

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization  
**Bioptik Technology, Inc.**  
**No. 188, Jhonghua South Road**  
**Gongguan Village**  
**Jhunan Township**  
**Miaoli County, 35057**  
**Taiwan**

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

**Design and Development, Manufacture and Distribution  
of in vitro diagnostic for self-testing  
(see attachment for products 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 60089706 0001

An audit was performed. Report No.: 10042449 001

This Certificate is valid until: 17.09.2018



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

Certification Body



X. Ren

Date 14.01.2014

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

**Attachment to**  
**Registration No.:** SX 60089706 0001  
**Report No.:** 10042449 002

**Organization:** Bioptik Technology, Inc.  
No. 188, Jhonghua South Road  
Gongguan Village  
Jhunan Township  
Miaoli County, 35057  
Taiwan

**Scope:** Products:

- Blood Glucose Monitoring Systems
- Blood Cholesterol Monitoring Systems
- Hemoglobin Monitoring Systems
- Blood Glucose/Uric Acid Monitoring Systems
- Blood Glucose/Cholesterol Monitoring Systems
- Blood Glucose/Hemoglobin Monitoring Systems
- Blood Glucose/Cholesterol/Uric Acid Monitoring Systems
- Blood Glucose/Cholesterol/Hemoglobin Monitoring Systems
- Blood Glucose/Cholesterol/Uric Acid/Hemoglobin Monitoring System
- Blood Pressure/Glucose/ Cholesterol Monitoring Systems (Monitoring System is including meter, strip and control solution)



**Date:** 2014-03-13

**Certification Body**

