ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 14 04 63505 036

Manufacturer:

OK Biotech Co., Ltd.
No. 91, Sec. 2, Gong Dao 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.

Report No.: 610211430301

Valid from: 2014-04-08
Valid until: 2019-04-07

Date, 2014-04-09

Hans-Heiner Junker

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

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No. V1 14 04 63505 036

Model(s):

Blood Glucose Test Strips
Model Name:
-UniStrip1

Facility(ies):

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

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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