# EC DECLARATION OF CONFORMITY

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| MANUFACTURER: | DIESSE DIAGNOSTICA SENESE SPA<br>STRADA DEI LAGHI 39<br>53035 MONTERIGGIONI (SI)<br>ITALY |
| EUROPEAN REPRESENTATIVE: | // |
| PRODUCT:<br>CODE: | **ENZY-WELL RUBELLA IgM**<br>**91031, 91177** |
| 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.

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| NOTIFIED BODY: | TÜV SÜD PRODUCT SERVICE GMBH<br>ZERTIFIZIERSTELLE<br>RIDLERST. 65 – 80339 MÜNCHEN<br>GERMANY<br>No. 0123 |
| (EC) CERTIFICATE: | V1 056726 0002 Rev. 00 |
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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

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