



Certificate

No. Q5 005305 0002 Rev. 00

Holder of Certificate: Genesystem Co., Ltd.

305, 310, 311, 506, 507

Daejeon Bio Venture Town, 1662, Yuseong-daero

Yuseong-gu, Daejeon 34054 REPUBLIC OF KOREA

Facility(ies): Genesystem Co., Ltd.

305, 310, 311, 506, 507, Daejeon Bio Venture Town, 1662, Yuseong-daero, Yuseong-gu, Daejeon 34054, REPUBLIC OF

KOREA

Certification Mark:



Scope of Certificate: Design, Development, Production and Distribution

of In Vitro Diagnostic Instruments for DNA & RNA Amplification and Instruments' Software for

Analysis

Production and Distribution of In Vitro Diagnostic

Reagents for DNA & RNA Amplification

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.: 74952437

Valid from: 2019-04-16 Valid until: 2022-04-15

Stefan Preiß

Date, 2019-04-16