

# 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



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