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 ANA-8 86010 - 86010/12
INTENDED PURPOSE:	CHORUS ANA-8 is an immunoassay kit for automated qualitative detection of IgG class antibodies against 8 cellular and nuclear antigens (Sm, U1-snRNP, SS-A, SS-B, snRNP/Sm, Scl-70, Jo-1 and CenpB). As ANA antibodies are widely used as a serologic marker of systemic autoimmune rheumatic disease, the kit is used as an aid to related diagnosis. The test, performed in human serum using a disposable device attached to the CHORUS and CHORUS TRIO instruments, must be used by professional laboratory users only.
BASIC UDI-DI	803389132CHORUSANA8003E
UDI-DI	08033891323110 - 08033891329112
RISK CLASS:	CLASS B
CLASSIFICATION RULE:	RULE 6
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, 28 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:

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, 2024-02-28

MAGDALENA STOCZKO
REGULATORY SUPERVISOR