DECLARATION OF CONFORMITY

MANUFACTURER: DIESSE DIAGNOSTICA SENESE SPA
VIA DELLE ROSE 10
53035 MONTERIGGIONI (SI), ITALY

EUROPEAN REPRESENTATIVE: //

PRODUCT: CHORUS MYCOPLASMA PNEUMONIAE IgA
CODE: 81033

CLASSIFICATION: IVD NOT IN ANNEX II OR SELF-TESTING IVD

CONFORMITY ASSESSMENT ROUTE: ANNEX APPLIED N° III

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PREVISIONS OF THE COUNCIL DIRECTIVE 98/79EC FOR IN VITRO DIAGNOSTIC MEDICAL DEVICE. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

NOTIFIED BODY: NOT NECESSARY

(EC) CERTIFICATE: N.A.

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PLACE, DATE OF ISSUE: MONTERIGGIONI, 5 JUNE 2019

EXPIRY DATE: 25 MAY 2022

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

SIGNATURE: 
CHIARA MUZZI
HEAD OF REGULATORY AFFAIRS

THIS IS THE CERTIFIED COPY OF THE ORIGINAL DOCUMENT STORED IN ARCHIVE OF DIESSE DIAGNOSTICA SENESE SPA

ISSUED: MONTERIGGIONI, 18/06/2019

MAGDALENA STOCZKO
REGULATORY AFFAIRS SPECIALIST