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:	CHORUS ZIKA IgM CAPTURE 81161
INTENDED PURPOSE:	CHORUS ZIKA IgM CAPTURE is an immunoassay kit for the automated qualitative determination of IgM class anti-Zika virus antibodies. The test is performed on human serum using a disposable device applied on CHORUS/ CHORUS TRIO/ CHORUS EVO. instruments. The kit is intended to detect exposure to Zika virus infection as an aid to related diagnosis. It is to be used only by professional laboratory personnel.
BASIC UDI-DI	803389132CHORUSZMC00DB
UDI-DI	08033891324292
RISK CLASS:	CLASS C
CLASSIFICATION RULE:	RULE 3e
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:	0
PLACE, DATE OF ISSUE:	MONTERIGGIONI, 27 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, 2024-06-27

MAGDALENA STOCZKO
REGULATORY SUPERVISOR