

MANUFACTURER:	DIESSSE DIAGNOSTICA SENESE SPA STRADA DEI LAGHI 39 53035 MONTERIGGIONI (SI), ITALY
SINGLE REGISTRATION NUMBER	IT-MF-000013311
AUTHORIZED REPRESENTATIVE:	NOT APPLICABLE
PRODUCT: CODE:	<b>CHORUS 25OH VITAMIN D TOTAL</b> <b>86900</b>
INTENDED PURPOSE:	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. 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. It must be used by professional laboratory users only.
BASIC UDI-DI	803389132 VITAMIND00 GP
UDI-DI	08033891329709
RISK CLASS:	CLASS B
CLASSIFICATION RULE:	RULE 6
CONFORMITY ASSESSMENT ROUTE:	ANNEX IX (CHAPTER I AND III, SECTION 4.4 TO 4.8)
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.	
REFERENCE TO ANY CS APPLIED:	NOT APPLICABLE
NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH ZERTIFIZIERSTELLE RIDLERST. 65 – 80339 MÜNCHEN GERMANY No. 0123
(EU) CERTIFICATE:	V12 056726 0004 Rev.00
REVISION:	0
PLACE, DATE OF ISSUE:	MONTERIGGIONI, 28 JUNE 2022
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, 2022-06-28



MAGDALENA STOCZKO  
REGULATORY SUPERVISOR