



## EC DECLARATION OF CONFORMITY

MANUFACTURER:

DIESSE DIAGNOSTICA SENESE SPA  
STRADA DEI LAGHI 39  
53035 MONTERIGGIONI (SI),  
ITALY

EUROPEAN REPRESENTATIVE:

//

PRODUCT:

CODE:

**CHORUS EPSTEIN BARR EARLY ANTIGEN IgM  
81059, 81059/12**

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:

FEBRUARY 2004

REVISION:

10

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 DIESSE DIAGNOSTICA SENESE SPA

ISSUED: MONTERIGGIONI, 24/05/2022

MAGDALENA STOCZKO  
REGULATORY SUPERVISOR