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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 002704 0013 Rev. 01

Manufacturer: **Sugentech, Inc.**
721-26, Jeongjungyeonje-ro, Osong-eup, Heungdeok-gu
Cheongju-si, Chungcheongbuk-do 28161
REPUBLIC OF KOREA

Product Category(ies): **In Vitro diagnostic devices for self testing for Pregnancy test, Ovulation test and COVID-19 test**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. 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:V1 002704 0013 Rev. 01

Report no.: 713211515/713209577

Valid from: 2021-05-07
Valid until: 2024-05-26

Date, 2021-05-07

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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

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Model(s):

Pregnancy test for self testing:
- Surearly Pregnancy Test Strip
- Surearly Digital Pregnancy Test
- Surearly Digital Multi Use Pregnancy Test
- Surearly Easy Pregnancy Test
- Surearly Early Sign Pregnancy Test

Ovulation test for self testing:
- Surearly Ovulation Test Strip
- Surearly Digital Ovulation Test

COVID-19 test for self-testing:
- SGTi-self COVID-19 IgM/IgG
- SGTi-flex COVID-19 Ag

Facility(ies):

Sugentech, Inc.
721-26, Jeongjungyeonje-ro, Osong-eup, Heungdeok-gu,
Cheongju-si, Chungcheongbuk-do 28161, REPUBLIC OF KOREA

Sugentech, Inc.
Room 216, Migun Techno World 2-cha, 187, Techno 2-ro,
Yuseong-gu, Daejeon 34025, REPUBLIC OF KOREA

Parameters: ./.

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