



DECLARATION OF CONFORMITY

Rev. 3

19/06/2019

MANUFACTURER: DIESE DIAGNOSTICA SENESE SPA
VIA DELLE ROSE 10
53035 MONTERIGGIONI (SI),
ITALY

EUROPEAN REPRESENTATIVE: //

PRODUCT: **ESR CONTROL CUBE**
CODE: **10435**

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: NOVEMBER 2016

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 DIESE DIAGNOSTICA SENESE SPA

ISSUED: MONTERIGGIONI, 18/06/2019

MAGDALENA STOCZKO
REGULATORY AFFAIRS SPECIALIST