

EC Certificate No. 1434-IVDD-123/2021

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

HCV Rapid Test, Cat. No. IHCV-C31

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 06.04.2021 to 27.05.2024

The date of issue of the Certificate: 10.03.2021

The date of the first issue of the Certificate: 06.04.2018



Issued under the Contract No. MD-14/2021 Application No: 245/2020 Certificate bears the qualified signature.

Warsaw, 10.03.2021 Module H7

lle H7 Vice-President