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 095295 0002 Rev. 03

Manufacturer:

Hangzhou Sejoy Electronics & Instruments Co., Ltd.
Area C, Building 2, No. 365, Wuzhou Road
Yuhang Economic Development Zone
311100 Hangzhou City, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Hangzhou Sejoy Electronics & Instruments Co., Ltd.
Area C, Building 2, No. 365, Wuzhou Road, Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **In Vitro diagnostic for self testing**

Model(s):

hCG One Step Pregnancy Test, LH One Step Ovulation Test, FSH One Step Menopause Test, Uric Acid Monitoring system and Hemoglobin Monitoring System include meter, test strip and control solution, Digital Fertility Testing System include Digital Fertility Tracker, LH One Step Ovulation Test, FSH One Step Menopause Test and hCG One Step Pregnancy 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 095295 0002 Rev. 03

Report no.: SH221676A01

Valid from: 2022-04-20
Valid until: 2025-05-26

Date, 2022-04-20

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