

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 MYCOPLASMA PNEUMONIAE IgM
81035**

INTENDED PURPOSE:

CHORUS Mycoplasma pneumoniae IgM (REF 81035) is an immunoassay kit for the automated qualitative determination of IgM antibodies against Mycoplasma pneumoniae.

Mycoplasma pneumoniae is the most common etiological agent causing pneumonia acquired in community environments. The IgM are more frequently found in case of primary infection; therefore, the kit is used as an aid in the diagnosis of pneumonia 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.

BASIC UDI-DI

803389132CHORUSMYM00D2

UDI-DI

08033891322267

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