EC DECLARATION OF CONFORMITY

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

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

Product/s:	Multi-drug Saliva Test Kit
Registration number:	NL-CA002-2022-69933
Catalog No:	MD-S31，MD-S32，MD-S33，MD-S34, MD-S35，MD-S36，MD-S37，MD-S38, MD-S39
Category:	Other Devices (All devices except Annex II and self-testing devices)
Conformity assessment route:	Declaration of Conformity IVDD Annex III excluding (6)

Applicable Standards:

EN ISO 13485:2016	*EN 13975:2003*	*EN 13612:2002/AC:2002*
EN ISO 14971:2019	*EN ISO 15223-1:2016*	*EN 13641:2002*
EN ISO 18113-1:2011	*EN ISO 18113-2:2011*	*IEC 62366-1: 2015*
EN ISO 23640:2015		

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

Lotus NL B.V.
Address: Koningin Julianaplein 10,
le Verd, 2595AA, The Hague, Netherlands
to act as our European Authorised Representative
as defined in the aforementioned Directive

Signed on 2022/05/20
Place Hangzhou, China

Signature: 

Name ofauthorized signatory: Eric Ling,General Manager

CE