# EU DECLARATION OF CONFORMITY

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| MANUFACTURER: | DIESSE DIAGNOSTICA SENESE SPA<br>STRADA DEI LAGHI 39<br>53035 MONTERIGGIONI (SI),<br>ITALY |
| SINGLE REGISTRATION NUMBER | IT-MF-000013311 |
| AUTHORIZED REPRESENTATIVE: | NOT APPLICABLE |
| PRODUCT:<br>CODE: | CHORUS CARDIOLIPIN-G<br>86046 - 86046/12 |
| INTENDED PURPOSE: | CHORUS Cardiolipin-G (REF 86046 - 86046/12) is an immunoassay kit for the automated semi-quantitative determination of IgG 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.<br>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 | 803389132CHORUSCLPG008Z |
| UDI-DI | 08033891323318 - 08033891329273 |
| 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.

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| REFERENCE TO ANY CS APPLIED: | NOT APPLICABLE |
| NOTIFIED BODY: | TÜV SÜD PRODUCT SERVICE GMBH<br>RIDLERSTAßE 65 – 80339 MUNICH<br>GERMANY<br>No. 0123 |
| (EU) CERTIFICATE: | V12 056726 0006 Rev. 02 |
| REVISION: | 1 |
| PLACE, DATE OF ISSUE: | MONTERIGGIONI, 05 JUNE 2024 |

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| 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, 2024-06-05

MAGDALENA STOCZKO
REGULATORY SUPERVISOR