

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.
ul. Żurawia 32/34
00-515 Warszawa

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.



2934

Validity date: 16.05.2022 – 26.05.2025

Issue date: 16.05.2022

Check it



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

www.cecet.pl
e-mail: biuro@cecet.pl

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

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

/Ce Cert logotipas/

SERTIFIKATAS

DIREKTYVA 98/79/EB
EB PROJEKTAVIMAS – TYRIMAS

CeCert Sp. z o.o. tvirtina, kad gamintojo

Hangzhou AllTest Biotech Co., Ltd.
#550, Yin Hai Street, Hangzhou Economic & Technological
Development Area, Hangzhou, 310018, Kinijos LR

in vitro diagnostinis medicinos prietaiso, nurodomo II priedo A sąrašė

HBsAg greito testo kasetė
(bendras kraujas / serumas / plazma)
Katalogo numeris: IHBSG-402

dizainas atitinka Direktyvos 98/79/EB (su pakeitimais) IV priedo 4
skirsnio reikalavimus, įgyvendintus Lenkijos teisėje, tai patvirtina
CeCert Sp. z o.o. atliktas auditas.

/CE 2934/

Galiojimo data: 2022.05.16 — 2025.05.26

Leidimo data: 2022.05.16

/parašas/

Kamil Szczurowski
In vitro diagnostinių prietaisų sertifikavimo
departamento direktorius

/QR kodas/

CeCert Sp. z o.o.
ul. Zurawia 3Z/34
OO-515 Warszawa

www.cecet.pl
E. paštas: biuro@cecet.pl

Sertifikato nr.: CeCert/101/W/E.1

SERTIFIKATAS

DIREKTYVA 98/79/EB VISAPUSIŠKA KOKYBĖS UŽTIKRINIMO SISTEMA

CeCert Sp. z o.o. tvirtina, kad kokybės užtikrinimo sistema organizacijoje

Hangzhou AllTest Biotech Co., Ltd.
#550, Yin Hai Street, Hangzhou Economic & Technological
Development Area, Hangzhou, 310018, Kinijos LR

dėl projektavimo, gamybos ir galutinio patikrinimo
in vitro diagnostikos medicinos prietaiso, nurodyto II priedo A sąraše

HBsAg greito testo kasetė (bendras kraujas / serumas / plazma)

Katalogo numeris: IHBSG-402

atitinka Direktyvos 98/79/EB (su pakeitimais) IV priedo (išskyrus 4 ir 6
skirsnius) reikalavimus, įgyvendintus Lenkijos teisėje, tai patvirtina
CeCert Sp. z o.o. atliktas auditas.

/CE 2934/

Galiojimo data: 2022.05.16 — 2025.05.26

Leidimo data: 2022.05.16

/QR kodas/

CeCert Sp. z o.o. ul.
Zurawia 3Z/34 OO-
515 Warszawa

/parašas/

Kamil Szczurowski
In vitro diagnostinių prietaisų sertifikavimo
departamento direktorius

Tikslus dokumento vertimas į lietuvių kalbą
Vertėja Akvilė Gegelevičienė
Data 2022-10-13
UAB Diamedica
Gėlių g. 2, Avižieniai, Lietuva

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

**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.

CE **2934**

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

www.cecert.pl
e-mail: biuro@cecert.pl

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

Certificate no: CeCert/106/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

**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.



2934

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

www.cecert.pl
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Kamil Szczurowski
Director of *in Vitro* Diagnostic Medical Device
Certification Department

Certificate no: CeCert/107/W/E.1

/Ce Cert. logotipas/

SERTIFIKATAS

DIREKTYVA 98/79/EB
EB DIZAINO TYRIMAS

CeCert Sp. z o.o. šiuo raštu tvirtina, kad gamintojo

Hangzhou AllTest Biotech Co., Ltd.
#550, Yin Hai Street, Hangzhou Economic & Technological
Development Area, Hangzhou, 310018, Kinijos LR

in vitro diagnostinio medicinos prietaiso (pagal II priedo A sąrašą)

**HCV greitojo testo kasetė (bendras
kraujas / serumas / plazma)**

Katalogo numeris: INC-402

dizainas atitinka Direktyvos 98/79/EB (su pakeitimais) IV priedo 4
skirsnio reikalavimus, įgyvendintus Lenkijos teisėje, tai patvirtina
CeCert Sp. z o.o. atliktas auditas.

/CE 2934 žyma/

Galiojimo data: 17.05.2022 — 26.05.2025

Leidimo data: 17.05.2022

/QR kodas/

/parašas/

Kamil Szczurowski
In vitro diagnostiniai medicinos prietaisai, direktorius
Sertifikatų išdavimo departamentas

CeCert Sp. z o.o.
ul. Zurawia 32/34
00-515 Varšuva

www.cecet.pl

Certificate no: CeCert/106/W/E.1

el. paštas: biuro@cecet.pl

/Ce Cert. logotipas/

SERTIFIKATAS

DIREKTYVA 98/79/EB
VISAPUSIŠKA KOKYBĖS UŽTIKRINIMO SISTEMA

CeCert Sp. z o.o. tvirtina, kad kokybės užtikrinimo sistema organizacijoje

Hangzhou AllTest Biotech Co., Ltd.
#550, Yin Hai Street, Hangzhou Economic & Technological
Development Area, Hangzhou, 310018, Kinijos LR

dėl projektavimo, gamybos ir galutinio patikrinimo *in vitro*
diagnostikos medicinos prietaiso (pagal II priedo A sąrašą):

**HCV greitojo testo kasetė (bendras
kraujas / serumas / plazma)**
Katalogo numeris: INC-402

atitinka Direktyvos 98/79/EB (su pakeitimais) IV priedo (išskyrus 4 ir 6
skirsnius) reikalavimus, įgyvendintus Lenkijos teisėje, tai patvirtina
CeCert Sp. z o.o. atliktas auditas.

/CE 2934 žyma/

Galiojimo data: 17.05.2022 — 26.05.2025

Leidimo data: 17.05.2022

/QR kodas/

/parašas/

Kamil Szczurowski
In vitro diagnostiniai medicinos prietaisai, direktorius
Sertifikatų išdavimo departamentas

CeCert Sp. z o.o.
ul. Zurawia 32/34
00-515 Varšuva

www.cecet.pl
el. paštas: biuro@cecet.pl

Certificate no: CeCert/106/W/E.1

Tikslus dokumento vertimas į lietuvių kalbą
Vertėja Akvilė Gegelevičienė
Data 2022-09-22
UAB Diamedica
Gėlių g. 2, Avižieniai, Lietuva

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

**HIV 1.2 Rapid Test Cassette
(Whole Blood/Serum/Plasma)**
catalogue number: IHI-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: 13.05.2022 – 26.05.2025

Issue date: 13.05.2022

Check it



CeCert Sp. z o.o.
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00-515 Warszawa

www.cecet.pl
e-mail: biuro@cecet.pl

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

Certificate no: CeCert/096/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

**HIV 1.2 Rapid Test Cassette
(Whole Blood/Serum/Plasma)**
catalogue number: IHI-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.



2934

Validity date: 13.05.2022 – 26.05.2025

Issue date: 13.05.2022

Check it



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

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

Certificate no: CeCert/097/W/E.1

/Ce Cert logotipas/

SERTIFIKATAS

DIREKTYVA 98/79/EB
EB PROJEKTAVIMAS – TYRIMAS

CeCert Sp. z o.o. tvirtina, kad gamintojo

Hangzhou AllTest Biotech Co., Ltd.
#550, Yin Hai Street, Hangzhou Economic & Technological
Development Area, Hangzhou, 310018, Kinijos LR

in vitro diagnostinis medicinos prietaiso, nurodomo II priedo A sąrašė

**HIV 1.2 greito testo kasetė
(bendras kraujas / serumas / plazma)**

Katalogo numeris: IHI-402

dizainas atitinka Direktyvos 98/79/EB (su pakeitimais) IV priedo 4
skirsnio reikalavimus, įgyvendintus Lenkijos teisėje, tai patvirtina
CeCert Sp. z o.o. atliktas auditas.

/CE 2934/

Galiojimo data: 2022.05.13 — 2025.05.26

Leidimo data: 2022.05.13

/QR kodas/

CeCert Sp. z o.o.
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/parašas/
Kamil Szczurowski
In vitro diagnostinių prietaisų sertifikavimo
departamento direktorius

Sertifikato nr: CeCert/096/W/E.1

/Ce Cert logotipas/

SERTIFIKATAS

DIREKTYVA 98/79/EB
VISAPUSIŠKA KOKYBĖS UŽTIKRINIMO SISTEMA

CeCert Sp. z o.o. tvirtina, kad kokybės užtikrinimo sistema organizacijoje

Hangzhou AllTest Biotech Co., Ltd.
#550, Yinhai Street, Hangzhou Economic & Technological
Development Area, Hangzhou, 310018, Kinijos LR

dėl projektavimo, gamybos ir galutinio patikrinimo
in vitro diagnostikos medicinos prietaiso, nurodyto II priedo A sąraše

HIV 1.2 greito testo kasetė
(bendras kraujas / serumas / plazma)

Katalogo numeris: IHI-4O2

atitinka Direktyvos 98/79/EB (su pakeitimais) IV priedo (išskyrus 4 ir 6
skirsnius) reikalavimus, įgyvendintus Lenkijos teisėje, tai patvirtina
CeCert Sp. z o.o. atliktas auditas.

/CE 2934/

Galiojimo data: 2022.05.13 — 2025.05.26

Leidimo data: 2022.05.13

/QR kodas/

CeCert Sp. z o.o.
ul. Zurawia 3Z/34
OO-515 Warszawa

/parašas/
Kamil Szczurowski
In vitro diagnostinių prietaisų sertifikavimo
departamento direktorius

Tikslus dokumento vertimas į lietuvių kalbą
Vertėja Akvilė Gegelevičienė
Data 2022-10-13
UAB Diamedica
Gėlių g. 2, Avižieniai, Lietuva

www.cecert.pl
E. paštas: biuro@cecert.pl

Sertifikato nr: CeCert/096/W/E.1

EC Declaration of Conformity

Manufacturer:

Name: HANGZHOU ALLTEST BIOTECH CO., LTD.

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

European Representative:

Name: MedNet GmbH

Address: Borkstrasse 10, 48163 Muenster, Germany

Product Name: H. pylori Antigen Rapid Test (Feces)

Model: Dipstick/Cassette

Classification: Other Device of IVDD 98/79/EC

Conformity Assessment Route: IVDD 98/79/EC Annex III

EDMA Code: 15 70 01 02 00

We, HANGZHOU ALLTEST BIOTECH CO., LTD., herewith declare that we are exclusively responsible for this declaration of conformity. We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices

Standard Applied: EN ISO13485:2016, EN ISO14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO23640:2015, EN 13641:2002, EN ISO 15223-1:2016



Place, Date of Issue: in Hangzhou on 18/12/2019

Signature: 

Name: Soar Gao (Position: General Manager)

EC Declaration of Conformity

Manufacturer:

Name: HANGZHOU ALLTEST BIOTECH CO., LTD.

Address: #550, Yin Hai Street, Hangzhou Economic & Technological Development Area, Hangzhou -310018, P.R. China

European Representative:

Name: Lotus NL B.V.

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Product Name: SARS-COV-2/InfluenzaA+B/RSV/Adenovirus Antigen Combo Rapid Test

Model: Cassette

Classification: Other Device of IVDD 98/79/EC

Conformity Assessment Route: IVDD 98/79/EC Annex III (excluding point 6)

EDMA Code: 15 70 90 90 00

We, HANGZHOU ALLTEST BIOTECH CO., LTD., herewith declare that we are exclusively responsible for this declaration of conformity. We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

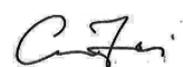
DIRECTIVES

General applicable directives:

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices

Standard Applied: EN ISO 13485:2016, EN ISO 14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO 23640:2015, EN 13641:2002, EN ISO 15223-1:2016

Place, Date of Issue: in Hangzhou on 18/11/2020

Signature: 

Name: GAO FEI (Position: General Manager)

15/03/2021

Date





TM

EC Declaration of Conformity

Manufacturer:

Name: HANGZHOU ALLTEST BIOTECH CO., LTD.

Address: #550, Yin Hai Street, Hangzhou Economic & Technological Development Area, Hangzhou -310018, P.R. China

European Representative:

Name: MedNet GmbH

Address: Borkstrasse 10, 48163 Muenster, Germany

Product Name: Strep A Rapid Test (Throat Swab)

Model: Cassette/Dipstick

Classification: Other Device of IVDD 98/79/EC

Conformity Assessment Route: IVDD 98/79/EC Annex III(excluding point 6)

EDMA Code: 15 70 01 03 00

We, HANGZHOU ALLTEST BIOTECH CO., LTD., herewith declare that we are exclusively responsible for this declaration of conformity. We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices

Standard Applied: EN ISO13485:2016, EN ISO14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO23640:2015, EN 13641:2002, EN ISO 15223-1:2016

Place, Date of Issue: in Hangzhou on 18/12/2019

Signature: 

Name: GAO FEI (Position: General Manager)

08/05/2021

Date





TM

EC Declaration of Conformity

Manufacturer:

Name: HANGZHOU ALLTEST BIOTECH CO., LTD.

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

European Representative:

Name: MedNet GmbH

Address: Borkstrasse 10, 48163 Muenster, Germany

Product Name: Multi-Drug Rapid Test with/without Adulteration

Model: Cassette/ Panel/Cup

Classification: Other Device of IVDD 98/79/EC

Conformity Assessment Route: IVDD 98/79/EC Annex III

EDMA Code: 12 70 09 70 00

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices

Standard Applied: EN ISO13485:2016, EN ISO14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO23640:2015, EN 13641:2002, EN ISO 15223-1:2016

Place, Date of Issue: in Hangzhou on 23/10/2018

Signature: 

Name: Soar Gao (Position: General Manager)



/logotipas/

EB atitikties deklaracija

Gamintojas:

Pavadinimas: HANGZHOU ALLTEST BIOTECH CO., LTD.

Adresas: #550, Yin Hai Street, Hangzhou Economic & Technological Development Area, Hangzhou -310018, Kinijos L. R.

Atstovas Europoje:

Pavadinimas: MedNet GmbH

Adresas: Borkstrasse 10, 48163 Muenster, Vokietija

Produkto pavadinimas: Multi-Drug Rapid Test with/without Adulteration

Modelis: kasetė/panelis/indelis

Klasifikacija: kitos IVDD 98/79/EC priemonės

Atitikties vertinimo būdas: IVDD 98/79/EC priedas III

EDMA kodas: 12 70 09 70 00

Šiuo raštu tvirtiname, jog aukščiau minimi produktai atitinka žemiau pateiktų EB tarybos direktyvų ir standartų reikalavimus bei jų perkėlimus į nacionalinę teisę. Visi papildantys dokumentai išlieka gamintojo žinioje.

DIREKTYVOS

Bendrai taikomos direktyvos:

EUROPOS PARLAMENTO DIREKTYVA 98/79/EC IR 1998 m. spalio 27 d. tarybos direktyva dėl in vitro diagnostinių medicinos priemonių.

Taikomi standartai: EN ISO13485:2016, EN ISO14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO23640:2015, EN 13641:2002, EN ISO 15223-1:2016.

/spaudas/

Leidimo vieta, data: Hangzhou, 23/10/2018

Parašas: /parašas/

Pavardė: Soar Gao (Pareigos: Generalinis direktorius)

Tikslus dokumento vertimas į lietuvių kalbą

Vertėja Akvilė Gegelevičienė

Data 2018-10-30

UAB Diamedica

Molėtų pl. 73, Vilnius, Lietuva

Tel. 8 5 279 0080

/rekvizitai/