

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 CALPROTECTIN 3RD GENERATION
86603

INTENDED PURPOSE:

CHORUS CALPROTECTIN 3RD GENERATION is an immunoassay kit for the automated quantitative detection of Calprotectin, performed in human stool using a disposable device applied on the CHORUS/ CHORUS TRIO instruments. High concentration of Calprotectin is observed in the stool of patients with chronic inflammatory diseases (IBD). The kit, intended for the determination of Calprotectin concentration is used as an aid to diagnosis and to allow monitor of related therapeutic measures. It is to be used only by professional laboratory personnel.

BASIC UDI-DI

803389132CHORUSCALP3009M

UDI-DI

08033891328436

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
RIDLERSTABE 65 – 80339 MUNICH
GERMANY
No. 0123

(EU) CERTIFICATE:

V12 056726 0006 Rev. 01

REVISION:

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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