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 082119 0009 Rev. 01

Manufacturer:
Co-Innovation Biotech Co. Ltd.
No.9 Baihe 3 Street
Economic And Technological Development East Zone
510530 Guangzhou, Guangdong
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):
Co-Innovation Biotech Co. Ltd.
No.9 Baihe 3 Street, Economic And Technological Development East Zone, 510530 Guangzhou, Guangdong, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):
Pregnancy test for self-testing
Ovulation test for self testing

Model(s):
One Step Human Chorionic Gonadotropin(HCG) Test;
One Step Luteinizing Hormones(LH) 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 082119 0009 Rev. 01

Report no.: GZ2107201

Valid from: 2021-12-08
Valid until: 2024-05-26

Date, 2021-12-08

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