



## DECLARATION OF CONFORMITY

Rev. 2

05/06/2019

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

EUROPEAN REPRESENTATIVE: //

PRODUCT: **AUTO-DAT MICROPLATE**  
CODE: **26005**

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: 2017

PLACE, DATE OF ISSUE: MONTERIGGIONI, 5 JUNE 2019

EXPIRY DATE: 25 MAY 2022


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

SIGNATURE:

  
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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, 14/06/2019

  
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MAGDALENA STOCZKO  
REGULATORY AFFAIRS SPECIALIST