



Product Service

EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
 (List A and B and devices for self-testing)

No. V1 15 07 63505 037

Manufacturer: **OK Biotech Co., Ltd.**
 No. 91, Sec. 2, Gongdao 5th Road
 30070 Hsinchu City
 TAIWAN



EC-Representative: **Medical Device Safety Service GmbH**
 Schiffgraben 41
 30175 Hannover
 GERMANY

Product Category(ies): **Blood glucose measuring systems for self testing
 (Blood glucose monitoring system)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. See also notes overleaf.

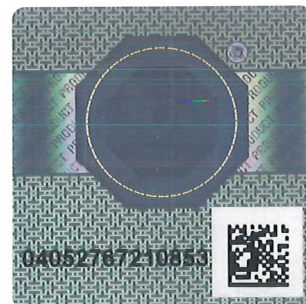
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Valid until: 2017-03-29

Date, 2015-12-29

Hans-Heiner Junker



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 2



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Model(s):

- Blood Glucose Monitoring System
(including Blood Glucose Meter, Blood Glucose Test Strips & Control Solution).
Model No. OK-XY (X=0~99 or blank, Y=A-Z or blank)
- Quick & Care Blood Glucose Monitoring System
(including Blood Glucose Meter, Blood Glucose Test Strips & Control Solution)
- Quick & Care - Direct Blood Glucose Monitoring System
(including Blood Glucose Meter, Blood Glucose Test Strips & Control Solution)
- Diacont Blood Glucose Monitoring System
(including Blood Glucose Meter, Blood Glucose Test Strips & Control Solution)
- glucoEASY Blood Glucose Monitoring System
- glucoEASY Plus Blood Glucose Monitoring System
- glucoEASY Meter
- glucoEASY Plus Meter
- glucoEASY Test Strips
- glucoEASY Control Solution
- Prodigy AutoCode Blood Glucose Monitoring System
(Including Blood Glucose Meter, Blood Glucose Test Strips & Control Solution)
- Prodigy Choice Blood Glucose Monitoring System
(Including Blood Glucose Meter, Blood Glucose Test Strips & Control Solution)
- Prodigy Connect Blood Glucose Monitoring System
(Including Blood Glucose Meter Module, Blood Glucose Test Strips & Control Solution)
- Prodigy Pocket Blood Glucose Monitoring System
(Including Blood Glucose Meter, Blood Glucose Test Strips & Control Solution)
- Prodigy Preferred Blood Glucose Monitoring System
(Including Blood Glucose Meter, Blood Glucose Test Strips & Control Solution)
- Prodigy Voice Blood Glucose Monitoring System
(Including Blood Glucose Meter, Blood Glucose Test Strips & Control Solution)
- Prodigy AutoCode Eject Blood Glucose Monitoring System
(Including Blood Glucose Meter, Blood Glucose Test Strips & Control Solution)
- Prodigy Astro Blood Glucose Monitoring System
(Including Blood Glucose Meter, Blood Glucose Test Strips & Control Solution)
- UniStrip1 Blood Glucose Test Strips

Facility(ies):

OK Biotech Co., Ltd.
No. 91, Sec. 2, Gongdao 5th Road, 30070 Hsinchu City, TAIWAN