Declaration of Conformity (DOC) Corrigendum

Product name:	SARS-CoV-2 Antigen Rapid Test
Brand:	*Flowflex*
Class:	Others according to Annex II of the directive 98/79/EC
Date of the DOC:	March 22, 2022

This corrigendum intends to correct the valid date for an extension to **26 May, 2027** in previous DoC of the above listed product.

According to the guidance MDCG 2020-16, rev.4, the device intended for the detection of SARS-CoV-2 is re-classified into Class B covered by the classification rule 6. Therefore, **the SARS-CoV-2 Antigen Rapid Test is currently classified as Class B device, and the DoC will be valid until 26 May, 2027 accordingly**, as per Regulation (EU) 2017/746 Article 110(3), amended by Regulation (EU) 2022/112.
This change concerning only the correction of the valid date of the DoC based on the current version of MDCG 2020-16.

According to Regulation (EU) 2017/746 (IVDR), for legacy devices according to Art. 110 (3), amended by Regulation (EU) 2022/112, Art. 1, no changes to DOCs signed prior to May 26, 2022 can be performed. In case of the above described non-significant change(s) (as defined in MDCG 2022-6), the existing DOC(s) is (are) still valid and this Corrigendum will be attached to the originally signed DOC(s). The DOC(s) will be updated upon transition to IVDR.

Signed this 31 day of March, 2025
in Hangzhou, China

Alyssa Lu
International RA Director
ACON Biotech (Hangzhou) Co., Ltd.

ACON BIOTECH (HANGZHOU) CO., LTD.
No.210 Zhenzhong Road, West Lake District, 310030 Hangzhou, P.R. China.
Tel: +86-571-87965615 Fax: +86-571-87968687 E-mail: ACONBio_RA@aconlab.com.cn

Declaration of Conformity

ACON Biotech (Hangzhou) Co., Ltd.
No.210 Zhenzhong Road, West Lake District,
Hangzhou, P.R. China, 310030

We declare under our sole responsibility that the in vitro diagnostic device:

Flowflex SARS-CoV-2 Antigen Rapid Test

classified as Others of the directive 98/79/EC, meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

This declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
MedNet EC-REP GmbH
Borkstrasse 10
48163 Muenster, Germany

This Declaration of Conformity is valid until 25 May, 2025.

Signed this 22 day of March, 2021
in Hangzhou, China

Alyssa Lu
International RA Director
ACON Biotech (Hangzhou) Co., Ltd.

ACON BIOTECH (HANGZHOU) CO., LTD.
No.210 Zhenzhong Road, West Lake District, Hangzhou, P.R. China, 310030
Tel: +86-571-87965615 Fax: +86-571-87968687 E-mail: ACONBio_RA@aconlab.com.cn