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:	//
PRODUCT: CODE:	VES MATIC Original 10340
INTENDED PURPOSE:	The VES MATIC Original is an automated instrument for the quantitative Erythrocyte Sedimentation Rate (ESR) determination with the modified Westergren method using venous whole blood anticoagulated in citrate. ESR is a non-specific parameter of inflammatory status used as an aid for monitoring the physiological or pathological state of the patient. The instrument is to be used only by professional laboratory users.
BASIC UDI-DI	803389132VMORIGINAL00NX
UDI-DI	08033891324551
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 61010-2-101:2017	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, 13 OCTOBER 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 COMPLIANCE

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

ISSUED: MONTERIGGIONI, 2022-10-13

MAGDALENA STOCZKO
REGULATORY SUPERVISOR