

Certificate

The Certification Body of
TÜV Rheinland Product Safety GmbH

hereby certifies that the organization
Bioptik Technology, Inc.
No. 188, Jhonghua South Road
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 diagnostica for self-testing
(see attachment for products included)**

Proof has been furnished that the requirements specified in

EN ISO 13485:2003 + AC:2007

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

Certificate Registration No.: SX 60027677 0001

An audit was performed. Report No.: 10022848 002

This Certificate is valid until: 25.09.2013



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



Certification Body

Cologne, 23.12.2009



Dr. H. Lüdemann

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TÜV Rheinland
Product Safety GmbH
Am Grauen Stein, D-51105 Köln

Attachment to
Registration No.: SX 60027677 0001
Report No.: 10022848 002

Organization: Bioptik Technology, Inc.
No. 188, Jhonghua South Road
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



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