EC Declaration of Conformity

Manufacturer:
General Life Biotechnology Co., Ltd.,
Address: 6, 7F., No.669, Jhongjheng Rd., Shin Juang Dist., New Taipei City 242, Taiwan

whose single Authorized Representative:
Name: MDSS GmbH
Address: Schiffgraben 41 30175 Hannover, Germany

We, the manufacturer, herewith declare that the following products

Product Name	EDMS Code	Model No.
BeneCheck Multi-Monitoring System	21 07 10 01	BK6-12M /BK6-12M-D
BeneCheck Multi-Monitoring System	21 07 10 01	BK6-12M-1 /BK6-12M-D-1
BeneCheck Multi-Monitoring System	21 07 10 01	BK6-12M-2 /BK6-12M-D-2
BeneCheck Multi-Monitoring System	21 07 10 01	BK6-12M-3 /BK6-12M-D-3
BeneCheck Multi-Monitoring Meter	21 07 10 01	BK6-12M /BK6-12M-D
BeneCheck Multi-Monitoring Meter	21 07 10 01	BK6-12M-1 /BK6-12M-D-1
BeneCheck Multi-Monitoring Meter	21 07 10 01	BK6-12M-2 /BK6-12M-D-2
BeneCheck Multi-Monitoring Meter	21 07 10 01	BK6-12M-3 /BK6-12M-D-3
BeneCheck Glucose Test Strip	11 70 01 01	BK6-G
BeneCheck Total Cholesterol Test Strip	11 70 01 02	BK-C2
BeneCheck Uric Acid Test Strip	11 70 01 90	BK-U1
BeneCheck II Glucose Control Solution	11 70 01 50	BK-CSG30 (Level 0) BK-CSG31 (Level 1) BK-CSG32 (Level 2)
BeneCheck II Total Cholesterol Control Solution		BK-CSC21(Level 1), BK-CSC22(Level 2)
BeneCheck Uric Acid Control Solution		PD-F006(Level 0), PD-F007(Level 1), PD-F008(Level 2)

meet the provisions of Directive 98/79/EC which apply to them.

The medical device has been assigned to List B, Self-testing for in vitro Diagnostic Monitoring System according to Annex II of the Directive 98/79/EC. It bears the mark

CE **0197**

The product concerned has been designed and manufactured under a quality management system according to Annex IV of Directive 98/79/EC.

Compliance of the designated product with the Directive 98/79/EC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Country : Germany
Certificate No.: HL 2029595-1
Issue date: 2022-05-18
Expiry date: 2025-05-26

following the procedure relating to the EC Declaration of Conformity set out in Annex IV, excluding section 4 and 6 of the Directive 98/79/EC.

This Declaration of conformity is valid in connection with the release document for the respective serial of produced devices.

The Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of compliance for all products concerned bearing the CE mark.

The above mentioned declaration of conformity is exclusively under the responsibility of
General Life Biotechnology Co., Ltd.

2022. 5. 18
Place,Date

Signature, CEO