

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 Promonitor ETANERCEPT
86706

INTENDED PURPOSE:

CHORUS Promonitor ETANERCEPT is an immunoassay kit for automated quantitative detection of ETANERCEPT (ETN) in human serum using a disposable device applied on the CHORUS TRIO instrument.

The product, used in conjunction with other clinical and laboratory findings, is useful as an aid in the management of patients treated with ETANERCEPT (ETN), like patients with rheumatic diseases.

The device must be used by professional laboratory users only.

BASIC UDI-DI

803389132CHORUSETN009C

UDI-DI

08033891328313

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, 22 DECEMBER 2023

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, 2023-12-22



MAGDALENA STOCZKO
REGULATORY SUPERVISOR