



DECLARATION OF CONFORMITY

Rev. 1

08/07/2019

MANUFACTURER: DIESSE DIAGNOSTICA SENESE SPA
VIA DELLE ROSE 10
53035 MONTERIGGIONI (SI),
ITALY

EUROPEAN REPRESENTATIVE: //

GENERIC NAME: AUTOMATIC INSTRUMENT FOR ESR ANALYSIS

PRODUCT: **CUBE 30 touch**
CODE: **10395**

TECNICAL DATA: 110-230 Vac (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)
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: FEBRUARY 2018

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



MAGDALENA STOCZKO
REGULATORY AFFAIRS SPECIALIST