



## 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:   | <b>CHORUS ENA-6 S</b><br><b>86012 - 86012/12</b>   |
| INTENDED PURPOSE:   | <p>CHORUS ENA-6 S is an immunoassay kit for the automated qualitative determination of IgG class antibodies against 6 cellular and nuclear antigens (SS-A, SS-B, Scl-70, Sm, snRNP/Sm and Jo-1).</p> <p>As ENA antibodies are widely used as a serologic marker of systemic autoimmune rheumatic disease, the kit is used as an aid to related diagnosis.</p> <p>The test performed in human serum, using a disposable device applied on the CHORUS and CHORUS TRIO instruments, must be used by professional laboratory users only.</p> |
| BASIC UDI-DI  | 803389132CHORUSENA6S00BK   |
| UDI-DI  | 08033891323134 - 08033891329129  |
| 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<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  |

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