



GeneReach Biotechnology Corporation

No. 19, Keyuan Second Road. Central Taiwan Science Park, Taiwan, 407

Tel: 886-4-2463-9869 Fax: 886-4-2463-8255 E-mail: sales@genereach.com

Declaration of Conformity

Manufacturer: **GeneReach Biotechnology Corporation**
Address: No. 19, Keyuan 2nd Road
Central Taiwan Science Park, Taichung City 407
Taiwan

Representative : Wellkang Ltd t/a Wellkang Tech Consulting
Address: 29 Harley Street, London W1G 9QR, UK

Declares that the product:

Product/s Name: taco Nucleic Acid Automatic Extraction System
Model: N/A

Conform to the following Directives and Norms

Applicable Standards: ISO 9001:2008
ISO 13485:2003
EN ISO 14971:2009
EN 980:2008

July 2011



Yu-Wen Huang
Director of Regulatory & Quality Assurance Department





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DET NORSKE VERITAS

MANAGEMENT SYSTEM CERTIFICATE

Certificate No. 61217-2009-AQ-RGC-NA

This is to certify that the Management System of

GeneReach Biotechnology Corp.

at

No. 19, Keyuan 2nd Rd., Central Taiwan Science park, Taichung 407, Taiwan, R.O.C.

has been found to conform to the Quality Management System Standard(s):

ISO 9001:2008

This Certificate is valid for the following product or service ranges:

**Design, Manufacture and Supply of
Nucleic Acid Based In Vitro Diagnostic Devices and Reagents.**

Initial Certification date:

2009.10.01

This Certificate is valid until:

2012.10.01

*The audit has been performed under the
supervision of*

Peter Lin
Lead Auditor



Place and date:

Høvik, 2009.10.05

for the Accredited Unit:
**DET NORSKE VERITAS
CERTIFICATION AS, NORWAY**

Mari-Anne Iversen
Mari-Anne Iversen
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.



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DET NORSKE VERITAS

MANAGEMENT SYSTEM CERTIFICATE

Certificate No. 61214-2009-AQ-RGC-NA

This is to certify that the Management System of

GeneReach Biotechnology Corp.

at

No. 19, Keyuan 2nd Rd., Central Taiwan Science park, Taichung 407, Taiwan, R.O.C.

has been found to conform to the Quality Management System Standard(s):

ISO 13485:2003

This Certificate is valid for the following product or service ranges:

**Manufacture and Supply of
Nucleic Acid Based In Vitro Diagnostic Devices and Reagents.**

Initial Certification date:

2009.10.01

This Certificate is valid until:

2012.10.01

*The audit has been performed under the
supervision of*

Peter Lin
Lead Auditor



Place and date:

Høvik, 2009.10.05

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Mari-Anne Iversen
Management Representative

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