

**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 IgG**  
**81020**

**INTENDED PURPOSE:**

CHORUS HERPES SIMPLEX 1+2 IgG is an immunoassay kit for the automated qualitative determination of IgG class antibodies against Herpes simplex virus 1+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**

803389132CHORUSHSG0093

**UDI-DI**

08033891322212

**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:



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



MAGDALENA STOCZKO  
REGULATORY SUPERVISOR