



# 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.

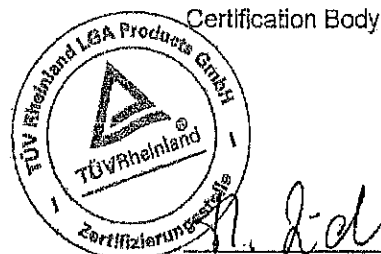
Certificate Registration No.: SX 60091860 0001

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



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-vaiddly@de.tuv.com <http://www.tuv.com/safety>



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 1/1, Rev. 0

**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



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**Certification Body**

Date: 2014-02-12

*H. Lüdemann*  
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

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.