

EC DESIGN-EXAMINATION CERTIFICATE

Number: 2103018DE01

Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex III (6)
(Devices for self-testing)

Manufacturer:

Sensitest v.o.f.

**Distributieweg 54
2645 EJ Delftgauw
The Netherlands**

For the product

-Human Chorionic Gonadotropin (HCG) for detection of pregnancy; Human Luteinizing Hormone (hLH) for prediction of ovulation

Documents, that form the basis of this certificate:

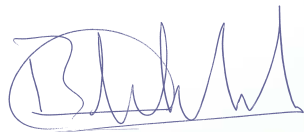
Certification Notice 2103018CN, initially dated 13 March 2007
Addendum, initially dated 13 March 2007

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit in-vitro diagnostica', the Dutch transposition of the Council Directive 98/79/EC of October 27, 1998 concerning In vitro diagnostic medical devices, including all subsequent amendments, based on an examination in accordance with Annex III (6) of this Directive.

The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 26 May 2025
Issued for the first time: 13 March 2007
Revised: 23 May 2022
Reissued: 1 April 2019

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
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ADDENDUM

Belonging to certificate: 2103018DE01

1/2

EC DESIGN-EXAMINATION IN VITRO DIAGNOSTIC MEDICAL DEVICES

-Human Chorionic Gonadotropin (HCG) for detection of pregnancy; Human Luteinizing Hormone (hLH) for prediction of ovulation

Issued to:

Sensitest v.o.f.
Distributieweg 54
2645 EJ Delftgauw
The Netherlands

This certificate covers the following product(s):

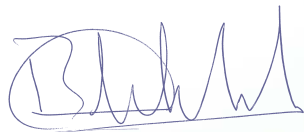
For Sensitest® Pregnancy test:

Sensitest® Pregnancy test dipstick (se-hcgdip)
 Sensitest® Pregnancy test dipstick (se-hcgdipx)
 Sensitest® Pregnancy test midstream (se-hcgmid)
 Sensitest® Pregnancy test midstream (se-hcgmidx)
 Sensitest® Pregnancy test cassette se-(hcgcas)
 Sensitest® Pregnancy test cassette se-(hcgcasx)

For Sensitest® Ovulation test:

Sensitest® Ovulation test strip (se-lhdip)
 Sensitest® Ovulation test strip (se-lhdip-s)
 Sensitest® Ovulation test strip (se-lhdip-pro)
 Sensitest® Ovulation test strip (se-lhdip-bas)
 Sensitest® Ovulation test midstream (se-lhmid)
 Sensitest® Ovulation test midstream (se-lhmid-s)
 Sensitest® Ovulation test midstream (se-lhmid-pro)
 Sensitest® Ovulation test midstream (se-lhmid-bas)
 Sensitest® Ovulation test cassette (se-lhcas)

DEKRA Certification B.V.



B.T.M. Holtus
 Managing Director



J.A. van Vugt
 Certification Manager

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ADDENDUM

Belonging to certificate: 2103018DE01

2/2

EC DESIGN-EXAMINATION IN VITRO DIAGNOSTIC MEDICAL DEVICES

-Human Chorionic Gonadotropin (HCG) for detection of pregnancy; Human Luteinizing Hormone (hLH) for prediction of ovulation

Issued to:

Sensitest v.o.f.
Distributieweg 54
2645 EJ Delftgauw
The Netherlands

For Sensibaby® Pregnancy test:

Sensibaby® Pregnancy test strip (sb-zwdip)
Sensibaby® Pregnancy test strip (sb-zwdipx)
Sensibaby® Pregnancy test midstream (sb-zwmid)
Sensibaby® Pregnancy test midstream (sb-zwmidx)

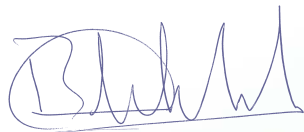
For Sensibaby® Ovulation test:

Sensibaby® Ovulation test strip (sb-ovdip)
Sensibaby® Ovulation test midstream (sb-ovmid)

Initial date: 13 March 2007

Revision date: 1 April 2019

DEKRA Certification B.V.

A blue ink signature of B.T.M. Holtus, consisting of stylized, overlapping loops and lines.

B.T.M. Holtus
Managing Director

A blue ink signature of J.A. van Vugt, featuring a large, sweeping initial 'J' followed by the name 'A. van Vugt' in a cursive script.

J.A. van Vugt
Certification Manager

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