



CERTIFICATE

EC Certificate No. 1434-IVDD-125/2021

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

HBsAg Rapid Test, Cat. No. IHBSG-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: 244/2020

Certificate bears the qualified signature.

Warsaw, 10.03.2021

Module H7

Vice-President