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. 01
REVISION:	0
PLACE, DATE OF ISSUE:	MONTERIGGIONI, 22 MARCH 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, 2024-03-22

M. Stoczko

MAGDALENA STOCZKO
REGULATORY SUPERVISOR