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 EPSTEIN-BARR EARLY ANTIGEN IgG** **81058 - 81058/12**
INTENDED PURPOSE:	CHORUS EPSTEIN-BARR EARLY ANTIGEN IgG is an Immunoassay kit for the qualitative determination of IgG class antibodies against Epstein Barr Early Antigen in human serum, using a disposable device applied on the CHORUS/CHORUS TRIO/CHORUS EVO instruments. The kit is intended to detect the exposure to Epstein Barr Virus infection as an aid to the related diagnosis. It must be used by professional laboratory users only. The test is not intended to detect the exposure of the transmissible agent in blood, blood components, cells, tissues, organs or any derivative thereof for the purpose of assessing its suitability for transfusion, transplantation or cell administration.
BASIC UDI-DI	803389132CHORUSEAG0044
UDI-DI	08033891322373 - 08033891328986
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:	0
PLACE, DATE OF ISSUE:	MONTERIGGIONI, 27 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, 2024-06-27

MAGDALENA STOCZKO
REGULATORY SUPERVISOR