



# Certificate

No. Q5 107415 0001 Rev. 00

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

**Facility(ies):** CALTH Inc.  
#321, 54 Changeop-ro, Sujeong-gu, Seongnam-si, Gyeonggi-do  
13449, REPUBLIC OF KOREA

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

**Certification Mark:**



**Scope of Certificate:** **Design, Development, Production and Distribution of In-Vitro Diagnostic Reagents for POCT (Rapid 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.:** 74956562  
**Valid from:** 2020-06-16  
**Valid until:** 2023-06-15

**Date,** 2020-06-16

Christoph Dicks  
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT

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