



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:

TPHA-DAT ADVANCED
26041

INTENDED PURPOSE:

TPHA-DAT ADVANCED (REF 26041) is a hemagglutination test for the semi-quantitative detection of specific antibodies directed against *Treponema pallidum*.

The test is performed on human serum by passive hemagglutination using the AUTO-DAT instrument (REF 26001). The kit is intended to determine exposure to *Treponema pallidum* infection and to be used as an aid in the diagnosis of Syphilis.

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

It should be used only by professional laboratory personnel.

BASIC UDI-DI

803389132TPHAD00ND

UDI-DI

08033891328429

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:

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PLACE, DATE OF ISSUE:

MONTERIGGIONI, 22 DECEMBER 2023

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, 2023-12-22



MAGDALENA STOCZKO
REGULATORY SUPERVISOR