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 CHIKUNGUNYA IgM** **81134**
INTENDED PURPOSE:	CHORUS CHIKUNGUNYA IgM is an immunoassay kit for automated qualitative detection of IgM class antibodies against Chikungunya. The test is performed in human serum, using a disposable device applied on the Chorus and Chorus TRIO instruments. The kit is intended to detect the exposure to Chikungunya infection as an aid to the relative diagnosis. It must be used by professional laboratory users only.
BASIC UDI-DI	803389132 CHIKUNGUNYA00 9F
UDI-DI	08033891320218
RISK CLASS:	CLASS B
CLASSIFICATION RULE:	RULE 6
CONFORMITY ASSESSMENT ROUTE:	ANNEX IX (CHAPTER I AND III, SECTION 4.4 TO 4.8)

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 ZERTIFIZIERSTELLE RIDLERST. 65 – 80339 MÜNCHEN GERMANY No. 0123
(EU) CERTIFICATE:	V12 056726 0004 Rev.00
REVISION:	0
PLACE, DATE OF ISSUE:	MONTERIGGIONI, 28 JUNE 2022
EXPIRY DATE:	2027-06-26

THE PRESENT EU DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE AND EXCLUSIVE RESPONSIBILITY OF THE MANUFACTURER.

SIGNATURE:

MARIA CLAUDIA ALCARO
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, 2022-06-28

MAGDALENA STOCZKO
REGULATORY SUPERVISOR