



## EC DECLARATION OF CONFORMITY

MANUFACTURER:

DIESSE DIAGNOSTICA SENESE SPA  
STRADA DEI LAGHI 39  
53035 MONTERIGGIONI (SI),  
ITALY

EUROPEAN REPRESENTATIVE:

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PRODUCT:  
CODE:

**ENZY-WELL HERPES SIMPLEX 2 IgM**  
**91025, 91187**

CLASSIFICATION:

IVD NOT IN ANNEX II OR SELF-TESTING IVD

CONFORMITY ASSESSMENT ROUTE:

ANNEX APPLIED N° III

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PREVISIONS OF THE COUNCIL DIRECTIVE 98/79EC FOR IN VITRO DIAGNOSTIC MEDICAL DEVICE. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

NOTIFIED BODY:

NOT NECESSARY

(EC) CERTIFICATE:

N.A.

START OF CE-MARKING:

DECEMBER 2003

REVISION:

8

PLACE, DATE OF ISSUE:

MONTERIGGIONI, 24 MAY 2022

EXPIRY DATE:

25 MAY 2026

**THE PRESENT EC DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE AND EXCLUSIVE RESPONSIBILITY OF THE MANUFACTURER.**

SIGNATURE:

CHIARA MUZZI  
REGULATORY AFFAIRS MANAGER

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ISSUED: MONTERIGGIONI, 24/05/2022

MAGDALENA STOCZKO  
REGULATORY SUPERVISOR