



## EC DECLARATION OF CONFORMITY

MANUFACTURER: DIESE DIAGNOSTICA SENESE SPA  
STRADA DEI LAGHI 39  
53035 MONTERIGGIONI (SI),  
ITALY

EUROPEAN REPRESENTATIVE: //

PRODUCT: ENZY-WELL TREPONEMA IgG  
CODE: 91050

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.

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**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