



# 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  
Elektronicznie  
podpisany przez Anna  
Małgorzata Wyroba  
Data: 2021.09.02  
09:46:30 +02'00'  
Vice-President