DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q1N 075369 0048 Rev. 00

Holder of Certificate:

SD Biosensor, Inc.
C-4th&5th, 16, Deogyeong-daero
1556beon-gil, Yeongtong-gu
Suwon-si, Gyeonggi-do 16690
REPUBLIC OF KOREA

Facility(ies):

SD Biosensor, Inc.
C-4th&5th, 16, Deogyeong-daero, 1556beon-gil, Yeongtong-gu,
Suwon-si, Gyeonggi-do 16690, REPUBLIC OF KOREA

SD Biosensor, Inc.
74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu,
Cheongju-si, Chungcheongbuk-do 28161, REPUBLIC OF KOREA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate:

Design, Development, Production and Distribution of Blood Glucose Monitoring System, Lipid Test System, G6PD Test System, Hemoglobin A1c Test System, In Vitro Diagnostic Medical Device for Immunochromatography and In Vitro Diagnostic Kits for ELISA

Applied Standard(s):

EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems
Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012
Upgrade required until 2019-03-31

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.:	74950513
Valid from:	2018-11-21
Valid until:	2021-11-20

Date, 2018-11-21

Stefan Preiß

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD
A4 / 07.17