DECLARATION OF CONFORMITY

Rev. 2 08/07/2019

MANUFACTURER:	DIESSE DIAGNOSTICA SENESE SPA VIA DELLE ROSE 10 53035 MONTERIGGIONI (SI), ITALY
EUROPEAN REPRESENTATIVE:	//
GENERIC NAME:	IMAGE ANALYZER FOR IMMUNOLOGY TESTS
PRODUCT: CODE:	**AUTO-DAT** **26000**
TECNICAL DATA:	13.5 V DC; 4 A
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:	MARCH 2017
PLACE, DATE OF ISSUE:	MONTERIGGIONI, 08 JULY 2019
EXPIRY DATE:	25 MAY 2022

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

SIGNATURE:

CHIARA MUZZI
HEAD OF REGULATORY AFFAIRS

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

ISSUED: MONTERIGGIONI, 08/07/2019

M. Stoczko

MAGDALENA STOCZKO
REGULATORY AFFAIRS SPECIALIST