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. 02
REVISION:	1
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

M. Stoczko

MAGDALENA STOCZKO
REGULATORY SUPERVISOR