

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 TG 86076-86076/12
INTENDED PURPOSE:	<p>CHORUS TG (REF 86076-86076/12) is an immunoassay kit for automated quantitative determination of Thyroglobin (TG), performed in human serum, using a disposable device applied on the Chorus and Chorus TRIO instruments.</p> <p>High TG level is reported in various Thyroid diseases like hyperthyroidism, non-toxic goitre, thyroiditis and differentiated Thyroid carcinoma. The main clinical application for the TG determination, however, is represented by the post-operative monitoring of differentiated thyroid carcinoma. For this reason, the kit is intended to be used as an aid in the relative diagnosis and monitoring.</p> <p>It must be used by professional laboratory users only.</p>
BASIC UDI-DI	803389132TG00BL
UDI-DI	08033891323615 - 08033891329471
RISK CLASS:	CLASS C
CLASSIFICATION RULE:	RULE 3h
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.	
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. 01

REVISION:

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PLACE, DATE OF ISSUE:

MONTERIGGIONI, 22 JANUARY 2024

EXPIRY DATE:

2027-06-26

THE PRESENT EU DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE AND EXCLUSIVE RESPONSIBILITY OF THE MANUFACTURER.



SIGNATURE:

CHIARA MUZZI
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, 2024-01-22



MAGDALENA STOCZKO
REGULATORY SUPERVISOR