

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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www.cecet.pl
e-mail: 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