



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 CLIA VIT B12
82252

INTENDED PURPOSE:

CHORUS CLIA VIT B12 is an immunological kit for the automated quantitative determination of Vitamin B12. The test is performed on human serum using a disposable device applied on CHORUS EVO instrument. The kit, intended to measure the level of Vitamin B12, is an aid in the diagnosis of vitamin B12 deficiency. It is to be used only by professional laboratory personnel.

BASIC UDI-DI

803389132CVITB-C0096

UDI-DI

08033891328498

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, 24 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, 2024-06-24



MAGDALENA STOCZKO
REGULATORY SUPERVISOR