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 17 07 63367 017

Manufacturer:

Nantong Egens Biotechnology Co., Ltd.
Building 15, Building 12 (west)
No. 1692 Xinghu Avenue
Nantong Economy & Technology Development Zone
226010 Nantong
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) 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.: SH17241EXT01

Valid from: 2017-08-25
Valid until: 2022-08-24

Date, 2017-08-02

Stefan Preiß

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

Digitally signed by Guţan Ghenadie
Date: 2020.02.05 14:17:48 EET
Reason: MoldSign Signature
Location: Moldova

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No. V1 17 07 63367 017

Model(s): Prostate Specific Antigen (PSA) Test, Pregnancy Test for Self Testing, Ovulation (LH) Test for Self Testing Follicle Stimulation Hormone (FSH) Test, Fast Diagnostic Screening Test for Sperm Concentration

Facility(ies): Nantong Egens Biotechnology Co., Ltd. Building 15, Building 12 (west), No. 1692 Xinghu Avenue, Nantong Economy & Technology Development Zone, 226010 Nantong, PEOPLE'S REPUBLIC OF CHINA

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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