

## CERTIFICATE

#### DIRECTIVE 98/79/EC EC DESIGN-EXAMINATION

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

#### Hangzhou AllTest Biotech Co., Ltd.

#550, Yinhai Street, Hangzhou Economic & Technological Development Area, Hangzhou, 310018, P.R. China

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

## HCV Rapid Test Cassette (Whole Blood/Serum/Plasma)

catalogue number: IHC-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.

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Validity date: 17.05.2022 - 26.05.2025

Issue date: 17.05.2022

Check it



CeCert Sp. z o.o. ul. Żurawia 32/34 00-515 Warszawa Kamil Szczurowski

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



### 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, Yinhai 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

# HCV Rapid Test Cassette (Whole Blood/Serum/Plasma)

catalogue number: IHC-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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