

MANUFACTURER:	DIESSSE DIAGNOSTICA SENESE SPA STRADA DEI LAGHI 39 53035 MONTERIGGIONI (SI), ITALY
SINGLE REGISTRATION NUMBER	IT-MF-000013311
AUTHORIZED REPRESENTATIVE:	//
PRODUCT: CODE:	CHORUS NEGATIVE CONTROL/SAMPLE DILUENT 83607
INTENDED PURPOSE:	To be used in immunoenzymatic tests in CHORUS instruments as negative control or diluent of samples that gave out-of-range results. It must only be used by professional laboratory personnel.
BASIC UDI-DI	803389132CHORUS0028
UDI-DI	08033891322595
RISK CLASS:	CLASS A
CLASSIFICATION RULE:	RULE 5A
CONFORMITY ASSESSMENT ROUTE:	ARTICLE 17, ANNEX II and ANNEX III
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:	NOT NECESSARY
(EU) CERTIFICATE:	//
REVISION:	0
PLACE, DATE OF ISSUE:	MONTERIGGIONI, 23 MAY 2022
EXPIRY DATE:	//

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

SIGNATURE:



MARIA CLAUDIA ALCARO
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, 2022-05-23

M. Stoczko

MAGDALENA STOCZKO
REGULATORY SUPERVISOR