



EU DECLARATION OF CONFORMITY

MANUFACTURER:

DIESSE DIAGNOSTICA SENESE SPA
STRADA DEI LAGHI 39
53035 MONTERIGGIONI (SI),
ITALY

SINGLE REGISTRATION NUMBER

IT-MF-000013311

AUTHORIZED REPRESENTATIVE:

NOT APPLICABLE

**PRODUCT:
CODE:**

**CHORUS EVO
82000**

INTENDED PURPOSE:

CHORUS EVO analyzer, including the installed software, is an automatic clinical analyzer designed to conduct qualitative, semiquantitative and quantitative immunometric assays testing samples in ready-to-use single test devices.
The intended purpose of the instrument is strictly related to each immunometric assays applied on it.
This bench-top instrument is intended to be used only by professional laboratory users.

BASIC UDI-DI

803389132CHORUSEVO009X

UDI-DI

08033891322670

RISK CLASS:

CLASS A

CLASSIFICATION RULE:

RULE 5B

CONFORMITY ASSESSMENT ROUTE:

ARTICLE 17, ANNEX II and ANNEX III

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT IS IN CONFORMITY WITH **REGULATION (EU) 2017/746** OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON IN VITRO DIAGNOSTIC MEDICAL DEVICE AND WITH THE FOLLOWING UNION LEGISLATION: **LOW VOLTAGE DIRECTIVE (2014/35/EU)**, **ELECTROMAGNETIC COMPATIBILITY DIRECTIVE (2014/30/EU)** AND **RESTRICTION OF HAZARDOUS SUBSTANCES IN ELECTRICAL AND ELECTRONIC EQUIPMENT DIRECTIVE – ROHS2 (2011/65/EU)**.
ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

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.

REFERENCE TO ANY CS APPLIED:	NOT APPLICABLE
NOTIFIED BODY:	NOT NECESSARY
(EU) CERTIFICATE:	NOT APPLICABLE
REVISION:	0
PLACE, DATE OF ISSUE:	MONTERIGGIONI, 29 FEBRUARY 2024
EXPIRY DATE:	NOT APPLICABLE

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

SIGNATURE:



MARIA CLAUDIA ALCARO
PERSON RESPONSIBLE FOR THE REGULATORY
COMPLIANCE

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

ISSUED: MONTERIGGIONI, 2024-02-29



MAGDALENA STOCZKO
REGULATORY SUPERVISOR