

| | |
|---|--|
| 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 25OH VITAMIN D TOTAL 86900 |
| INTENDED PURPOSE: | <p>CHORUS 25OH VITAMIN D TOTAL is an immunoassay kit for automated quantitative detection of 25(OH) Vitamin D, performed in human serum using a disposable device applied on the Chorus and Chorus TRIO instruments.</p> <p>Since 25(OH) Vitamin D is considered the main form of storage of Vitamin D, the kit is intended to monitor the overall Vitamin D status and the relative therapeutic measures.</p> <p>It must be used by professional laboratory users only.</p> |
| BASIC UDI-DI | 803389132VITAMIND00GP |
| UDI-DI | 08033891329709 |
| 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 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.</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: | 2 |
| 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:



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