



Certificate

No. Q5 057264 0021 Rev. 00

Holder of Certificate:

Humasis Co., Ltd.

Rm.114,502,504,604,604-1,B03-1,B03-2
88, Jeonpa-ro, Dongan-gu
Anyang-si, Gyeonggi-do 14042
REPUBLIC OF KOREA

Facility(ies):

Humasis Co., Ltd.
Rm.114,502,504,604,604-1,B03-1,B03-2, 88, Jeonpa-ro, Dongan-gu,
Anyang-si, Gyeonggi-do 14042, REPUBLIC OF KOREA

See Scope of Certificate

Certification Mark:



Scope of Certificate:

Design, Development, Production and Distribution of In-Vitro Diagnostic Reagents and Instruments - Cardiac Markers, Fertility Tests, Pregnancy Tests, Infection Markers, Tumor Markers, Urinalysis and Other IVDs

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_057264_0021_Rev.00

Report No.: 74959417
Valid from: 2021-05-01
Valid until: 2024-04-30

Date, 2021-04-28

Christoph Dicks
Head of Certification/Notified Body