# DECLARATION OF CONFORMITY

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| MANUFACTURER: | DIESSE DIAGNOSTICA SENESE SPA<br>VIA DELLE ROSE 10<br>53035 MONTERIGGIONI (SI),<br>ITALY |
| EUROPEAN REPRESENTATIVE: | // |
| GENERIC NAME | KIT FOR INSTALLATION OF INTEGRATED AUTOMATED PIPETTOR INSTRUMENT |
| PRODUCT:<br>CODE: | AUTOSAMPLER UPGRADE KIT<br>81215 |
| TECHNICAL DATA: | 90-264 V (50-60 Hz); Pwr: 100 VA |
| CLASSIFICATION: | IVD NOT IN ANNEX II OR SELF-TESTING IVD |
| CONFORMITY ASSESSMENT ROUTE: | ANNEX APPLIED N° III EXCLUDING (6)<br>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 |

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| **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)**

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| NOTIFIED BODY: | NOT NECESSARY |
| (EC) CERTIFICATE: | N.A. |
| START OF CE-MARKING: | DECEMBER 2017 |
| REVISION: | 2 |
| 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

M. Stoczko

MAGDALENA STOCZKO
REGULATORY SUPERVISOR