SGS

EC Certificate Full Quality Assurance System: Certificate KR11/01748

The management system of

MiCoBioMed Co.,Ltd.

116, Gongdan 1-ro, Anseong-si, Gyeonggi-do, Korea

has been assessed and certified as meeting the requirements of

Directive 98/79/EC

on in vitro diagnostic medical devices Annex IV (excluding Sections 4, 6)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 14 May 2019 until 28 December 2022 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 13 December 2020 Issue 14. Certified since 28 December 2011

Certification is based on reports numbered KR/SEL Y-PC/11282

Authorised by

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SGS CE 08 0315 M2

Page 1 of 2





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EC Certificate Full Quality Assurance System: Certificate KR11/01748, continued

MiCoBioMed Co.,Ltd.

Directive 98/79/EC

on in vitro diagnostic medical devices Annex IV (excluding Sections 4, 6)

Issue 14

For the following products

Blood Glucose Monitoring System for self-testing (Brand name: VERI-Q

BALANCE, Healthy-Q)

Meter: MGD-1001, MGD-2001

Test strips: MGS01A, MGS01B

Control solution: MGCS-1 (Blood glucose)

Check strip: MGD-CKS (Blood glucose)

Blood Glucose Monitoring System for self-testing (Brand name: VERI-Q

BALANCE PRO, Healthy-Q)

Meter: MGD-1002, MGD-1002A (VERI-Q BALANCE PRO)

Test strips: MGS01A, MGSC

Control solution: MGCS-1 (Blood glucose)

Check strip: MGD-CKS (Blood glucose)

Multi Function (Glucose / Cholesterol / Hemoglobin) Blood Monitoring System

for self-testing (Brand name: VERI-Q MULTI, Healthy-Q, QDx Lipidcheck™)

Meter: MMD-1BL

Test strip:MLS-1, MCHS-1, MCS-1, MTS-1, MDS-1 (Lipid), MGS01A &

MGS01B (Glucose), MHS-1 (Hemoglobin)

Control solution: MGCS-1 (Blood glucose), MTCCS-1 (Cholesterol), MTGCS-1

(Triglyceride), MHDLCS-1 (HDL), MHCS-1 (Hemoglobin)

Check Strip: MGD-CKS(Blood glucose), MHD-CKS2 (Hemoglobin), MMD-CKS

Hemoglobin monitoring system for self-testing (Brand name: VERI-Q RED,

Family Dr™Hb, Healthy-Q, CareStart™Hb, CareStart™Biosensor 1 Hb)

Meter: MHD-1

Test strip: MHS-2

Check strip: MHD-CKS1

Control solution: MHCS-1

Where the above scope includes List A IVD medical device(s), a valid EC Design Examination Certificate according to Annex IV (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on