

EC DECLARATION OF CONFORMITY

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

MANUFACTURER **Assure Tech. (Hangzhou) Co., Ltd.**
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EUROPEAN Lotus NL B.V.
Address: Koningin Julianaplein 10,
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PRODUCTS **Human Chorionic Gonadotrophin 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	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, 90431 Nürnberg
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



Certified manufacturer
according to ISO13485

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