EU DECLARATION OF CONFORMITY

MANUFACTURER:	DIESSE 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** **26030**
INTENDED PURPOSE:	RPR-DAT (REF 26030) is an agglutination test kit for qualitative detection of reagins in human serum, to be applied on the AUTO-DAT instrument or to be used in manual technique. The test may also be used to detect reagins in samples serially diluted to establish titer information (semi-quantitative test). Since non-treponemal tests are based on the detection of reagins, an antibody class present in Syphilis (disease caused by Treponema pallidum infection), the kit is intended to determine the exposure to Treponema pallidum infection and to be used as an aid to the relative diagnosis. It must be used by professional laboratory users only and it is not intended for screening blood or tissue donors.
BASIC UDI-DI	803389132TREPONEMADAT0048
UDI-DI	08033891323936
RISK CLASS:	CLASS C
CLASSIFICATION RULE:	RULE 3a
CONFORMITY ASSESSMENT ROUTE:	ANNEX IX

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.

REFERENCE TO ANY CS APPLIED:	NOT APPLICABLE
NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTAßE 65 – 80339 MUNICH GERMANY No. 0123

(EU) CERTIFICATE:	V12 056726 0006 Rev. 02
REVISION:	2
PLACE, DATE OF ISSUE:	MONTERIGGIONI, 05 JUNE 2024
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