



EC DECLARATION OF CONFORMITY

MANUFACTURER: DIESE DIAGNOSTICA SENESE SPA
STRADA DEI LAGHI 39
53035 MONTERIGGIONI (SI),
ITALY

EUROPEAN REPRESENTATIVE: //

PRODUCT: **CHORUS BORDETELLA PERTUSSIS TOXIN IgG**
CODE: **81272**

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.

START OF CE-MARKING: NOVEMBER 2018

REVISION: 5

PLACE, DATE OF ISSUE: MONTERIGGIONI, 24 MAY 2022

EXPIRY DATE: 25 MAY 2026

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


SIGNATURE:



CHIARA MUZZI
REGULATORY AFFAIRS MANAGER

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

ISSUED: MONTERIGGIONI, 24/05/2022



MAGDALENA STOCZKO
REGULATORY SUPERVISOR