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 I Test Cassette
Analyte: cardiac Troponin I (cTnI) in human whole blood, serum or plasma
Reader/Analyzer: Fluorescence Immunoassay Analyzer
Model: Cassette
Cat. No.: FI-CTI-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 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 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.
#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
http:// www.alltests.com.cn

电话：+86 571 56267891
邮箱：info@alltests.com.cn
网址：www.alltests.com.cn

Manufacturer's Declaration

in relation to Regulation (EU) 2024/1860 amending Regulation (EU) 2017/746 (IVDR) as regards the transitional provisions for certain *in vitro* diagnostic medical devices, in particular with respect to

- the extended transitional periods for devices for which the conformity assessment procedure pursuant to Directive 98/79/EC (IVDD) did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to Regulation (EU) 2017/746 (IVDR) requires the involvement of a notified body *and/or*
- the validity of certificates issued under Directive 98/79/EC (IVDD) (Directive Certificate) *and/or*
- the compliance of the devices and us, as their manufacturer, with the conditions for the continued placing on the market and putting into service

Manufacturer name	Hangzhou Alltest Biotech Co., Ltd.
Manufacturer address and contact details	#550 Yinhai street,Hangzhou Economic and Technologic Development Area 310018, P.R China
Single Registration Number (SRN) (if available)	CN-MF-000010710

Authorised Representative name (if applicable)	MedNet EC-REP GmbH
Authorised Representative address and contact details	Borkstrasse, 10 48163 Münster, Germany Tel: +49 251 322 66 64 Email: ecrep@medneteurope.com
Single Registration Number (SRN) (if available)	DE-AR-000000002

Notified body name (if applicable)	☐ See attached schedule ☒ Not applicable
Notified body number (if applicable)	☐ See attached schedule ☒ Not applicable
Directive Certificate number(s) to which this confirmation is made (if applicable)	☐ See attached schedule ☒ Not applicable
Original expiry date as indicated on the Directive Certificate(s) prior to the extension of the validity (if	☐ See attached schedule ☒ Not applicable

applicable)	
End date of extended validity/transition period	☒ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the **device(s)** listed in the attached schedule the conditions for the legal extension of transitional periods as required in Article 110.3b of the IVDR are met *and/or*
- for the **Directive Certificate(s)** listed in the attached schedule the conditions for the legal extension of validity as required in Article 110.2 of the IVDR are met *and/or*
- the **device(s)** listed in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 110.3c of the IVDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Devices which were self-declared under the IVDD and require notified body involvement under the IVDR**

In case of devices for which the conformity assessment procedure pursuant to IVDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to IVDR requires the involvement of a notified body:

Choose applicable statement:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has/have been lodged or will be lodged by us to a notified body for the device(s) listed in the attached schedule or its/their substitutes no later than:

☐ 26 May 2025 for class D devices

☒ 26 May 2026 for class C devices

☐ 27 May 2027 for class B and class A (sterile) devices

☒ Signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII IVDR for the device(s) listed in the attached schedule or its/their substitutes no later than:

☐ 26 September 2025 for class D devices

☒ 26 September 2026 for class C devices

☐ 27 September 2027 for class B and class A (sterile) devices

☐ We do not intend to lodge an application for conformity for the device as indicated on the attached schedule.

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the device(s) listed in the attached schedule was/were issued after 25 May 2017, was/were valid on 26 May 2022 and has/have not been withdrawn afterwards.

Choose applicable statements:

☐ Original expiry date *before 9 July 2024*:

☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII IVDR for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of its/their substitute(s), or

☐ Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 54(1) IVDR (may be provided upon request), or

☐ Competent Authority has required us as the manufacturer, in accordance with Article 92(1) IVDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 54(1) or a requirement per Article 92(1) has been granted by a Competent Authority:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has/have been lodged or will be lodged by us to a notified body no later than 26 May 2025 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII IVDR before 26 September 2025.

☐ We do not intend to lodge an application for conformity assessment by 26 May 2025, therefore the transition period will end on 26 May 2025.

☐ Original expiry date *after 9 July 2024*:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has/have been lodged or will be lodged by us to a notified body no later than 26 May 2025 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII IVDR before 26 September 2025.

☐ We do not intend to lodge an application for conformity assessment by 26 May 2025 for the devices as indicated on the attached schedule, therefore the transition period will end on 26 May 2025.

☐ assessment by 26 May 2025, therefore the transition period will end on 26 May 2025.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐QMS in accordance with Article 10(8) IVDR will be put in place by no later than 26 May 2025.

☒QMS in accordance with Article 10(8) IVDR is in place.

☐Notified body has issued the attached certificate for the IVDR-compliant QMS.

➢ **Device(s) listed in the attached schedule (apart from the device indicated to be withdrawn)**

- The device(s) continue(s) to comply with the IVDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name: Hangzhou Alltest Biotech Co., Ltd.

Location & Date: #550 Yinhai street,Hangzhou Economic and Technologic Development Area 310018, P.R China

Signature, Print Name, Title: Yan Zhang, QA Manager

Contact Details (at least email): Yan.zhang@alltests.com.cn

Date: 28 May 2025

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[1] (e.g., device name, family/group name device model or catalogue number)	**End date of extended validity / transition period**[2]	**Substitute Device(s)** (if applicable)	**Directive Certificate number to which this declaration is issued** (if applicable)	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the IVDR application was lodged/contract signed** (if applicable)
Malaria P.f. Rapid Test Cassette,IMA-402	2028.12.31	/	/	/	/	/
Procalcitonin(PCT) Rapid Test Cassette(WB/S/P), FI-PCT-402	2028.12.31	/	/	/	/	/
D-Dimer Tes Cassette (WB/P), FI-DDM-402	2028.12.31	/	/	/	/	/
cTnI Test Cassette(WB/S/P), FI-CTI-402	2028.12.31	/	/	/	/	/
HbA1c Test Cassette(WB), FI-HBA-402	2028.12.31	/	/	/	/	/
N-GAL Test Cassette(Urine), FI-NGAL-102	2028.12.31	/	/	/	/	/

[1] for devices with IVDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above

[2] The final extended date is subject to the signed extension agreement, and the company reserves the right of final interpretation of this declaration.