



DECLARATION OF CONFORMITY

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| 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 |
| TECHNICAL 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:

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| 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

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