# 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 dsDNA-M**<br>**86034 - 86034/12** |
| INTENDED PURPOSE: | CHORUS dsDNA-M (REF 86034 - 86034/12) is an immunoassay kit for automated semiquantitative determination of IgM class antibodies against dsDNA.<br>As dsDNA antibodies are widely used as a serologic marker of systemic lupus erythematosus (SLE), the kit is used as an aid to related diagnosis and clinical monitoring.<br>The test, performed in human serum using a disposable device applied to the CHORUS and CHORUS TRIO instruments, must be used by professional laboratory users only. |
| BASIC UDI-DI | 803389132CHORUSDSDNAM00V6 |
| UDI-DI | 08033891327408 - 08033891329211 |
| 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. 01 |
| REVISION: | 0 |
| PLACE, DATE OF ISSUE: | MONTERIGGIONI, 28 FEBRUARY 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, 2024-02-28

MAGDALENA STOCZKO
REGULATORY SUPERVISOR