

APPROVAL
EC Directive 98/79/EC Annex IV, Article 3
Full Quality Assurance System
In vitro diagnostic medical devices

Registration No.: HL 60027676 0001

Report No.: 10022848 002

Manufacturer: Bioptik Technology, Inc.
No. 188, Jhonghua South Road
Jhunan Township
Miaoli County, 35057
Taiwan

Scope: Design and Development, Manufacture of
in-vitro diagnostica for self-testing

(see attachment for products included)

Replaces Approval, Registration No.: HL 60022475 0001

Date of Expiry: 25.09.2013

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex IV, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex IV, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Cologne, 23.12.2009



Notified Body


Dr. H. Lüdemann

TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. **0197** to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with.

CE

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

Attachment to
Registration No.: HL 60027676 0001
Report No.: 10022848 002

Manufacturer: 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

Cologne, 23.12.2009



Certification Body


Dr. H. Lüdemann