



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 12 08 61120 012

Manufacturer: **VISGENEER Inc.**
No. 188, Sec. 3, Gongdao 5th Rd.
30069 Hsinchu City
TAIWAN

EC-Representative: **EMERGO EUROPE**
Molenstraat 15
2513 BH The Hague
THE NETHERLANDS

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.: 610211232401

Valid from: 2012-12-18

Valid until: 2017-04-12

Date, 2012-12-21

Hans-Heiner Junker



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

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Model(s):

Blood Glucose Monitoring System:

Blood Glucose Meter

eBsensor, eBsugar, eBcarryon, eBchek, eBwell, eBcare,

1. eB-GXY (X=0-9 or blank, Y=0-9 or blank)

2. eB-AXY (X=0-9 or blank, Y=0-9 or blank)

3. eB-SXY (X=0-9 or blank, Y=0-9 or blank)

4. eB-WXY (X=0-9 or blank, Y=0-9 or blank)

5. eB-CXY (X=0-9 or blank, Y=0-9 or blank)

Blood Glucose Test Strip

eBsensor, eBsugar, eBcarryon, eBchek, eBwell, eBcare,

eBsensor II, eBcarryon II, eBsugar II,

LS-XY (X=0-9 or blank, Y=0-9 or blank)

eB- series Control Solution

eB-CSXY (X=0-9 or blank, Y=0-9 or blank)

Facility(ies):

VISGENEER Inc.

No. 188, Sec. 3, Gongdao 5th Rd., 30069 Hsinchu City, TAIWAN