

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:

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.

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.

It must be used by professional laboratory users only.

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. 02

REVISION:

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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:



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, 2024-06-05



MAGDALENA STOCZKO
REGULATORY SUPERVISOR