EC DECLARATION OF CONFORMITY

MANUFACTURER:	DIESSE DIAGNOSTICA SENESE SPA STRADA DEI LAGHI 39 53035 MONTERIGGIONI (SI) ITALY
EUROPEAN REPRESENTATIVE:	//
PRODUCT: CODE:	**iRAPID SARS-CoV-2 QUANT "NEUTRALIZING" Ab** **70100**
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:	JUNE 2021
REVISION:	2
PLACE, DATE OF ISSUE:	MONTERIGGIONI, 16 MAY 2022
EXPIRY DATE:	25 MAY 2025

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

SIGNATURE:

CHIARA MUZZI
REGULATORY AFFAIRS MANAGER

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

ISSUED: MONTERIGGIONI, 16/05/2022

MAGDALENA STOCZKO
REGULATORY SUPERVISOR