EC Declaration of Conformity

Manufacturer:
Name: Hunan Qankorey Biotechnology Company Ltd.
Address: 12F, Building 15, No. 188 Middle Huanbao Road, Yuhua District, Changsha, Hunan,410116,China

Whose Authorized Representative:
Name: MedUnion S.L.（ES-AR-000019366）
Address: Carrer de Tapioles, 33, 2-1, 08004, Barcelona, Spain
Tel: +0034-644173535

We, Hunan Qankorey Biotechnology Company Ltd. (Manufacturer), here declare that the below mentioned medical device meets the provisions of Directive 98/79/EC which apply to them. The declaration of conformity is exclusively under the responsibility of Hunan Qankorey Biotechnology Company Ltd. (Manufacturer).

Product Name: One Step Dementia Test Kit (Colloidal Gold Lateral Immunochromatography)

Classification: IVD Others

Conformity Assessment Route: IVDD 98/79/EC Annex III (excluding section 6).

Applicable Standards:

EN ISO 13485:2016	*EN ISO 18113-2:2011*	*EN 13612:2002*
EN ISO 14971:2019	*EN 13641:2002*	*EN ISO 23640:2015*
EN ISO 18113-1:2011	*EN ISO 15223-1:2016*	*IEC 62366-1:2015*

CE

Name of Authorized Signatory	Zhengqian Dai
Position	CEO
Signature	
Date	May 3rd 2023
Place	12F, Building 15, No. 188 Middle Huanbao Road, Yuhua District, Changsha, Hunan,410116, China