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

Product Service

Certificate

No. Q5 001395 0012 Rev. 00

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:

tuv-sud.com/ps-cert

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 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.: 74952328

Valid from: 2019-03-26
Valid until: 2021-01-31

Date, 2019-03-26

Stefan Preiß

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

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