



## 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:	<b>CHORUS CLIA FOLATE</b> <b>82254</b>
INTENDED PURPOSE:	<p>CHORUS CLIA FOLATE is an immunological kit for the automated determination of Folate.</p> <p>The test is performed on human serum using a disposable device applied on the CHORUS EVO instrument.</p> <p>The kit is intended to measure levels of Folate and is an aid in the diagnosis of Folate deficiency.</p> <p>It is to be used only by professional laboratory personnel.</p>
BASIC UDI-DI	803389132CFLT-C00MH
UDI-DI	08033891328504
RISK CLASS:	CLASS B
CLASSIFICATION RULE:	RULE 6
CONFORMITY ASSESSMENT ROUTE:	ANNEX IX
<p>WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT IS IN CONFORMITY WITH <b>REGULATION (EU) 2017/746</b> 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.</p>	
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, 24 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:



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, 2024-06-24



MAGDALENA STOCZKO  
REGULATORY SUPERVISOR