



EC DECLARATION OF CONFORMITY

MANUFACTURER:

DIESE DIAGNOSTICA SENESE SPA
VIA DELLE ROSE 10
53035 MONTERIGGIONI (SI),
ITALY



EUROPEAN REPRESENTATIVE:

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PRODUCT:

CHORUS TREPONEMA IgG CONTROL SERUM

CODE:

81527

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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5

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

SIGNATURE:

CHIARA MUZZI
QUALITY & REGULATORY MANAGER

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ISSUED: MONTERIGGIONI, 07/04/2021

MAGDALENA STOCZKO
REGULATORY SUPERVISOR