



PRC

Medical Device Manufacturing Enterprise License

No.: SSYJSCX 2004-0108

Legal Representative: Ou Weijun

Enterprise Name: Nantong Egens Biotechnology Co., Ltd.

Enterprise Principal: Ou Weijun

Registration Address: Block A, No.15 Factory Building, No.1692, Xinghu Road,

Nantong Economic Development Zone, Nantong City

Production Address: West of No.15 and No.12 Factory Building, No.1692,

Xinghu Road, Nantong Economic Development Zone, Nantong City

Production Scope: Class III 6840 In-Vitro Diagnostic Reagent; Class II 6840

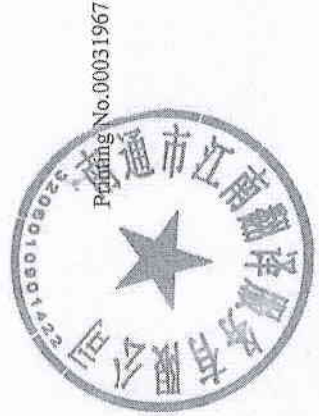
Clinical Analytical Instruments

Issuing Authority: Jiangsu Food and Drug Administration (seal)

Date of Issuing: May 12, 2014

Valid Until: May 12, 2019

United Printed by China Food and Drug Administration (CFDA)





Nantong Egens Biotechnology Co.,Ltd

Block A No.15. building No.1692 xinghu avenue, Nantong, 226010, China
Tel:86-0513-85355017 Fax:86-0513-85327120

Declaration of Conformity

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

European

Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffelstrasse 80, 20537 Hamburg, Germany

Product Name: Pregnancy Test

Model: Strip / Cassette / Midstream

Trade name: Egens

Classification (IVDD, Annex II): Self-testing

Conformity Assessment Route: Annex IV

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

General applicable directives:

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices

Standard Applied: See attached list of (harmonised – EN) standards for which documented evidence of compliance can be provided.

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany

Identification number: CE0123

(EC) Certificate(s): No. V1 12 08 63367 011

Expire date of the Certificate: 2017-08-24

Start of CE Marking: 2012-10-17

Place, Date of Issue: Nantong, 2012-10-17

Signature: Weijun Ou

Position: General Manager

