ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 16 03 76482 004

Manufacturer:

Shanghai Chemtron Biotech. Co., Ltd.
No 518, Qingdai Rd
International Medical Park
Pudong
201318 Shanghai
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

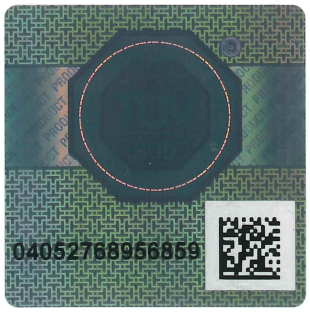
Product Category(ies):

Products for determination of tumor markers (PSA) Chlamydia 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. See also notes overleaf.

Report No.: SH16677EXT01

Valid from: 2016-06-15
Valid until: 2021-06-14



Date, 2016-04-18

Stefan Preiß

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

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Model(s):

Chlamydia Rapid Test,
Prostate Specific Antigen Rapid Test,
One-Step HCG Pregnancy Test,
Fecal Occult Blood Rapid Test,
One-Step LH Ovulation Test,
One-Step Microalbuminuria (MAU) Test,
One-Step FSH Menopause Test,
H.pylori Antigen Rapid Test

Facility(ies):

Shanghai Chemtron Biotech. Co., Ltd.
No 518, Qingdai Rd, International Medical Park,
Pudong, 201318 Shanghai, PEOPLE'S REPUBLIC OF CHINA

Shanghai Chemtron Biotech. Co., Ltd.
No.118, West Heli Rd., Hangtou Town, Pudong,
201317 Shanghai, PEOPLE'S REPUBLIC OF CHINA

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