



EU DECLARATION OF CONFORMITY

MANUFACTURER:	DIESSSE DIAGNOSTICA SENESE SPA STRADA DEI LAGHI 39 53035 MONTERIGGIONI (SI), ITALY
SINGLE REGISTRATION NUMBER	IT-MF-000013311
AUTHORIZED REPRESENTATIVE:	NOT APPLICABLE
PRODUCT: CODE:	RPR-DAT ADVANCED 26031
INTENDED PURPOSE:	<p>RPR-DAT ADVANCED (REF 26031) is a non-treponemal agglutination assay for the qualitative and semi-quantitative detection of reagines in human serum to be applied to the AUTO-DAT (REF 26001) instrument.</p> <p>Because non-treponemal tests are based on the detection of reagines, a class of antibodies found in Syphilis (a disease caused by <i>Treponema pallidum</i> infection), the kit is intended to determine exposure to <i>Treponema pallidum</i> infection and to be used as an aid in its diagnosis.</p> <p>The test is not intended to be used to detect exposure to <i>Treponema pallidum</i> infection in blood, blood components, cells, tissues, organs, or any derivatives thereof in order to assess their suitability for transfusion, transplantation, or cell administration.</p> <p>It should only be used by professional laboratory personnel.</p>
BASIC UDI-DI	803389132RPRD-A00YC
UDI-DI	08033891328412
RISK CLASS:	CLASS C
CLASSIFICATION RULE:	RULE 3a
CONFORMITY ASSESSMENT ROUTE:	ANNEX IX
<p>WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT IS IN CONFORMITY WITH REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON IN VITRO DIAGNOSTIC MEDICAL DEVICE. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.</p>	
REFERENCE TO ANY CS APPLIED:	NOT APPLICABLE
NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTABE 65 – 80339 MUNICH GERMANY No. 0123

(EU) CERTIFICATE:

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EXPIRY DATE:

2027-06-26

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



SIGNATURE:

CHIARA MUZZI
PERSON RESPONSIBLE FOR THE REGULATORY
COMPLIANCE

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

ISSUED: MONTERIGGIONI, 2024-06-05



MAGDALENA STOCZKO
REGULATORY SUPERVISOR