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 095791 0002 Rev. 04

Manufacturer:

NewScen Coast Bio-Pharmaceutical Co., Ltd.
No. 65, 6th Street
Tianjin TEDA
300457 Tianjin
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Screening test for Hepatitis C marker
HIV markers and Products for self testing

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 095791 0002 Rev. 04

Report no.: SH221073A03

Valid from: 2022-05-02
Valid until: 2025-05-26

Date, 2022-05-02

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):

Human Chorionic Gonadotropin (hCG) tests (Pregancy tests)
Luteinizing Hormone (LH) tests (Ovulation tests)
Follicle Stimulating Hormone (FSH) tests (Menopause tests)
One-Step Fecal Occult Blood (FOB) Diagnostic Kit
Serum Ferritin Test Kit (SF)
HIV(1+2) Antibody Rapid Test
HCV Antibody Rapid Test

Facility(ies):

NewScen Coast Bio-Pharmaceutical Co., Ltd.
No. 65, 6th Street, Tianjin TEDA, 300457 Tianjin, PEOPLE'S REPUBLIC OF CHINA

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