



DECLARATION OF CONFORMITY

MANUFACTURER:	DIESSE DIAGNOSTICA SENESE SPA VIA DELLE ROSE 10 53035 MONTERIGGIONI (SI), ITALY
EUROPEAN REPRESENTATIVE:	//
GENERIC NAME	AUTOMATIC INSTRUMENT FOR ESR ANALYSIS
PRODUCT: CODE:	VES-MATIC CUBE 200 FOR BECKMAN COULTER (5 POSITIONS) 10370/BC5
TECHNICAL DATA:	90-264 Vac (50-60 Hz); Pwr: 265 VA
CLASSIFICATION:	IVD NOT IN ANNEX II OR SELF-TESTING IVD
CONFORMITY ASSESSMENT ROUTE:	ANNEX APPLIED N° III EXCLUDING (6) ESSENTIAL REQUIREMENTS OF ANNEX I

WE HEREWITH DECLARE THAT THE DESIGN, TYPE OF MANUFACTURE OF THE IN VITRO MEDICAL DIAGNOSTIC DEVICE DESCRIBED ABOVE AND THE VERSION DISTRIBUTED ON THE MARKET, CONFORMS TO THE 98/79/EEC DIRECTIVE RELEVANT TO THE IN VITRO MEDICAL-DIAGNOSTICS DEVICES (IVD)

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 61010-2-101:2002	SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL, AND LABORATORY USE - PART 2-101: SAFETY 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 61326-2-6:2006

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)

NOTIFIED BODY:

NOT NECESSARY

(EC) CERTIFICATE:

N.A.

START OF CE-MARKING:

NOVEMBER 2005

REVISION:

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PLACE, DATE OF ISSUE:

MONTERIGGIONI, 26 NOVEMBER 2020

EXPIRY DATE:

25 MAY 2022

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

SIGNATURE:



CHIARA MUZZI
QUALITY & REGULATORY MANAGER

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

ISSUED: MONTERIGGIONI,

26/11/2020



MAGDALENA STOCZKO
REGULATORY SUPERVISOR