



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



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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,
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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

Brand

AGM-512S

GlucoDr.GOLD™

ABM-512S

GlucoDr.GOLD™ BLE

AGM-513S

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

ABM-513S

GlucoDr.S™ BLE/ familyDr.™ BLE

ANM-513S

GlucoDr.S™ NFC

AGM-514P

GlucoDr.PRO™

ABM-514P

GlucoDr.PRO™ BLE

Blood Glucose Monitoring System

-Blood Glucose Test Meter

-Blood Glucose Test Strip

-Control Solution

Model

Brand

AGM-2100

GlucoDr, GlucoDr Smart, Trister™

AGM-2200

GlucoDr SuperSensor, GlucoDr Smart+

AGM-4000

GlucoDr auto, GlucoSafe, GlucoZen.auto™

GlucoDr.auto™A

AGM-4100

GlucoDr TOP

AGM-4200

GlucoDr One

Blood Glucose Monitoring System

- Blood Glucose Monitor

- Blood Glucose Test Strip

- Control Solution

Model

Brand

AGM-4000

Alere™ G1, G1 Advance