



EC DECLARATION OF CONFORMITY

MANUFACTURER:	DIESSSE DIAGNOSTICA SENESE SPA STRADA DEI LAGHI 39 53035 MONTERIGGIONI (SI), ITALY
EUROPEAN REPRESENTATIVE:	//
PRODUCT: CODE:	CHORUS TSH 86516
CLASSIFICATION:	IVD NOT IN ANNEX II OR SELF-TESTING IVD
CONFORMITY ASSESSMENT ROUTE:	ANNEX APPLIED N° III

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PREVISIONS OF THE COUNCIL DIRECTIVE 98/79EC FOR IN VITRO DIAGNOSTIC MEDICAL DEVICE. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

NOTIFIED BODY:	NOT NECESSARY
(EC) CERTIFICATE:	N.A.
START OF CE-MARKING:	APRIL 2018
REVISION:	5
PLACE, DATE OF ISSUE:	MONTERIGGIONI, 16 MAY 2022
EXPIRY DATE:	25 MAY 2027

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


SIGNATURE:



CHIARA MUZZI
REGULATORY AFFAIRS MANAGER

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ISSUED: MONTERIGGIONI, 16/05/2022



MAGDALENA STOCZKO
REGULATORY SUPERVISOR