



## EC DECLARATION OF CONFORMITY

MANUFACTURER:

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



EUROPEAN REPRESENTATIVE:

//

PRODUCT:  
CODE:

**CHORUS SARS-CoV-2 IgA**  
**81402**

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:

SEPTEMBER 2020

REVISION:

1

PLACE, DATE OF ISSUE:

MONTERIGGIONI, 7 APRIL 2021

EXPIRY DATE:

25 MAY 2022

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

SIGNATURE:

CHIARA MUZZI  
QUALITY & REGULATORY MANAGER

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

ISSUED: MONTERIGGIONI, 07/04/2021

MAGDALENA STOCZKO  
REGULATORY SUPERVISOR