DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 053740 0007 Rev. 00

Holder of Certificate: **RapiGEN, Inc.**
3-4F, 16, LS-ro 91beon-gil, Dongan-gu
Anyang-si, Gyeonggi-do 14119
REPUBLIC OF KOREA

Facility(ies): RapiGEN, Inc.
3-4F, 16, LS-ro 91beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do 14119, REPUBLIC OF KOREA

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design, Development, Production and Distribution of In Vitro Diagnostic Medical Device - Immunochromatographic assay**

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.: 74956286

Valid from: 2020-06-14
Valid until: 2023-06-13

Date, 2020-04-16

Christoph Dicks
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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