

DAKKS CRT2 / A4 07.17 ZN



CERTIFICATE

No. Q1N 17 10 01395 006

Holder of Certificate: OSANG Healthcare Co., Ltd.

132, Anyangcheondong-ro, Dongan-gu

Anyang-si, Gyeonggi-do 14040

REPUBLIC OF KOREA

Facility(ies): OSANG Healthcare Co., Ltd.

132, Anyangcheondong-ro, Dongan-gu,

Anyang-si, Gyeonggi-do 14040, REPUBLIC OF

KOREA

Certification Mark:



Scope of Certificate: Design, Development, Production and Distribution

of In Vitro Diagnostic Reagents and Instruments -

Blood Glucose Monitoring System,

Glycosylated Hemoglobin (HbA1C) Measuring System,

Lipid Profile Measuring System, Immuno Diagnosis Measuring System and Molecular Diagnostic Reagent Kits

Production and Distribution of Medical Device -

Sterile Lancets, Lancing Device

Applied

EN ISO 13485:2012 + AC:2012

Medical devices - Quality management systems -Standard(s):

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.

74949482 Report No.:

Valid from: 2018-02-12 Valid until: 2021-01-31

Date, 2018-02-12

Stefan Preiß

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