



Certificate

No. Q5 107415 0001 Rev. 02

Holder of Certificate: **CALTH Inc.**
#321, 54 Changeop-ro, Sujeong-gu
Seongnam-si, Gyeonggi-do 13449
REPUBLIC OF KOREA

Certification Mark:



Scope of Certificate: **Design, Development, Production and Distribution of In-Vitro Diagnostic Reagents for POCT(Rapid immunochromatographic assay)**
Production and Distribution of In-Vitro Diagnostic Instruments for POCT(Rapid immunochromatographic assay)

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 107415 0001 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_107415_0001_Rev_02)

Report No.: 74964908

Valid from: 2023-06-16
Valid until: 2026-06-15

Date, 2023-05-31



Christoph Dicks
Head of Certification/Notified Body

Certificate

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Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

CALTH Inc.

#321, 54 Changeop-ro, Sujeong-gu, Seongnam-si, Gyeonggi-do
13449, REPUBLIC OF KOREA

Distribution of In-Vitro Diagnostic Reagents for POCT (Rapid
immunochromatographic assay)

CALTH Inc.

#7508, 140, Beolmal-ro, Dongan-gu, Anyang-si, Gyeonggi-do
14057, REPUBLIC OF KOREA

Design and Development of In-Vitro Diagnostic Reagents for
POCT (Rapid immunochromatographic assay)

CALTH Inc.

#1201~1203, #1215~1218, #1306, 52, Gongdan-ro 140beon-gil,
Gunpo-si, Gyeonggi-do 15847, REPUBLIC OF KOREA

Production and Distribution of In-Vitro Diagnostic Reagents and
Instruments for POCT (Rapid immunochromatographic assay)

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