DECLARATION OF CONFORMITY

Rev. 3 19/06/2019

MANUFACTURER:	DIESSE DIAGNOSTICA SENESE SPA VIA DELLE ROSE 10 53035 MONTERIGGIONI (SI), ITALY
EUROPEAN REPRESENTATIVE:	//
PRODUCT:	**STREPTO SLIDE**
CODE:	**0210**
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:	2003
PLACE, DATE OF ISSUE:	MONTERIGGIONI, 19 JUNE 2019
EXPIRY DATE:	25 MAY 2022

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

SIGNATURE:

CHIARA MUZZI
HEAD OF REGULATORY AFFAIRS

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

ISSUED: MONTERIGGIONI, 20/04/2020

MAGDALENA STOCZKO
REGULATORY AFFAIRS SPECIALIST