

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 27 January 2017 until 28 December 2019 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 13 December 2017

Issue 10. Certified since 28 December 2011

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

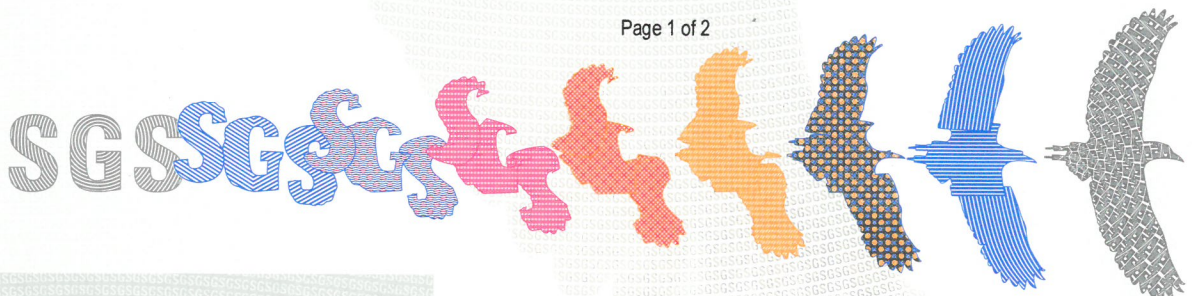
Authorised by

SGS United Kingdom Ltd, Notified Body 0120

202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 08 0315 M2

Page 1 of 2



MiCoBioMed Co.,Ltd.

Directive 98/79/EC

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

Issue 10

For the following products

Devices

**Blood Glucose Monitoring System for self-testing;
Multi Function (Glucose/Cholesterol/Hemoglobin)
Blood Monitoring System for self-testing;
Haemoglobin monitoring system for self-testing.**

Model names

[set] MMDS 1, MMDS 2

**[meter] Glucose : MGD-1001, MGD-1002, MGD-2001, MGD-1002A /
Multi : MMD-1, MMD-1 BL / Hemoglobin: MHD-1**

**[test strip] Glucose : MGS01A, MGS01B, MGSC series / Cholesterol :
MLS-1, MCS-1, MTS-1, MCHS-1, MDS-1 / Hemoglobin : MHS-1, MHS-2**

**[control solution] Glucose : MGCS-1 / Cholesterol : MTCCS-1, MTGCS-
1, MHDLCS-1 / Haemoglobin : MHCS-1**

Brand names

[Glucose] VERI-Q BALANCE, VERI-Q BALANCE Pro

[Multi] VERI-Q MULTI (Healthy-Q, QDx Lipidcheck™)

[Hemoglobin] VERI-Q RED, (CareStart™ Hb, Family Dr.™ Hb)

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 the market