

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

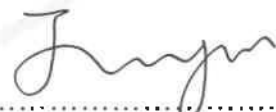
**classified as Others according to the Annex II of the directive 98/79/EC,
meets all the provisions of the directive 98/79/EC on *in vitro*
diagnostic medical devices which apply to it**

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

Authorized Representative:
MedNet GmbH
Borkstrasse 10
48163 Muenster, Germany

This Declaration of Conformity is valid until 25 May, 2022.

Signed this 28 day of 9, 2020
in Hangzhou, China



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



ACON BIOTECH (HANGZHOU) CO., LTD.
No.210 Zhenzhong Road, West Lake District, Hangzhou, P.R. China, 310030
Tel: +86-571-87963569 Fax: +86-571-87963570 E-mail: css@aconlab.com.cn



Certificate

No. Q5 042074 0031 Rev. 01

Holder of Certificate: **Acon Biotech (Hangzhou) Co., Ltd.**

No.210 Zhenzhong Road
 West Lake District
 310030 Hangzhou
 PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Acon Biotech (Hangzhou) Co., Ltd.
 No.210 Zhenzhong Road, West Lake District, 310030 Hangzhou,
 PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development,
 Production and Distribution of
 In Vitro Diagnostic Test Kits
 and Related Instruments,
 Lancet and Lancing Device**

Applied Standard(s): EN ISO 13485:2016
 Medical devices - Quality management systems -
 Requirements for regulatory purposes
 (ISO 13485:2016)
 DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1910622

Valid from: 2019-07-15

Valid until: 2022-07-14

Date, 2019-07-09

Stefan Preiß
 Head of Certification/Notified Body

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