



# DECLARATION OF CONFORMITY

## Regarding In Vitro Diagnostic Directive (98/79/EC)

**Manufacturer:**

Shenzhen IMDK Medical Technology Co.,Ltd.

**Address:**

C Zone,10F,Building 16,Yuanshan Industrial B Area,Gongming  
Street,Guangming District,518106, Shenzhen.PEOPLE'S  
REPUBLIC OF CHINA

**EC Representative:**

SUNGO Europe B.V.

**Address:**

Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

**Product Name:**

Blood Glucose Meter

**Model:**

BGM-T1,BGM-T2

**Classification:**

Others (IVDD)

**Conformity Assessment**

**Procedure:**

Annex III of In Vitro Diagnostic Directive (98/79/EC)

We herewith declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

EN ISO 14971:2019

EN ISO 18113-1:2011

EN ISO 18113-3:2011

EN ISO 20417: 2021

Signature:

  


Position: GM

Date:

2022.05.09

Place: Shenzhen/ China