DIESSE

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 MYCOPLASMA PNEUMONIAE IgA** **81033**

INTENDED PURPOSE:

CHORUS Mycoplasma pneumoniae IgA (REF 81033) is an immunoassay kit for the automated semi-quantitative determination of IgA antibodies against Mycoplasma pneumoniae.

Mycoplasma Pneumoniae is the most common etiological agent causing pneumonia acquired in community environments. The IgA represent the highest sensitivity marker in case of an infection in progress, a reinfection, or a recent 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. The device is For In Vitro Diagnostic Use Only.

BASIC UDI-DI	803389132CHORUSMYA00B6
UDI-DI	08033891327552
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:	0
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