



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 051016 0042 Rev. 02

Manufacturer:

All Medicus Co., Ltd.

#7102~7107, #7402, #7403, #7406
140, Beolmal-ro, Dongan-gu
Anyang-si, Gyeonggi-do 14057
REPUBLIC OF KOREA

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

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 051016 0042 Rev. 02

Report no.:

74962411

Valid from:

2022-05-20

Valid until:

2025-05-26

Date,

2022-05-20

Christoph Dicks
Head of Certification/Notified Body



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 051016 0042 Rev. 02

Model(s):

See attached

Facility(ies):

All Medicus Co., Ltd.

#7102~7107, #7402, #7403, #7406, 140, Beolmal-ro, Dongan-gu,
Anyang-si, Gyeonggi-do 14057, REPUBLIC OF KOREA



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 051016 0042 Rev. 02

Blood Glucose Monitoring System

-Blood Glucose Test Meter

-Blood Glucose Test Strip

-Control Solution

Model Number: AGM-5xxy, ABM-5xxy, ANM-5xxy series

(xx=11~17, 20~27, y=A~Z)

Model

AGM-512S

ABM-512S

AGM-513S

ABM-513S

ANM-513S

AGM-514P

ABM-514P

Brand

GlucDr.GOLD™

GlucDr.GOLD™ BLE

GlucDr.S™ / GlucoMate/ Lifecek Gold/
WELLEX/ familyDr.™

GlucDr.S™ BLE/ familyDr.™ BLE

GlucDr.S™ NFC

GlucDr.PRO™

GlucDr.PRO™ BLE

Blood Glucose Monitoring System

-Blood Glucose Test Meter

-Blood Glucose Test Strip

-Control Solution

Model

AGM-2100

AGM-2200

AGM-4000

AGM-4100

AGM-4200

Brand

GlucDr, GlucDr Smart, Trister™

GlucDr SuperSensor, GlucDr Smart+

GlucDr auto, GlucoSafe, GlucoZen.auto™

GlucDr.auto™A

GlucDr TOP

GlucDr One

Blood Glucose Monitoring System

- Blood Glucose Monitor

- Blood Glucose Test Strip

- Control Solution

Model

AGM-4000

Brand

Alere™ G1, G1 Advance