



## EU DECLARATION OF CONFORMITY

MANUFACTURER:	DIESE DIAGNOSTICA SENESE SPA STRADA DEI LAGHI 39 53035 MONTERIGGIONI (SI), ITALY
SINGLE REGISTRATION NUMBER	IT-MF-000013311
AUTHORIZED REPRESENTATIVE:	NOT APPLICABLE
PRODUCT: CODE:	<b>CUBE 30 TOUCH 10395</b>
INTENDED PURPOSE:	<p>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.</p> <p>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.</p> <p>The instrument is to be used only by professional laboratory users.</p>
BASIC UDI-DI	803389132CUBE30T00V6
UDI-DI	08033891322069
RISK CLASS:	CLASS B
CLASSIFICATION RULE:	RULE 6
CONFORMITY ASSESSMENT ROUTE:	ANNEX IX

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. 01

REVISION:

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PLACE, DATE OF ISSUE:

MONTERIGGIONI, 31 JANUARY 2024

EXPIRY DATE:

2027-06-26

**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, 2024-01-31



MAGDALENA STOCZKO  
REGULATORY SUPERVISOR