



QUALITY SYSTEM

CERTIFICATE

Directive 98/79/EC

Manufacturer: General Life Biotechnology Co. Ltd.
No. 53 Jung Jeng Road, Shin Juang
Taipei Hsien
Taiwan R.O.C.

Coverage of Certificate: Design, manufacture and final inspection

Product category: Blood glucose, uric acid and total cholesterol
test devices for self-testing

Valid until: 21st December, 2009

The manufacturer's quality system for the design, manufacture and final inspection of the aforesaid product category has been evaluated and meets the provisions of Council Directive 98/79/EC as set out in Annex IV Section 3. This approval is valid until the expiry date provided that the manufacturer fulfils the obligations imposed by Annex IV in Directive 98/79/EC. This Certificate is based on decision no. VTT-C-1207-02-1111-267-06-P0.

Tampere, 21st December, 2006

Kaarle Kylmä

Certificate no.

VTT-C-1207-02-1111-267-06




Markku Helminen

Notified Body no. 0537:
VTT Technical Research Centre of Finland
P.O. Box 1300 (Tekniikankatu 1)
FI-33101 TAMPERE
Tel.+358 20 722 111

DECISION

on a quality system and product range covered, based on Council Directive 98/79/EC of 27 October 1998 on In vitro diagnostic medical devices, Annex IV Section 3.

Decision no.:	VTT-C-1207-02-1111-267-06-P0
Manufacturer:	General Life Biotechnology Co. Ltd. No. 53 Jung Jeng Road, Shin Juang, Taipei Hsien Taiwan R.O.C.
Date of application:	6.9.2006
Activity and product category:	Design, manufacture and final inspection; blood glucose, uric acid and total cholesterol test devices for self-testing.
Decision:	A certificate will be issued for the manufacturer. The certificate covers the following products: <ul style="list-style-type: none"> - BeneCheck Plus Multi-Monitoring System - BeneCheck Plus Multi-Monitoring Meter PD-G001 - BeneCheck Plus Glucose Test Strip BKP-G-S001 - BeneCheck Plus Glucose Control Solution PD-F003, PD-F004, PD-F005 - BeneCheck Plus Uric Acid Test Strip BKP-U-S001 - BeneCheck Plus Uric Acid Control Solution PD-F006, PD-F007, PD-F008 - BeneCheck Plus Total Cholesterol Test Strip BKP-C-S001 - BeneCheck Plus Cholesterol Control Solution PD-F009, PD-F010, PD-F011
Justification:	The manufacturer's quality system has been assessed and VTT has found that the quality system and the products meet the requirements of Annex IV of In Vitro Diagnostic Medical Device Directive 98/79/EC in design, manufacture and final inspection. The decision is based on report no. NB-1111-A1. The company has signed the undertaking to follow the obligations of Annex IV of the Directive.
Certificate related to decision:	VTT-C-1207-02-1111-267-06
Valid until:	This decision is valid until 21 st December, 2009.
Date:	Tampere, 21 st December, 2006 <div style="text-align: center;">  <p>Kaarle Kylmäla Markku Helminen</p> </div>

VTT is Notified Body no 0537 under Council Directive 98/79/EC.