OffiSoins

TESTS

Vroege Zwangerschapstest

MEDISCH HULPMIDDEL

+ Betrouwbaarheid > 99 %
+ Snel resultaat binnen 2 minuten
+ Vroegtijdige detectie: 25 mUI/ml
+ Kan worden uitgevoerd vanaf de eerste dag na de vermoedelijke menstruatiedatum
+ CE 0123

4265567

Omschrijving	EAN13	CNK	Verpakt per
OFFISOINS Vroege Zwangerschapstest	7141254959485	4265567	12

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 087008 0004 Rev. 01

Model(s):

**One step HCG Pregnancy Test,
One step LH Ovulation Test,
Semi-quantitative hCG One-step Pregnancy Test (5 in 1 dipcard),
Semi-quantitative LH One step Ovulation Test (3 in 1 dipcard).**

Facility(ies):

Beijing Jinhuake Biological Technology CO., Ltd.
Room 402, Buliding 3, No.2 Xingye Street, Beijing Economic-Technological Development Area, 100176 Beijing, PEOPLE'S REPUBLIC OF CHINA

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

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

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Manufacturer:
Beijing Jinhuake Biological Technology CO., Ltd.
Room 402, Buliding 3, No.2 Xingye Street
Beijing Economic-Technological Development Area
100176 Beijing
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:
Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

Product Category(ies):
Self test for determination of fertile days
Pregnancy test 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.: BJ1895007

Valid from: 2019-04-24
Valid until: 2024-04-23

Date, 2019-04-23

Stefan Preiß

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