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global healthcare solutions

Manufacturer's Declaration

in relation to 2024/0021 (COD) amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, information obligation in case of interruption of supply and the transitional provisions for certain in vitro diagnostic medical devices.

Manufacturer name	ACON Biotech (Hangzhou) Co., Ltd.
Manufacturer address and contact details	No.210 Zhenzhong Road, West Lake District, Hangzhou, P.R. China, 310030
Single Registration Number (SRN) (if available)	CN-MF-000006977

Authorised Representative name (if applicable)	MedNet EC-REP GmbH
Authorised Representative address and contact details	Borkstrasse 10 48163 Muenster, Germany
Single Registration Number (SRN) (if available)	DE-AR-000000002

Notified body name (if applicable)	TÜV SÜD Product Service GmbH
Notified body number (if applicable)	0123
Directive Certificate number(s) to which this confirmation is made (if applicable)	V9 042074 0032 Rev.00
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024-05-26

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We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 110 (2) of the IVDR are met *and/or*
- the **listed device** in the **attached schedule** and we as their manufacturer are in compliance with the conditions listed in Article 110 (3a) of the IVDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate** as listed above.

- Directive Certificate covering the listed device was issued after 25 May 2017, was valid on 26 May 2022 and have not been withdrawn afterwards.
- Before the original date of expiry as indicated on the Directive Certificate, we and the notified body TÜV SÜD Product Service GmbH have signed a written agreement in accordance with Section 4.3(2) of Annex VII to IVDR for the conformity assessment in respect of the device covered by the expired certificate.

➢ **Quality Management System (QMS)**

- A QMS in accordance with Article 10(9) IVDR is in place.

➢ **Device(s) as listed in the attached schedule**

- The device continue to comply with the Directive 98/79/EC.
- There are no significant changes in the design and intended purpose.
- The device do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer ACON Biotech (Hangzhou) Co., Ltd.

2024-05-23

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

Schedule of Devices

The above Manufacturer's Declaration is valid for the following device:

Identification of the device(s)	Directive Certificate number(s) to which this confirmation is made	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the IVDR application was lodged/contract signed	End date of extended validity/ transition period
Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	V9 042074 0032 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	2027-12-31