

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 ANTI-CCP 86094 - 86094/12
INTENDED PURPOSE:	<p>CHORUS ANTI-CCP is an immunoassay kit for automated semi-quantitative detection of IgG class antibodies against cyclic citrullinated peptide (anti-CCP). Since the anti-CCP antibodies are highly specific for Rheumatoid Arthritis (RA) and their detection is one of the ACR (American College of Rheumatology) criteria for classification of RA, the kit is used as an aid to the relative diagnosis.</p> <p>The test, performed in human serum using a disposable device applied on the Chorus and Chorus TRIO instruments, must be used by professional laboratory users only.</p>
BASIC UDI-DI	803389132 CCP00 5G
UDI-DI	08033891328672 - 08033891329228
RISK CLASS:	CLASS B
CLASSIFICATION RULE:	RULE 6
CONFORMITY ASSESSMENT ROUTE:	ANNEX IX (CHAPTER I AND III, SECTION 4.4 TO 4.8)
<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 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