

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 VARICELLA IgM
81079 - 81079/12

INTENDED PURPOSE:

CHORUS VARICELLA IgM is an Immunoassay kit for the automated qualitative determination of IgM class against Varicella Zoster Virus antibodies.

The test is performed on human serum, using a disposable device applied on the CHORUS/CHORUS TRIO/CHORUS EVO instruments.

The test is intended to detect the immune status of the patients against the transmitting agent as an aid to the related diagnosis, especially to evaluate the exposure or level of immune response in pregnant women.

Accordingly, the target population is represented by patients suspected to be affected By Varicella Zoster virus including pregnant women.

The test is to be used only by professional laboratory personnel properly trained.

BASIC UDI-DI

803389132CHORUSVZM00GC

UDI-DI

(01)08033891322489 - (01)08033891329044

RISK CLASS:

CLASS C

CLASSIFICATION RULE:

RULE 3d

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, 30 SEPTEMBER 2025

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, 2025-09-30



MAGDALENA STOCZKO
REGULATORY SUPERVISOR