC Annex V, Article 3
Quality Assurance System Production

Registration No.: DD 60039804 0001

Report No.: 21167959 002

Manufacturer:
Qiagen Gaithersburg Inc.
1201 Clopper Road
Gaithersburg MD 20878
USA

Scope:
The scope covers only aspects of manufacture concerned with securing and maintaining sterile conditions

(see attachment for products included)

Date of Expiry: 30.06.2016

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex V, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex V, Article 4 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Notified Body

Date 01.07.2011

Dr. H. Lüdemann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. 0197 to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE

TÜVRheinland

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: DD 60039804 0001
Report No.: 21167959 002

Manufacturer: Qiagen Gaithersburg Inc.
1201 Clopper Road
Gaithersburg MD 20878
USA

Scope: included products:

Hybrid Capture Female Swab Specimen Collection Kit
(Catalogue # 5123-1220), sterile

Certification Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Dr. H. Lüdemann

Date 01.07.2011

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

ZERTIFIKAT

Die Zertifizierungsstelle der Swiss TS Technical Services AG
bescheinigt, dass die Firma

Qiagen Instruments AG
CH-8634 Hombrechtikon

Qiagen Lake Constance GmbH
D-78333 Stockach

für den Geltungsbereich:

Entwicklung, Produktion, Vertrieb und Service automatisierter Instrumente für die Molekularbiologie und optische Systeme für industrielle Zwecke

ein Managementsystem eingeführt hat und anwendet nach:

ISO 9001:2008 **Qualitätsmanagement**
ISO 13485:2003 **für Medizinprodukte**

	ISO 9001	ISO 13485
Registriernummer:	**03-198-049**	**12-198-615**
Erstzertifizierung:	**22.06.2003**	**22.06.2003**
Gültig bis:	**21.06.2015**	**21.06.2015**

Heinrich A. Bieler
Leiter der Zertifizierungsstelle

Wallisellen, 25.05.2012
Zertifizierungsstelle
der Swiss TS Technical Services AG
Ein Unternehmen des SVTI und des TÜV SÜD

SCESm013

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

CERTIFICATE

The certification body of Swiss TS Technical Services AG
hereby confirms that the company

Qiagen Instruments AG
CH-8634 Hombrechtikon

Qiagen Lake Constance GmbH
D-78333 Stockach

has introduced and applies a management system for

Design and development, production, sales and services of automated equipment for molecular biology and optical systems for industrial purposes

according to:

ISO 9001:2008 **Quality management**
ISO 13485:2003 **for medical devices**

	ISO 9001	ISO 13485
Registration number:	**03-198-049**	**12-198-615**
Initial certification date:	**22.06.2003**	**22.06.2003**
Valid until:	**21.06.2015**	**21.06.2015**

Heinrich A. Bieler
Head of the certification body

Wallisellen, 25.05.2012
The certification body
of Swiss TS Technical Services AG
A SVTI and TÜV SÜD company

SCESm013

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

QIAGEN Manchester Ltd.
Lloyd Street North
Skelton House
Manchester
Greater Manchester
M15 6SH
United Kingdom

has established and applies a quality management system for medical devices

Design and development and manufacture of molecular diagnostic products for human genetic analysis (see attachment for additional sites included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2003 + AC:2009

are fulfilled. The quality management system is subject to yearly surveillance.

Certificate Registration No.: SX 60041948 0001

An audit was performed. Report No.: 21171569 002

This Certificate is valid until: 07.11.2016

Certification Body

Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-995.00.01-46

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 08.11.2011

Dipl.-Ing. C. Wiora

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

QIAGEN Manchester Ltd.
Lloyd Street North
Skelton House
Manchester
Greater Manchester
M15 6SH
United Kingdom

has established and applies a quality management system
for the following scope:

Provision of analytical services primarily for the healthcare industry

Proof has been furnished that the requirements specified in

EN ISO 9001:2008

are fulfilled. The quality management system is subject to yearly surveillance.

Certificate Registration No.: SY 60041949 0001

An audit was performed. Report No.: 21171569 002

This Certificate is valid until: 07.11.2016

Certification Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierung

Date 08.11.2011

Dipl.-Ing. C. Wiora

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

Certificate

TÜVRheinland®

TUV Rheinland of North America, Inc., a CMDCAS recognized registrar, certifies that

QIAGEN Manchester Ltd.
Lloyd Street North
Skelton House
Manchester
Greater Manchester M15 6SH
United Kingdom

has established and maintained a

Quality Management System
according to
ISO 13485:2003

Audit Report No.:	31192142 001
Certificate Registration No.:	74 500 4106
Expiry Date:	November 08, 2014

For the Design and development and manufacture of molecular diagnostic products for human genetic analysis

(see attachment for additional sites included)

SCC Accredited
CB-MS™

Certification Officer: Dipl.-Ing. D. Meier

TUV Rheinland of North America, Inc.
Newtown, Connecticut

Effective Date: November 09, 2011

TÜVRheinland®

Doc. 1/1, Rev. 0

Attachment

Quality Management System according to ISO 13485:2003

for

QIAGEN Manchester Ltd.
Lloyd Street North
Skelton House
Manchester
Greater Manchester M15 6SH
United Kingdom

The scope of the registration includes the following sites:

QIAGEN Manchester Ltd.
46 Grafton Street Manchester
Manchester, M13 9XX, UK

Activities related to manufacture of
molecular diagnostic products for human genetic analysis

QIAGEN Manchester Ltd.
48 Grafton Street Manchester
Manchester, M13 9XX, UK

Activities related to manufacture of
molecular diagnostic products for human genetic analysis

Audit Report No.:	31192142 001
Certificate Registration No.:	74 500 4106
Expiry Date:	November 08, 2014

SCC Accredited
CB-MS™

Certification Officer: Dipl.-Ing. D. Meier

TUV Rheinland of North America, Inc.
Newtown, Connecticut

Effective Date: November 09, 2011

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

PSB Singapore

CERTIFICATE

The Certification Body
of TÜV SÜD PSB Pte Ltd

certifies that

QIAGEN SINGAPORE PTE LTD

73 Ayer Rajah Crescent #04-16
Singapore 139952

has established and applies
a Good Distribution Practice for Medical Devices for the scope

Import, Storage, Distribution & Servicing of
In Vitro Diagnostics Devices and Single-use Devices
[Special storage condition of product at ambient temperature
of -15 to -30 degree Celsius & +2 to +8 degree Celsius]
(See Appendix to Certificate for Details)

according to

HSA TS-01-R1 : 2008

are fulfilled. The certificate is valid from **2010-02-19** to **2013-02-18**
Certificate Registration No. **GDP-2010-0036**
Date of Issue : **2010-02-22**

Chiew Wan TAN
Vice President
Certification Department

ACCREDITED CERTIFICATION BODY
SAC
Cert No: GDPMDS-2009-04

TÜV SÜD PSB Pte Ltd · 1 Science Park Drive · Singapore 118221

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

PSB Singapore

APPENDIX

To Certificate Number: GDP-2010-0036

Issue Number : 1

Date of Issue: 2010-02-22

Issued to: QIAGEN SINGAPORE PTE LTD
73 Ayer Rajah Crescent #04-16
Singapore 139952

Process or service in respect of which the company is Certified:

Import, Storage, Distribution & Servicing of In Vitro Diagnostics Devices and Single-use Devices
[Special storage condition of product at ambient temperature of -15 to -30 degree Celsius & +2 to +8 degree Celsius]

Process Detail(s)/Location(s):

The scope of certification include :

Warehouse located at 73 Ayer Rajah Crescent #01-04/05, Singapore 139952.

Chiew Wan TAN
Vice President
Certification Department

ACCREDITED CERTIFICATION BODY
SAC
Cert No: GDPMDS-2009-04