

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 PARVOVIRUS B19 IgM
81152**

INTENDED PURPOSE:

CHORUS Parvovirus B19 IgM (REF 81152) is an immunoassay kit for the automated qualitative determination of IgM class antibodies against Parvovirus B19.

The test is performed on human serum using a disposable device applied to the CHORUS /CHORUS TRIO and CHORUS EVO instruments. The kit is intended to detect the exposure to virus as an aid to the related diagnosis. Accordingly, the target population is represented by patients with suspected Parvovirus infection. The kit is to be used by professional laboratory personnel only properly trained.

BASIC UDI-DI

803389132CHORUSVPM00E6

UDI-DI

(01)08033891320256

RISK CLASS:

C

CLASSIFICATION 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. 03

REVISION:

0

PLACE, DATE OF ISSUE:

MONTERIGGIONI, 2026-03-12

EXPIRY DATE:

2027-06-26

THE PRESENT EU DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE AND EXCLUSIVE RESPONSIBILITY OF THE MANUFACTURER.

SIGNATURE:



MARIA CLAUDIA ALCARO
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, 2026-03-12



MAGDALENA STOCZKO
REGULATORY SUPERVISOR