

MANUFACTURER:

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

SINGLE REGISTRATION NUMBER

IT-MF-000013311

AUTHORIZED REPRESENTATIVE:

NOT APPLICABLE

PRODUCT:
CODE:

CHORUS EPSTEIN-BARR EARLY ANTIGEN IgM
81059 - 81059/12

INTENDED PURPOSE:

CHORUS EPSTEIN-BARR EARLY ANTIGEN IgM is an immunoassay kit for the automated qualitative determination of IgM class antibodies against Epstein Barr Early Antigen.

The test is performed on human serum, using a disposable device applied on the CHORUS/CHORUS TRIO/CHORUS EVO instruments. The kit is intended to detect the exposure to Epstein Barr Virus infection as an aid to the related diagnosis. It must be used by professional laboratory users only.

The test is not intended to detect the exposure of the transmissible agent in blood, blood components, cells, tissues, organs or any derivative thereof for the purpose of assessing its suitability for transfusion, transplantation or cell administration.

BASIC UDI-DI

803389132CHORUSEAM0052

UDI-DI

08033891322380 - 08033891328979

RISK CLASS:

C

CLASSIFICATION RULE:

3e

CONFORMITY ASSESSMENT ROUTE:

ANNEX IX

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT IS IN CONFORMITY WITH **REGULATION (EU) 2017/746** OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON IN VITRO DIAGNOSTIC MEDICAL DEVICE. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

REFERENCE TO ANY CS APPLIED:

NOT APPLICABLE

NOTIFIED BODY:

TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTAßE 65 – 80339 MUNICH
GERMANY
No. 0123

(EU) CERTIFICATE:

V12 056726 0006 Rev. 03

REVISION:

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PLACE, DATE OF ISSUE:

MONTERIGGIONI, 2026-03-05

EXPIRY DATE:

2027-06-26

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

SIGNATURE:



CHIARA MUZZI
PERSON RESPONSIBLE FOR THE REGULATORY
COMPLIANCE

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

ISSUED: MONTERIGGIONI, 2026-03-05



MAGDALENA STOCZKO
REGULATORY SUPERVISOR