



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 IgA
81062**

INTENDED PURPOSE:

CHORUS HELICOBACTER PYLORI IgA (REF 81062) is an immunoassay kit for the automated qualitative determination of IgA antibodies against Helicobacter pylori. Helicobacter pylori infection causes a systemic (IgM, IgG) and local (IgA) immune response; therefore, 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

803389132CHORUSPYA00C7

UDI-DI

08033891322403

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. 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:



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, 2024-06-05



MAGDALENA STOCZKO
REGULATORY SUPERVISOR