EC DECLARATION OF CONFORMITY

MANUFACTURER:	DIESSE DIAGNOSTICA SENESE SPA STRADA DEI LAGHI 39 53035 MONTERIGGIONI (SI) ITALY
EUROPEAN REPRESENTATIVE:	//
PRODUCT: CODE:	ENZY-WELL RUBELLA IgG AVIDITY 91095
CLASSIFICATION:	IVD IN ANNEX II B
CONFORMITY ASSESSMENT ROUTE:	ANNEX APPLIED N° IV EXCLUDING (4, 6)

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:	TÜV SÜD PRODUCT SERVICE GMBH ZERTIFIZIERSTELLE RIDLERST. 65 – 80339 MÜNCHEN GERMANY No. 0123
(EC) CERTIFICATE:	V1 056726 0002 Rev. 00
START OF CE-MARKING:	DECEMBER 2003
REVISION:	14
PLACE, DATE OF ISSUE:	MONTERIGGIONI, 11 MAY 2022
EXPIRY DATE:	26 MAY 2025

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

SIGNATURE:

CHIARA MUZZI
REGULATORY AFFAIRS MANAGER

THIS IS THE CERTIFIED COPY OF THE ORIGINAL DOCUMENT STORED IN ARCHIVE OF DIESSE DIAGNOSTICA SENESE SPA

ISSUED: MONTERIGGIONI, 11/05/2022

MAGDALENA STOCZKO
REGULATORY SUPERVISOR