



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-SCREEN
86014 - 86014/12

INTENDED PURPOSE:

CHORUS ANA-Screen (REF 86014 - 86014/12) is an immunoassay kit for the automated qualitative determination of IgG class antibodies against HEp2 cells.

The American College of Rheumatology has indicated the use of the Hep-2 cell as the "gold standard" for the screening of ANA as a serological marker for systemic autoimmune rheumatic disease. Therefore the kit can be used as an aid to the relative diagnosis.

The test is performed in human serum using a disposable device applied on the CHORUS/CHORUS TRIO and CHORUS EVO instruments and it must be used by professional laboratory users only

BASIC UDI-DI

803389132CHORUSANASCR00SF

UDI-DI

08033891323141 - 08033891329136

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. 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:



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, 2024-06-05



MAGDALENA STOCZKO
REGULATORY SUPERVISOR