



EC DECLARATION OF CONFORMITY

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

EUROPEAN REPRESENTATIVE: //

PRODUCT: ENZY-WELL TOSCANA VIRUS IgG/IgM
CODE: 91067

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: 7

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