





Product Service

Certificate

No. Q5 102797 0002 Rev. 01

Holder of Certificate: DCGEN Co., Ltd.

#902, 130, Sajik-ro, Jongno-gu

Seoul 03170

REPUBLIC OF KOREA

Facility(ies): DCGEN Co., Ltd.

#902, 130, Sajik-ro, Jongno-gu, Seoul 03170, REPUBLIC OF

KOREA

See Scope of Certificate

Certification Mark:



Scope of Certificate: Design, Development, Production and Distribution

of In Vitro Molecular Diagnostic Reagent Kits for utilization of Next Generation Sequencing (NGS)

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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 102797 0002 Rev. 01

Report No.: 74963299

 Valid from:
 2022-09-17

 Valid until:
 2025-09-16

Christoph Dicks

Head of Certification/Notified Body

2022-09-06

Date,