



## EU DECLARATION OF CONFORMITY

MANUFACTURER:	DIESSSE DIAGNOSTICA SENESE SPA STRADA DEI LAGHI 39 53035 MONTERIGGIONI (SI), ITALY
SINGLE REGISTRATION NUMBER	IT-MF-000013311
AUTHORIZED REPRESENTATIVE:	NOT APPLICABLE
PRODUCT: CODE:	<b>CHORUS MYCOPLASMA PNEUMONIAE IgA 81033</b>
INTENDED PURPOSE:	<p>CHORUS Mycoplasma pneumoniae IgA (REF 81033) is an immunoassay kit for the automated semi-quantitative determination of IgA antibodies against Mycoplasma pneumoniae.</p> <p>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.</p> <p>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.</p>
BASIC UDI-DI	803389132CHORUSMYA00B6
UDI-DI	08033891327552
RISK CLASS:	CLASS C
CLASSIFICATION RULE:	RULE 3e
CONFORMITY ASSESSMENT ROUTE:	ANNEX IX
<p>WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT IS IN CONFORMITY WITH <b>REGULATION (EU) 2017/746</b> 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.</p>	
REFERENCE TO ANY CS APPLIED:	NOT APPLICABLE
NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTABE 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