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

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

TÜV SÜD 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 001311 0006 Rev. 01

Manufacturer:

Autobio Biochemistry Co., Ltd
Building 17 &18, No.13 Courtyard, Mintai Road, Beiwu Town
Shunyi District
101399 Beijing
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Autobio Biochemistry Co., Ltd
Building 17 &18, No.13 Courtyard, Mintai Road, Beiwu Town,
Shunyi District, 101399 Beijing, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Products for determination of tumor markers (PSA)**

Model(s): **Prostate Specific Antigen (PSA) Assay Kit (Latex Enhanced Immunoturbidimetric Method).**

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.: BJ19021901

Valid from: 2020-04-23
Valid until: 2023-03-11

Date, 2020-04-23

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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