



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:

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PRODUCT:
CODE:

AUTO-DAT
26000

INTENDED PURPOSE:

AUTO-DAT, including installed software, is an automated clinical analyzer designed for conducting qualitative and semi-quantitative agglutination assays. Samples are tested in dedicated microplate samples using specific reagents. The intended purpose of the analyzer is closely related to each reagent used.
This instrument is intended for use by professional laboratory users only.

BASIC UDI-DI

803389132 AUTODATINS00 9B

UDI-DI

08033891322007

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. 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.

THE PRODUCT CONFORMS, AS A WHOLE AND IN ITS PARTS, WITH THE FOLLOWING STANDARDS AND THEIR AMENDMENTS:

EN 61010-1:2010

SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL, AND LABORATORY USE - PART 1: GENERAL REQUIREMENTS

EN 61010-2-081:2015 SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL, AND LABORATORY USE - PART 2-081: PARTICULAR REQUIREMENTS FOR AUTOMATIC AND SEMI-AUTOMATIC LABORATORY EQUIPMENT FOR ANALYSIS AND OTHER PURPOSES

EN 61010-2-101:2017 SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL, AND LABORATORY USE - PART 2-101: PARTICULAR REQUIREMENTS FOR IN VITRO DIAGNOSTIC (IVD) MEDICAL EQUIPMENT

EN 61326-1:2013 ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL AND LABORATORY USE - EMC REQUIREMENTS - PART 1: GENERAL REQUIREMENTS

EN 61326-2-6:2013 ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL AND LABORATORY USE - EMC REQUIREMENTS - PART 2-6: PARTICULAR REQUIREMENTS - IN VITRO DIAGNOSTIC (IVD) MEDICAL EQUIPMENT

AND THEREFORE MEETS THE ESSENTIAL REQUIREMENTS OF THE FOLLOWING COMMUNITY DIRECTIVES AND THEIR AMENDMENTS:

LOW VOLTAGE DIRECTIVE (2014/35/EU)

ELECTROMAGNETIC COMPATIBILITY DIRECTIVE (2014/30/EU)

RESTRICTION OF HAZARDOUS SUBSTANCES IN ELECTRICAL AND ELECTRONIC EQUIPMENT DIRECTIVE – ROHS2 (2011/65/EU)

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

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

ISSUED: MONTERIGGIONI, 2022-05-20



MAGDALENA STOCZKO
REGULATORY SUPERVISOR