

## CERTIFICATE

DIRECTIVE 98/79/EC  
EC DESIGN-EXAMINATION

CeCert Sp. z o.o. hereby confirms that manufactured by

**Hangzhou AllTest Biotech Co., Ltd.**  
#550, Yin Hai Street, Hangzhou Economic & Technological  
Development Area, Hangzhou, 310018, P.R. China

*in vitro* diagnostic medical device referred to in List A in Annex II

**HBsAg Rapid Test Cassette  
(Whole Blood/Serum/Plasma)**  
catalogue number: IHBSG-402

in term of the design conforms to the requirements of Annex IV  
section 4 to Directive 98/79/EC (as amended) implemented into Polish  
Law, as evidenced by the audit conducted by CeCert Sp. z o.o.

**CE** **2934**

Validity date: 16.05.2022 – 26.05.2025

Issue date: 16.05.2022

Check it



CeCert Sp. z o.o.  
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e-mail: [biuro@cecet.pl](mailto:biuro@cecet.pl)

**Kamil Szczurowski**  
Director of *in Vitro* Diagnostic Medical Device  
Certification Department

Certificate no: CeCert/101/W/E.1

## CERTIFICATE

DIRECTIVE 98/79/EC  
FULL QUALITY ASSURANCE SYSTEM

CeCert Sp. z o.o. hereby confirms that  
the quality assurance system in the organization

**Hangzhou AllTest Biotech Co., Ltd.**  
#550, Yin Hai Street, Hangzhou Economic & Technological  
Development Area, Hangzhou, 310018, P.R. China

with regard to the design, manufacture and final inspection  
of *in vitro* diagnostic medical device referred to in List A in Annex II

**HBsAg Rapid Test Cassette  
(Whole Blood/Serum/Plasma)**  
catalogue number: IHBSG-402

conforms to the requirements of Annex IV (excluding section 4 and 6)  
to Directive 98/79/EC (as amended) implemented into Polish Law,  
as evidenced by the audit conducted by CeCert Sp. z o.o.



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**Kamil Szczurowski**  
Director of *in Vitro* Diagnostic Medical Device  
Certification Department

Certificate no: CeCert/102/W/E.1