



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 Test Strip
Model: TS-25, TS-50, TS-100.
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 18113-2:2011
EN 13612:2002+AC:2002	EN ISO 23640:2015	EN 13641:2002
EN ISO 20417: 2021		

Signature: Changchun
Position: GM



Date: 2022.05.09
Place: Shenzhen/ China