EU Declaration of Conformity

Manufacturer: HANGZHOU ALLTEST BIOTECH CO., LTD.
Address: #550, Yinhai Street, Hangzhou Economic & Technological Development Area, Hangzhou -310018, P.R. China
Single Registration Number: CN-MF-000010710

European Representative: MEDNET EC-REP GmbH
Address: Borkstrasse 10, 48163 Muenster, Germany
Single Registration Number: DE-AR-000000002

Product Name: Fluorescence Immunoassay Analyzer
Analyte: For quantitative or qualitative detection of human samples with specific in vitro diagnostic test units including Inflammation Markers, Tumor Markers, Nephrology, Diabetes, Cardiac Markers, Coagulation, Endocrinology, Autoimmunity, Infectious Diseases and etc.

REF	AFR-100/ AFR-100S	AFR-200/ AFR-200S	AFR-300/ AFR-300S	AFR-301/ AFR-302	AFR-400	AFR-900	AFR-901

Model: Instrument
Classification according to Rule 5(b) of IVDR Annex VIII: Class A
Conformity Assessment Procedure: Annex II and III
EMDN Code: W0201020201
Basic UDI-DI: 6970277510002PYF

We, HANGZHOU ALLTEST BIOTECH CO., LTD, herewith declare that the product we sell is covered by technical files (doc. No.: RTD900501, RTD900502, RTD900503, RTD900506, RTD900507, RTD900508, RTD900510, RTD900512). The technical files provided to and kept up to date by European Authorized Representative MEDNET EC-REP GmbH. And, the EU declaration of conformity is issued under the sole responsibility of above manufacturer. The above mentioned product is in conformity with following Regulation and Standards:
Regulation Applied: REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
Standard Applied: EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 15223-1:2021, EN 13612:2002/AC:2002, IEC 62366-1:2015, IEC 61326-1:2012, IEC 61326-2-6:2012, EN 61010-1:2010+A1:2019, EN 61010-2-101:2017, IEC 62304:2015, EN ISO 18113-1:2011, EN ISO 18113-3:2011.

Place, Date of First Issue of DOC: in Hangzhou on 2022-02-25
Date of Issue of DOC on 2024-11-01

Signature:
Name: Gao Fei
Position: General Manager

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
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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 EC-REP GmbH*
Address: Borkstrasse 10, 48163 Muenster, Germany

Product Name: Cardiac Troponin T Test Cassette
Analyte: Cardiac Troponin T (cTnT) in human whole blood, serum or plasma
Analyzer/Reader: Fluorescence Immunoassay Analyzer
Model: Cassette
Cat. No.: FI-CTNT-402
Classification: Other Device, non-listed in Annex II of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex III (Excluding point 6)
EDMA Code: 12 13 01 07 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 29/04/2022

Signature: _____

Name: GAO FEI (Position: General Manager)

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

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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: VidaQuick Biotech S.L.
Address: No.132, Rosello Street, Barcelona, Barcelona Province, 08036, Spain

Product (Group) Name: High-Sensitivity Cardiac Troponin T Test Cassette
Model: Cassette
Cat. No.: FI-SCTT-402

Classification: non-listed Device of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex III (excluding point 6)
EDMA Code: 12 70 13 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 ISO14971:2019, 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

Date of First of DOC: in Hangzhou on 29/04/2022

Signature:
Name: GAO FEI (Position: General Manager)

Hangzhou AllTest Biotech Co.,Ltd.
#550, Yinhai Street,
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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 EC-REP GmbH
Address: Borkstrasse 10, 48163 Muenster, Germany

Product Name: D-Dimer Test Cassette
Analyte: D-dimer in human Whole Blood/ Plasma
Reader/Analyzer: Fluorescence Immunoassay Analyzer
Model: Cassette
Cat.No.: FI-DDM-402
Classification: Other Device, non-listed in Annex II of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex III (Excluding point 6)
EDMA Code: 12 70 13 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 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 First issue of DOC: in Hangzhou on 16/07/2018
Date of Issue of DOC on 05/05/2022

Signature: _____
Name: Gao Fei (Position: General Manager)

Hangzhou AllTest Biotech Co.,Ltd.
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Hangzhou -310018, P.R. China

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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 EC-REP GmbH*
Address: Borkstrasse 10, 48163 Muenster, Germany

Product Name: CK-MB Test Cassette
Analyte: Creatine Kinase MB (CK-MB) in human whole blood, Serum or plasma
Reader/Analyzer: Fluorescence Immunoassay Analyzer
Model: Cassette
Cat. No.: FI-CKMB-402
Classification: Other Device, non-listed in Annex II of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex III (Excluding point 6)
EDMA Code: 12 70 13 01 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 First Issue of DOC: in Hangzhou on 02/04/2019
Date of Issue of DOC on 05/05/2022

Signature: _____
Name: GAO FEI (Position: General Manager)

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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 EC-REP GmbH*
Address: Borkstrasse 10, 48163 Muenster, Germany

Product Name: Myoglobin Test Cassette
Analyte: Myoglobin in human whole blood, Serum or plasma
Reader/Analyzer: Fluorescence Immunoassay Analyzer
Model: Cassette
Cat. No.: FI-MYO-402
Classification: Other Device, non-listed in Annex II of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex III (Excluding point 6)
EDMA Code: 12 70 13 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 First Issue of DOC: in Hangzhou on 02/04/2019
Date of Issue of DOC on 05/05/2022

Signature:
Name: GAO FEI (Position: General Manager)

Hangzhou AllTest Biotech Co.,Ltd.
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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: VidaQuick Biotech S.L.
Address: No.132, Rosello Street, Barcelona, Barcelona Province, 08036, Spain

Product (Group) Name: High-Sensitivity NT-proBNP Test Cassette
Model: Cassette
Cat. No.: FI-SNBNP-402

Classification: non-listed Device of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex III (excluding point 6)

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 ISO14971:2019, 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

Date of Issue of DOC: in Hangzhou on 29/04/2022

Signature:
Name: GAO FEI (Position: General Manager)

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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 EC-REP GmbH*
Address: Borkstrasse 10, 48163 Muenster, Germany

Product Name: NT-proBNP Test Cassette
Analyte: N-terminal of the Prohormone brain natriuretic peptide (NT-proBNP) in human whole blood, serum or plasma
Reader/Analyzer: Fluorescence Immunoassay Analyzer
Model: Cassette
Cat. No.: FI-NBNP-402
Classification: Other Device, non-listed in Annex II of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex III (Excluding point 6)
EDMA Code: 12 70 13 04 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 First Issue of DOC: in Hangzhou on 03/04/2019
Date of Issue of DOC on 05/05/2022

Signature: _____
Name: GAO FEI (Position: General Manager)

Hangzhou AllTest Biotech Co.,Ltd.
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