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:	**CUBE 30 TOUCH** **10395**
INTENDED PURPOSE:	The CUBE 30 TOUCH (REF 10395) is an automated instrument for the quantitative Erythrocyte Sedimentation Rate (ESR) determination, measured using a modified Westergren method on venous whole blood anticoagulated with K2EDTA or K3EDTA. ESR is a non-specific parameter of an inflammatory status, used as an aid for the monitoring of the physiological or pathological state of the patient. The instrument is to be used only by professional laboratory users.
BASIC UDI-DI	803389132CUBE30T00V6
UDI-DI	08033891322069
RISK CLASS:	CLASS B
CLASSIFICATION RULE:	RULE 6
CONFORMITY ASSESSMENT ROUTE:	ANNEX IX

Digitally signed by Ceaicovschi Tudor
Date: 2025.11.28 14:37:27 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTAßE 65 – 80339 MUNICH GERMANY No. 0123
(EU) CERTIFICATE:	V12 056726 0006 Rev. 03
REVISION:	2
PLACE, DATE OF ISSUE:	MONTERIGGIONI, 6 NOVEMBER 2024
EXPIRY DATE:	2027-05-26

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, 2024-11-06

MAGDALENA STOCZKO
REGULATORY SUPERVISOR

EC DECLARATION OF CONFORMITY

MANUFACTURER:	DIESSE DIAGNOSTICA SENESE SPA STRADA DEI LAGHI 39 53035 MONTERIGGIONI (SI), ITALY
EUROPEAN REPRESENTATIVE:	//
PRODUCT: CODE:	ESR CONTROL CUBE 10435
CLASSIFICATION:	IVD NOT IN ANNEX II OR SELF-TESTING IVD
CONFORMITY ASSESSMENT ROUTE:	ANNEX APPLIED N° III

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PREVISIONS OF THE COUNCIL DIRECTIVE 98/79EC FOR IN VITRO DIAGNOSTIC MEDICAL DEVICE. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

NOTIFIED BODY:	NOT NECESSARY
(EC) CERTIFICATE:	N.A.
START OF CE-MARKING:	NOVEMBER 2016
REVISION:	6
PLACE, DATE OF ISSUE:	MONTERIGGIONI, 25 MAY 2022
EXPIRY DATE:	25 MAY 2027

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

SIGNATURE:

CHIARA MUZZI
REGULATORY AFFAIRS MANAGER

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

ISSUED: MONTERIGGIONI, 25/05/2022

MAGDALENA STOCZKO
REGULATORY SUPERVISOR