EU Declaration of Conformity

Manufacturer:	ACON Biotech (Hangzhou) Co., Ltd. No.210 Zhenzhong Road, West Lake District, Hangzhou, P.R.China 310030
Manufacturer SRN:	CN-MF-000006977
Authorized Representative:	MedNet EC-REP GmbH Borkstrasse 10 48163 Muenster, Germany
Authorized Representative SRN:	DE-AR-000000002

We, the manufacturer, under compliance to Regulation (EU) 2017/746, declare under our sole responsibility that medical devices:

Device Name:	SARS-CoV-2 Antigen Rapid Test (Self-Testing)
Brand Name:	Flowflex, Hughes
Basic UDI-DI:	6921756499990035X8
Intended Use:	The SARS-CoV-2 Antigen Rapid Test is a lateral flow test for the qualitative detection of the nucleocapsid antigen from SARS-CoV-2 in anterior nasal swab specimens directly from individuals suspected of COVID-19 within the first seven days of the onset of symptoms. The test can also test specimens from individuals without symptoms. The SARS-CoV-2 Antigen Rapid Test is intended to be used for self-testing by lay users as an aid to diagnosis of SARS-CoV-2 infection. Children under 14 years should be supervised by an adult.
Risk Class and Classification Rule:	Class D, as per EU Regulation 2017/746, Annex VIII, Rule 1
Common Specifications:	Regulation (EU) 2022/1107

is in conformity with Regulation (EU) 2017/746

Conformity assessment:	Annex IX of the Regulation (EU) 2017/746
Notified Body:	TÜV SÜD Product Service GmbH (notified under No. 0123) Ridlerstraße 65, 80339 MÜNCHEN, Germany.
EU certificate:	No. V70 042074 0033 Rev.00 Expired date: 2029-07-23

Signed this 8 day of 8, 2024
in Hangzhou, China

Junny You
International RA Senior Director
ACON Biotech (Hangzhou) Co., Ltd.

No.210 Zhenzhong Road, West Lake District, Hangzhou, P.R. China, 310030
Tel: +86-571-87775615 Fax: +86-571-87968687 E-mail: ACONBio_RA@aconlab.com.cn