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
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

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
T +31 88 96 83000 F +31 88 96 83100 www.dekra.nl Company registration 09085396