



## 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 FECAL ELASTASE  
86114**

INTENDED PURPOSE:

CHORUS FECAL ELASTASE (REF 86114) is an immunoenzymatic assay kit for the automated quantitative determination of human fecal pancreatic elastase using a disposable device attached to the CHORUS TRIO instruments. Since the measurement of pancreatic elastase in feces has assumed an important role in the diagnosis of pancreatic insufficiency, the kit is intended to be used as an aid in the relevant diagnosis and subsequent monitoring. It is to be used only by professional laboratory personnel.

BASIC UDI-DI

803389132FEL-C007J

UDI-DI

08033891322786

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:

1

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