ASSURE TECH. (HANGZHOU) CO., LTD.
Building 4, No. 1418-50, Moganshan Road, Gongshu District, Hangzhou, 310011 Zhejiang, China
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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	**Assure Tech. (Hangzhou) Co., Ltd**
Manufacturer address and contact details	Building 4, No. 1418-50, Moganshan Road, Gongshu District, Hangzhou, 310011 Zhejiang, P.R. China E-mail: contact@diareagent.com
Single Registration Number (SRN) (if available)	CN-MF-000002170

Authorised Representative name (if applicable)	**Lotus NL B.V.**
Authorised Representative address and contact details	Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands peter@luotusnl.com
Single Registration Number (SRN) (if available)	NL-AR-000000121

Authorised Representative name (if applicable)	**MedUnion S.L.**
Authorised Representative address and contact details	Carrer de Tapioles, 33, 2-1, Barcelona, 08004, Spain
Single Registration Number (SRN) (if available)	ES-AR-000019366

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 applicable)	☒ See attached schedule ☐ Not 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:	Assure Tech. (Hangzhou) CO., Ltd.
Location & Date:	Hangzhou, December 23, 2024
Signature, Print Name, Title:	Allen Chen, PRRC
Contact Details (at least email):	allen.chen@diareagent.com

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**	**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)
D-Dimer Rapid Test	2028.11.28	/	/	/	/	2797 - BSI Group The Netherlands B.V.
Cardiac Troponin I Rapid Test	2028.11.28	/	/	/	/	2797 - BSI Group The Netherlands B.V.
Myoglobin Rapid Test	2028.11.28	/	/	/	/	2797 - BSI Group The Netherlands B.V.
Cardiac Markers Combo Rapid Test	2028.11.28	/	/	/	/	2797 - BSI Group The Netherlands B.V.
Multiple Drugs Test Cup	2029.12.31	/	/	/	/	0344 - DEKRA Certification B.V.
Human Chorionic Gonadotropin Combo Rapid Test	2029.12.31	/	/	/	/	0344 - DEKRA Certification B.V.
Hepatitis E IgM Test	2028.11.28	/	/	/	/	2797 - BSI

[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

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**	**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)
						Group The Netherlands B.V.
Syphilis Rapid Test	2028.11.28	/	/	/	/	2797 - BSI Group The Netherlands B.V.
Respiratory Syncytial Virus Rapid Test	2029.12.31	/	/	/	/	2797 - BSI Group The Netherlands B.V
Strep A Rapid Test	2029.06.12	/	/	/	/	0197- TÜV Rheinland LGA Products GmbH
Strep B Rapid Test	2028.11.28	/	/	/	/	2797 - BSI Group The Netherlands B.V.
Influenza A/B Rapid Test	2028.11.28	/	/	/	/	2797 - BSI Group The Netherlands B.V.
Tuberculosis Rapid Test	2028.11.28	/	/	/	/	2797 - BSI Group The Netherlands B.V.
Adenovirus Rapid Test	2028.11.28	/	/	/	/	2797 - BSI Group The Netherlands

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						B.V.
Adenovirus Respiratory Test	2028.11.28	/	/	/	/	2797 - BSI Group The Netherlands B.V.
Salmonella Typhi/ Paratyphi Antigen Rapid Test	2028.11.28	/	/	/	/	2797 - BSI Group The Netherlands B.V.
H. pylori Antibodies Rapid Test	2028.11.28	/	/	/	/	2797 - BSI Group The Netherlands B.V.
H. pylori Antigens Rapid Test	2028.11.28	/	/	/	/	2797 - BSI Group The Netherlands B.V.
Rotavirus Rapid Test	2028.11.28	/	/	/	/	2797 - BSI Group The Netherlands B.V.
Cholesterol Test Device and Cholesterol Meter	2028.12.31	/	/	/	/	0197- TÜV Rheinland LGA Products GmbH
Hemoglobin Test Strips and Hemoglobin Meter	2029.12.31	/	/	/	/	0197- TÜV Rheinland LGA Products GmbH
Faecal Occult Blood Rapid Test	2028.12.31	/	HL 2074650-1	2025.05.26	0197- TÜV	0344 - DEKRA

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**	**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)
					Rheinland LGA Products GmbH	Certification B.V.
Human Chorionic Gonadotrophin Rapid Tests	2029.12.31	/	HL 2074650-1	2025.05.26	0197- TÜV Rheinland LGA Products GmbH	0344 - DEKRA Certification B.V.
Follicle Stimulating Hormone Tests	2029.12.31	/	HL 2074650-1	2025.05.26	0197- TÜV Rheinland LGA Products GmbH	0344 - DEKRA Certification B.V.
Human Luteinizing Hormone Rapid Tests	2029.12.31	/	HL 2074650-1	2025.05.26	0197- TÜV Rheinland LGA Products GmbH	0344 - DEKRA Certification B.V.
Blood Cholesterol Monitoring Systems (Blood Cholesterol Meter, Test Strip)	2028.12.31	/	HL 2074650-1	2025.05.26	0197- TÜV Rheinland LGA Products GmbH	0197- TÜV Rheinland LGA Products GmbH
Digital Pregnancy Tests	2029.12.31	/	HL 2074650-1	2025.05.26	0197- TÜV Rheinland LGA Products GmbH	
Blood Glucose Monitoring Systems (Blood Glucose Meter, Test Strip)	2028.12.31	/	HL 2074650-1	2025.05.26	0197- TÜV Rheinland LGA Products GmbH	0197- TÜV Rheinland LGA Products GmbH
Vaginal pH Test Device	2029.12.31	/	2020-IVD/DE-006/A	2025.05.26	2265- 3EC International a.s.	/

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Prostate Specific Antigen Rapid Test Device	2028.12.31	/	2020-IVD/QS-003/B	2025.03.12	2265- 3EC International a.s.	/
Chlamydia Rapid Test Device	2028.11.28	/	2020-IVD/QS-003/B	2025.03.12	2265- 3EC International a.s.	2797 - BSI Group The Netherlands B.V.
COVID-19 & Influenza A/B Antigen Nasal Test Kit	2027.12.31	/	CeCert/081/W/E.2	2025.05.26	2934- CeCert Sp. z o.o.	0344 - DEKRA Certification B.V.
SARS-CoV-2 Antigen Rapid Tests for Self-Testing	2027.12.31	/	HL 2074650-1	2025.05.26	0197- TÜV Rheinland LGA Products GmbH	/
COVID-19 Antigen Saliva Test Kit	2027.12.31	/	2258023DE01	2025.05.26	0344- DEKRA Certification B.V.	/
COVID-19 Antigen Nasal Test Kit	2027.12.31	/	1434-IVDD-078/2022	2025.05.27	1434- POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A.	0344 - DEKRA Certification B.V.
HIV Rapid Test Device (Whole blood/Serum/Plasma)	2027.12.31	/	CeCert/076/W/E.1	2025.05.26	2934- CeCert Sp. z o.o.	0344 - DEKRA Certification B.V.
Sperm Concentration Rapid Test	2029.12.31	/	/	/	/	0197-TÜV Rheinland LGA Products GmbH

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**	**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)
C-Reactive Protein Rapid Test Kit	2028.12.31	/	/	/	/	0344-DEKRA Certification B.V.
Multi-drug Urine Test Cup	2029.12.31	/	/	/	/	0344 - DEKRA Certification B.V.
FLU A/FLU B/RSV/ADV/MP/COVID-19 Combo Test	2027.12.31	/	/	/	/	/