

CERTIFICATE

EC Certificate No. 1434-IVDD-455/2021

EC Design-examination Directive 98/79/EC concerning *in vitro* diagnostic medical devices

Polish Centre for Testing and Certification certifies that manufactured by:

HANGZHOU BIOTEST BIOTECH CO., LTD 17#, Futai Road, Zhongtai Street, Yuhang District, Hangzhou, P.R. China

in vitro diagnostic medical devices for self-testing

The list of medical devices covered by this certificate is provided in the annex 1

in terms of design documentation, comply with requirements of Annex III (Section 6) to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC Validity of the Certificate: from 01.09.2021 to 27.05.2024

The date of issue of the Certificate: 01.09.2021

The date of the first issue of the Certificate: 01.09.2021



Issued under the Contract No. MD-39/2021 Application No: 052/2021 Certificate bears the qualified signature. Warsaw, 01.09.2021 Module A1

Anna Małgorzata Wyroba Vice-President