

**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:**

CLASS C

**CLASSIFICATION RULE:**

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. 02

REVISION:

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PLACE, DATE OF ISSUE:

MONTERIGGIONI, 27 JUNE 2024

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, 2024-06-27



MAGDALENA STOCZKO  
REGULATORY SUPERVISOR