



Date: Jan. 18<sup>th</sup>, 2024

## Declaration Letter of Transition Period

To whom it may concern,

We, **ACON Biotech (Hangzhou) Co., Ltd.**, located at No.210 Zhenzhong Road, West Lake District, Hangzhou, P.R. China 310030, as the legal manufacturer, hereby declare that the following products were certificated in accordance with Directive 98/79/EC prior to 26 May 2022, therefore, these devices could be placed on the market during various transitional period per risk class provided for in Article 110 Regulation (EU) 2017/746 (IVDR).

Product name	IVDR Classification
Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	Class D
Flowflex Influenza A/B Rapid Test	Class B

During the transitional period, the EC Declarations of Conformity according to the EU Directive 98/79/EC for in vitro diagnostic medical devices are still valid. We are in the process of classifying these products according to IVDR. The new Declarations of Conformity will be issued according to Regulation (EU) 2017/746 after get the IVDR certificate.

Sincerely,

  
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Alyssa Lu

International RA Director

**ACON Biotech (Hangzhou) Co., Ltd.**

