TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Diamedix Corporation
2145 North Miami Avenue
Miami FL 33127
USA

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

(see attachment for scope and additional sites included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2012
EN ISO 13485:2012/AC:2012

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

Certificate Registration No.: SX 60091860 0001

An audit was performed. Report No.: 31292711 002

This Certificate is valid until: 11.02.2017

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

Date 12.02.2014

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

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: SX 60091860 0001
Report No.: 31292711 002

Organization:
Diamedix Corporation
2145 North Miami Avenue
Miami FL 33127
USA

Scope:

Design and Development, Manufacture and Distribution of in vitro diagnostic reagents and kits for the determination of infectious disease status and autoimmune disease status

Distribution, Installation and Service of automated EIA processors

Sites included:
Diamedix Corporation
2115 North Miami Avenue
Miami FL 33127, USA

Scope: Activities related to storage of finished products

Diamedix Corporation
14100 NW 57th Court
Miami Lakes FL 33014, USA

Scope: Activities related to installation and service of automated EIA processors

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

Date: 2014-02-12

Dr. H. Lüdemann

TÜVRheinland®

EC Certificate

Directive 98/79/EC Annex IV, excluding Sections 4 and 6
Full Quality Assurance System
In Vitro Diagnostic Medical Devices

Registration No.: HL 60091858 0001

Report No.: 31292711 002

Manufacturer:
Diamedix Corporation
2145 North Miami Avenue
Miami FL 33127
USA

Products:
Immunosimplicity (Is) ELISA kits
- Is Toxoplasma IgG, IgM Capture
- Is Rubella IgG, IgM Capture
- Is CMV IgG, IgM Capture

Replaces approval, registration no.: HL 60024198 0001

Expiry Date: 2019-02-11

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Effective Date: 2014-02-12

Date: 2014-02-12

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Dr. H. Lüdemann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.