

MANUFACTURER:	DIESSSE DIAGNOSTICA SENESE SPA STRADA DEI LAGHI 39 53035 MONTERIGGIONI (SI), ITALY
SINGLE REGISTRATION NUMBER	IT-MF-000013311
AUTHORIZED REPRESENTATIVE:	//
PRODUCT: CODE:	<b>CHORUS Vitamin Extraction</b> <b>86500</b>
INTENDED PURPOSE:	Kit for the extraction of samples to be tested with the CHORUS VIT B12 (REF. 86400) and CHORUS FOLATE (REF. 86402) tests.
BASIC UDI-DI	803389132CHORUSVEX00DG
UDI-DI	08033891324582
RISK CLASS:	CLASS A
CLASSIFICATION RULE:	RULE 5A
CONFORMITY ASSESSMENT ROUTE:	ARTICLE 17, ANNEX II and ANNEX III

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.

REFERENCE TO ANY CS APPLIED:	NOT APPLICABLE
NOTIFIED BODY:	NOT NECESSARY
(EU) CERTIFICATE:	//
REVISION:	0
PLACE, DATE OF ISSUE:	MONTERIGGIONI, 21 DECEMBER 2022
EXPIRY DATE:	//

**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
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THIS IS THE CERTIFIED COPY OF THE ORIGINAL DOCUMENT STORED IN ARCHIVE OF DIESSE DIAGNOSTICA SENESE SPA

ISSUED: MONTERIGGIONI, 2022-12-21

*M. Stoczko*

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MAGDALENA STOCZKO  
REGULATORY SUPERVISOR