EC DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex IV

MANUFACTURER **Assure Tech. (Hangzhou) Co., Ltd.**
Building 4,No. 1418-50, Moganshan Road, Gongshu District, Hangzhou, 310011 Zhejiang, P.R. China

EUROPEAN Lotus NL B.V.
Address: Koningin Julianaplein 10, leVerd, 2595AA,The Hague, Netherlands

PRODUCTS **Human Luteinizing Hormone Rapid Tests**

Registration number **NL-CA002-2020-49480**
CATEGORY Self-testing devices

Conformity assessment route: Annex IV, excluding sections 4 and 6 of the directive 98/79/EC

We, the Manufacturer, herewith declare with sole responsibility
that our product/s mentioned above meet/s the provisions
of the Directive 98/79/EC
of the European Parliament and of the Council
on In-Vitro Diagnostic Medical Devices.
We hereby explicitly appoint

Applicable Standards:

EN ISO 13485:2016	*EN ISO 14971:2019*	*EN ISO 23640:2015*
EN 13612:2002/AC:2002	*EN 13641:2002*	*IEC 62366-1:2015*
EN ISO 18113-1:2011	*EN ISO 15223-1:2016*	*EN 13532:2002*
EN ISO 18113-4:2011	*EN 13975:2003*	

Notified Body	TÜV Rheinland LGA Products GmbH, Tillystraße 2, 90431Nürnberg
EC Certificate No.	HL 2074650-1
Expiry date	2025-05-26

Date of issue 2022/3/8
Place Hangzhou, China

Signature:

Name of authorized signatory: Eric Ling, General Manager

ASSURE TECH. (HANGZHOU) CO., LTD.

Assure Tech

CE 0197

Certified manufacturer
according to ISO13485

No.: DOC-C192
Version 1.3