



## EU DECLARATION OF CONFORMITY

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 HERPES SIMPLEX 1+2 IgM  
81021**

INTENDED PURPOSE:

CHORUS HERPES SIMPLEX 1+2 IgM is an Immunoassay kit for the automated qualitative determination of IgM class antibodies against Herpes Simplex Virus type 1 and type 2. The test, performed in human serum, using a disposable device applied on the Chorus and Chorus TRIO instruments. The kit is intended to detect the exposure to Herpes simplex virus (Type 1 and Type 2) infection as an aid to the related diagnosis.

It must be used by professional laboratory users only.

BASIC UDI-DI

803389132CHORUSHSM009Z

UDI-DI

08033891322229

RISK CLASS:

CLASS C

CLASSIFICATION RULE:

RULE 3a

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:

1

PLACE, DATE OF ISSUE:

MONTERIGGIONI, 05 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:



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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, 2024-06-05



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MAGDALENA STOCZKO  
REGULATORY SUPERVISOR