



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 CLIA MEASLES IgG
82400**

INTENDED PURPOSE:

CHORUS CLIA MEASLES IgG (REF 82400) is an immunoassay kit for the quantitative automated determination of class IgG anti-Measles virus antibodies.
The test is performed on serum using a disposable device applied on instruments Chorus EVO.
The kit is intended to detect exposure to infection by Measles virus as an aid to related diagnosis.
It is to be used only by professional laboratory personnel.

BASIC UDI-DI

803389132CMVG00AU

UDI-DI

08033891328528

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:

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