EU DECLARATION OF CONFORMITY

MANUFACTURER:	DIESSE DIAGNOSTICA SENESE SPA STRADA DEI LAGHI 39 53035 MONTERIGGIONI (SI), ITALY
SINGLE REGISTRATION NUMBER	IT-MF-000013311
AUTHORIZED REPRESENTATIVE:	NOT APPLICABLE
PRODUCT: CODE:	AUTO-DAT 26001
INTENDED PURPOSE:	The AUTO-DAT is a semi-automatic instrument for the execution, interpretation and reporting of microplate agglutination serological tests. The instrument processes the images, taken from the instrument cameras, by evaluating the agglutination reactions that occurred in the microplate as a result of mixing and provides semi-quantitative results, using a specific software. Only materials supplied by DIESSE Diagnostica Senese S.p.A and intended for use with this instrument should be used for agglutination tests. This instrument is intended to be used only by professional laboratory users. It is prohibited to use AUTO-DAT for any activity unrelated to its intended use.
BASIC UDI-DI	803389132AUTODAT2005Y
UDI-DI	08033891328368
RISK CLASS:	CLASS A
CLASSIFICATION RULE:	RULE 5B
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 AND WITH THE FOLLOWING UNION LEGISLATION: **LOW VOLTAGE DIRECTIVE (2014/35/EU), ELECTROMAGNETIC COMPATIBILITY DIRECTIVE (2014/30/EU) AND RESTRICTION OF HAZARDOUS SUBSTANCES IN ELECTRICAL AND ELECTRONIC EQUIPMENT DIRECTIVE – ROHS2 (2011/65/EU).**

ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

THIS CERTIFICATE WILL LOSE ITS VALIDITY IN THE EVENT OF:

- MODIFICATIONS MADE TO THE MACHINE IN QUESTION WITHOUT OUR AUTHORIZATION
- INCORRECT USE OF THE INSTRUMENT
- TECHNICAL INTERVENTIONS PERFORMED BY UNAUTHORIZED PERSONNEL
- INSTALLATION OF NON-ORIGINAL SPARE PARTS.

REFERENCE TO ANY CS APPLIED:	NOT APPLICABLE
NOTIFIED BODY:	NOT NECESSARY
(EU) CERTIFICATE:	NOT APPLICABLE
REVISION:	0
PLACE, DATE OF ISSUE:	MONTERIGGIONI, 20 DECEMBER 2023
EXPIRY DATE:	NOT APPLICABLE

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, 2023-12-20

MAGDALENA STOCZKO
REGULATORY SUPERVISOR