

EC Declaration of Conformity

Manufacturer:

Sejoy Biomedical Co., Ltd.
Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic Development Zone,
Hangzhou City, 311100 Zhejiang P.R.China

whose single Authorized Representative:

Shanghai International Holding
Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

We, the manufacturer, herewith declare that the products

Product Name	Models	EDMA-Code
Blood Glucose Meter	BG-101, BG-102, BG-103, BG-108, BG-201, BG-202, BG-203, BG-205, BG-208, BG-207, BG-209, BG-207b, BG-209b, BG-707, BG-707b, BG-709, BG-709b, BG-210, BG-210b, BG-710, BG-710b, BG-211, BG-211b, BG-708, BG-705b, BG-705, BG-713r Ease, BG-713t Ease	21.07.10.01
Blood Glucose Test Strips	BS-101, BS-102, BS-302, BS-602	11.70.01.01
Blood Glucose Test Controls	CS-101, CS-102	11.50.02.05

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

The medical device has been assigned to List B according to Annex II of the Directive 98/79/EEC. It bears the mark

CE 0197

The product concerned has been designed and manufactured under a quality management system according to Annex IV, excluding section 4 and 6 of the Directive 98/79/EEC.

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

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany

Certificate No.: HL 60149972 0001

Issue date: 2020.9.8

Expiry date: 2024.05.26

following the procedure relating to the EC Declaration of Conformity set out in Annex IV of Directive 98/79/EEC.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Sejoy Biomedical Co., Ltd.

Address: Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic Development Zone, Hangzhou City, 311100 Zhejiang P.R.China

Hangzhou, August 15, 2023

Yunhui Ren, General Manager

Place, date

浙江世佳生物医疗有限公司
SEJOY BIOMEDICAL CO., LTD.
Legally binding signature, Function