



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 ADVANCED
26031**

INTENDED PURPOSE:

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.

Because non-treponemal tests are based on the detection of reagines, a class of antibodies found in Syphilis (a disease caused by *Treponema pallidum* infection), the kit is intended to determine exposure to *Treponema pallidum* infection and to be used as an aid in its diagnosis.

The test is not intended to be used to detect exposure to *Treponema pallidum* infection in blood, blood components, cells, tissues, organs, or any derivatives thereof in order to assess their suitability for transfusion, transplantation, or cell administration.

It should only be used by professional laboratory personnel.

BASIC UDI-DI

803389132RPRD-A00YC

UDI-DI

08033891328412

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:

0

PLACE, DATE OF ISSUE:

MONTERIGGIONI, 29 FEBRUARY 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, 2024-02-29



MAGDALENA STOCZKO
REGULATORY SUPERVISOR