



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. 01

REVISION:

1

PLACE, DATE OF ISSUE:

MONTERIGGIONI, 22 JANUARY 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, 2024-01-22



MAGDALENA STOCZKO
REGULATORY SUPERVISOR