EC Certificate - Full Quality Assurance

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV, excluding Sections 4 and 6

No. **CE 737269**

Issued To: **MiCo BioMed Co., Ltd.**
116 Gongdan 1-ro
Anseong-si
Gyeonggi-do
17575
Republic of Korea

In respect of:

Design and manufacture of blood glucose, hemoglobin and cholesterol self-testing monitoring systems.

on the basis of our examination under the requirements of Council Directive 98/79/EC, Annex IV, the quality system was found to meet the requirements of 98/79/EC Annex IV.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2021-04-09** Date: **2022-04-07** Expiry Date: **2025-05-26**

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Supplementary Information to CE 737269

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Device code	Device name	Intended purpose per IFU
Annex II List B		
IVD0309 IVD0401	Multi-Function Blood Monitoring Systems	The Multi-Function (Glucose/Cholesterol/Hemoglobin) Blood Monitoring Systems are intended for self-testing for in vitro diagnostics use only. It is used for testing lipid profile, hemoglobin and monitoring glucose level in the whole (capillary) blood. This testing system is intended to measure the quantitative measurement of the concentration of glucose (GLU) and lipid profile by diabetic or metabolism disorder's patients and total hemoglobin (Hb) is for anemia screening. The lipid profile is for total cholesterol (TC), triglycerid (TG) and high density lipoprotein-cholesterol (HDL), low density lipoprotein-cholesterol (LDL). LDL is calculated by other items.
IVD0309	Blood Glucose Monitoring Systems	The Blood Glucose Monitoring systems are intended for self-testing for in vitro diagnostics use only. It is used for the quantitative measurement of the concentration of glucose in whole blood from fingertip, ventral palm and forearm by diabetic patients as an aid in the management of diabetes. It is intended for use outside of the body (in vitro diagostic use), and not for diagnosis of or screening for diabates, nor for use on neonates or arterial blood. The alternative site testing (ventral palm and forearm) in this system can only be used during steady-state blood glucose conditions.

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Device code	Device name	Intended purpose per IFU
Non-Annex II Self-test		
IVD0401	Physiological Markers Monitoring systems	The monitoring systems are intended for self-testing for in vitro diagnostics use only. It is used for testing lipid profile or total hemoglobin level in the whole blood (capillary or vein blood) for quantitative measurement of diabetic patients or anemia screening.

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EC Certificate - Full Quality Assurance Certificate History

Certificate No: **CE 737269**
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Date	Reference Number	Action
09 April 2021	3297802	First Issue.
12 November 2021	3551439	Update of statement from Device Name to Generic Device Group and the Intended Purposes; Correction of classification statement.
07 April 2022	3659346	Change of IVDD expiry date according to Regulation (EU) 2022/112.
Non-significant changes approved after the 26th May 2022 as per the Transitional Provisions of IVDR Article 110.3		
14 November 2022	3774217	Change of address for EU Representative MT Promedt Consulting GmbH from: Altenhofstraße 80, 66386 St. Ingbert, Germany To: Ernst-Heckel-Straße 7, 66386 St. Ingbert, Germany

Inspiring trust for a more resilient world.

14 November 2022

MiCo BioMed Co., Ltd.
116 Gongdan 1-ro
Anseong-si
Gyeonggi-do
17575
South Korea

To whom it may concern,

The transitional provisions specified in IVDR Article 110(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing IVDD certificates from 26th May 2022.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under IVDR Article 110(3) and as per the guidance provided in MDCG 2022-6. The related IVDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 737269	98/79/EC Annex IV excl sec 4 & 6	3774217	Change of address for EU Representative MT Promedt Consulting GmbH from: Altenhofstraße 80, 66386 St. Ingbert, Germany To: Ernst-Heckel-Straße 7, 66386 St. Ingbert, Germany

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices