EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.:	HL 2074650-1
Manufacturer:	Assure Tech. (Hangzhou) Co., Ltd. Building 4, No. 1418-50, Moganshan Road, Gongshu District, Hangzhou, 310011 Zhejiang P.R. China
Products:	HCG Pregnancy Rapid Tests, LH Ovulation Rapid Tests, Follicle Stimulating Hormone Rapid Tests, Fecal Occult Blood Rapid Tests, Blood Glucose Monitoring Systems (Blood Glucose Meter, Test Strip), Blood Cholesterol Monitoring Systems (Blood Cholesterol Meter, Test Strip), Digital Pregnancy Tests, SARS-CoV-2 Antigen Rapid Tests for Self-Testing

The Notified Body hereby declares that the requirements of Annex IV, excluding sections 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.