



CERTIFICATE

EC Certificate No. 1434-IVDD-064/2022

**Full Quality Assurance System
Directive 98/79/EC concerning
in vitro diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Hangzhou Biotest Biotech Co., Ltd
#17, Futai Road, Zhongtai Street, Yuhang District
Hangzhou, P.R. China

for the design, manufacture and final inspection of *in vitro* diagnostic medical device
List A

HIV 1.2.O Rapid Test, Cat. No. IHIV-C42

complies with requirements
of Annex IV (excluding Section 4, 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 23.03.2022 to 27.05.2025

The date of issue of the Certificate: 23.03.2022

The date of the first issue of the Certificate: 16.11.2018



Issued under the Contract No. MD-132/2021
Application No: 237/2021
Certificate bears the qualified signature.
Warsaw, 23/03/2022
Module H7

President