

MANUFACTURER:	DIESESE DIAGNOSTICA SENESE SPA STRADA DEI LAGHI 39 53035 MONTERIGGIONI (SIENA), ITALY
EUROPEAN REPRESENTATIVE:	//
PRODUCT: CODE:	CHORUS DENGUE IgM CAPTURE 81157
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 2022
REVISION:	0
PLACE, DATE OF ISSUE:	MONTERIGGIONI, 28 APRIL 2022
EXPIRY DATE:	25 MAY 2027

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


SIGNATURE:



GRAZIA DAL MASO
QUALITY UNIT DIRECTOR

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

ISSUED: MONTERIGGIONI, 28/04/2022



MAGDALENA STOCZKO
REGULATORY SUPERVISOR