



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 HELICOBACTER PYLORI IgG
81060**

INTENDED PURPOSE:

CHORUS HELICOBACTER PYLORI IgG (REF 81060) is an immunoassay kit for the automated semi-quantitative determination of IgG antibodies against Helicobacter pylori. Helicobacter pylori infection causes a systemic (IgM, IgG) and local (IgA) immune response. Since IgG levels rise during infection and remain constant over time, the kit is used as an aid in the diagnosis of Helicobacter pylori infection. The test, performed in human serum using a disposable device applied to the CHORUS and CHORUS TRIO instruments, must be used by professional laboratory personnel only. The device is For In Vitro Diagnostic Use Only.

BASIC UDI-DI

803389132CHORUSPYG00D5

UDI-DI

08033891322397

RISK CLASS:

CLASS C

CLASSIFICATION RULE:

RULE 3e

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. 01

REVISION:

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PLACE, DATE OF ISSUE:

MONTERIGGIONI, 8 MARCH 2024

EXPIRY DATE:

2027-06-26

THE PRESENT EU DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE AND EXCLUSIVE RESPONSIBILITY OF THE MANUFACTURER.

SIGNATURE:



CHIARA MUZZI
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, 2024-03-08



MAGDALENA STOCZKO
REGULATORY SUPERVISOR