



## 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 ANTI-CCP**  
**86094 - 86094/12**

INTENDED PURPOSE:

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.

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.

BASIC UDI-DI

803389132CCP005G

UDI-DI

08033891328672 - 08033891329228

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:

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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