

MANUFACTURER:	DIESSSE 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:	<p>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.</p> <p>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.</p> <p>The device must be used by professional laboratory users only.</p>
BASIC UDI-DI	803389132CHORUSETN009C
UDI-DI	08033891328313
RISK CLASS:	CLASS B
CLASSIFICATION RULE:	RULE 6
CONFORMITY ASSESSMENT ROUTE:	ANNEX IX
<p>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.</p>	
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