



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07



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 077360 0016 Rev. 02

Manufacturer:

BioCare Corporation

4F, No. 12, Ln. 5, Sec. 2, Nanshan Rd.
Luzhu Dist.
338028 Taoyuan City
TAIWAN

**Product Category(ies): In Vitro diagnostic devices 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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:V1 077360 0016 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:V1_077360_0016_Rev.02)

Report no.:

TW2100102

Valid from:

2021-12-29

Valid until:

2024-05-26

Date,

2021-12-29

Christoph Dicks
Head of Certification/Notified Body



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 077360 0016 Rev. 02

Model(s):

Blood Glucose Monitoring System:

DIAVUE series, TESTAmed, EverChek Max, EverChek Ultra

-Blood Glucose Meter:

DIAVUE series, TESTAmed, EverChek Max, EverChek Ultra

-Blood Glucose Test Strip:

DIAVUE series, TESTAmed, EverChek Max, EverChek Ultra

-Control Solution:

TESTAmed, DIAVUE series, EverChek

Facility(ies):

BioCare Corporation

4F, No. 12, Ln. 5, Sec. 2, Nanshan Rd., Luzhu Dist., 338028

Taoyuan City, TAIWAN