



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: THC (Marijuana) Rapid Test (Whole Blood/Serum/Plasma)

Model: Cassette

Classification: Other Device of IVDD 98/79/EC

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

EDMA Code: 12 70 09 05 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:

23/07/2021

Name: GAO FEI (Position: General Manager)

Date





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: AMP (Amphetamine) Rapid Test (Whole Blood/Serum/Plasma)

Model: Cassette

Classification: Other Device of IVDD 98/79/EC

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

EDMA Code: 12 70 09 01 00

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

Signature: GAO FEI

Name: GAO FEI (Position: General Manager)

22/07/2021

Date





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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: BZO (Benzodiazepines) Rapid Test (Whole Blood/Serum/Plasma)

Model: Cassette

Classification: Other Device of IVDD 98/79/EC

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

EDMA Code: 12 07 09 04 00

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

Signature: GAO FEI 22/07/2021

Name: GAO FEI (Position: General Manager) Date





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: MET (Methamphetamine) Rapid Test (Whole Blood/Serum/Plasma)

Model: Cassette

Classification: Other Device of IVDD 98/79/EC

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

EDMA Code: 12 70 09 02 00

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

Signature:

Name: GAO FEI (Position: General Manager)

23/07/2021

Date





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: MOP (Morphine) Rapid Test (Whole Blood/Serum/Plasma)

Model: Cassette

Classification: Other Device of IVDD 98/79/EC

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

EDMA Code: 12 70 09 08 00

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23/07/2021

Date





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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: MTD (Methadone) Rapid Test (Whole Blood/Serum/Plasma)

Model: Cassette

Classification: Other Device of IVDD 98/79/EC

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

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

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Name: GAO FEI (Position: General Manager)

23/07/2021

Date





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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: TML (Tramadol) Rapid Test (Whole Blood/Serum/Plasma)

Model: Cassette

Classification: Other Device of IVDD 98/79/EC

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

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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: MDPV (3, 4-methylenedioxypyrovalerone) Rapid Test (Urine)

Model: Cassette/Dipstick/Panel

Classification: Other Device of IVDD 98/79/EC

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

EDMA Code: 12 70 09 90 00

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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:

22/07/2021

Name: GAO FEI (Position: General Manager) Date





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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: α -PVP (alpha-Pyrrolidinovalerophenone) Rapid Test (Urine)

Model: Cassette/Dipstick/Panel

Classification: Other Device of IVDD 98/79/EC

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

EDMA Code: 12 70 09 90 00

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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:

22/07/2021

Name: GAO FEI (Position: General Manager)

Date

Hangzhou AllTest Biotech Co.,Ltd.
#550, Yinhai Street,
Hangzhou Economic & Technological
Development Area,
Hangzhou -310018, P.R. China

杭州奥泰生物技术股份有限公司
地 址: 杭州市经济技术开发区
银海街550号
邮 编: 310018

TEL : +86 571 56267891
EMAIL : info@alltests.com.cn
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电 话 : +86 571 56267891
邮 箱 : info@alltests.com.cn
网 址 : www.alltests.com.cn





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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: LSD (Lysergic Acid Diethylamide) Rapid Test (Urine)

Model: Cassette/Dipstick/Panel

Classification: Other Device of IVDD 98/79/EC

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

EDMA Code: 12 70 09 90 00

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

Signature:

Name: Gao Fei (Position: General Manager)

09/07/2021

Date





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: COC (Cocaine) Rapid Test (Whole Blood/Serum/Plasma)

Model: Cassette

Classification: Other Device of IVDD 98/79/EC

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

EDMA Code: 12 70 09 06 00

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

Signature: GAO FEI 22/07/2021

Name: GAO FEI (Position: General Manager) Date





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: BAR (Barbiturate) Rapid Test (Whole Blood/Serum/Plasma)

Model: Cassette

Classification: Other Device of IVDD 98/79/EC

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

EDMA Code: 12 70 09 03 00

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

Signature:

Name: GAO FEI (Position: General Manager)

22/07/2021

Date





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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: TCA (Tricyclic Antidepressants) Rapid Test (Whole Blood/Serum/Plasma)

Model: Cassette

Classification: Other Device of IVDD 98/79/EC

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

EDMA Code: 12 70 09 10 00

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

Signature:

23/07/2021

Name: GAO FEI (Position: General Manager)

Date



TM

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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: MDMA (Methylenedioxy-methamphetamine) Rapid Test (Whole Blood/Serum/Plasma)

Model: Cassette

Classification: Other Device of IVDD 98/79/EC

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

EDMA Code: 12 09 01 02 00

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Signature:

Name: GAO FEI (Position: General Manager)

23/07/2021

Date

