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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 CARDIOLIPIN-M** **86048 - 86048/12**
INTENDED PURPOSE:	CHORUS Cardiolipin-M (REF 86048 - 86048/12) is an immunoassay kit for the automated semi-quantitative determination of IgM antibodies against Cardiolipin, an acid phospholipid derived from glycerol. Since the detection of antibodies against Cardiolipin IgG and/or IgM is one of the Sydney criteria to define antiphospholipid syndrome (APS), the kit is used as an aid to the related diagnosis. The test, performed in human serum using a disposable device applied to the CHORUS/CHORUS TRIO/CHORUS EVO instruments, must be used by professional laboratory personnel only.
BASIC UDI-DI	803389132CHORUSCLPM009X
UDI-DI	08033891323332 - 08033891329280
RISK CLASS:	CLASS B
CLASSIFICATION RULE:	RULE 6
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: | |

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MARIA CLAUDIA ALCARO
PERSON RESPONSIBLE FOR THE REGULATORY
COMPLIANCE