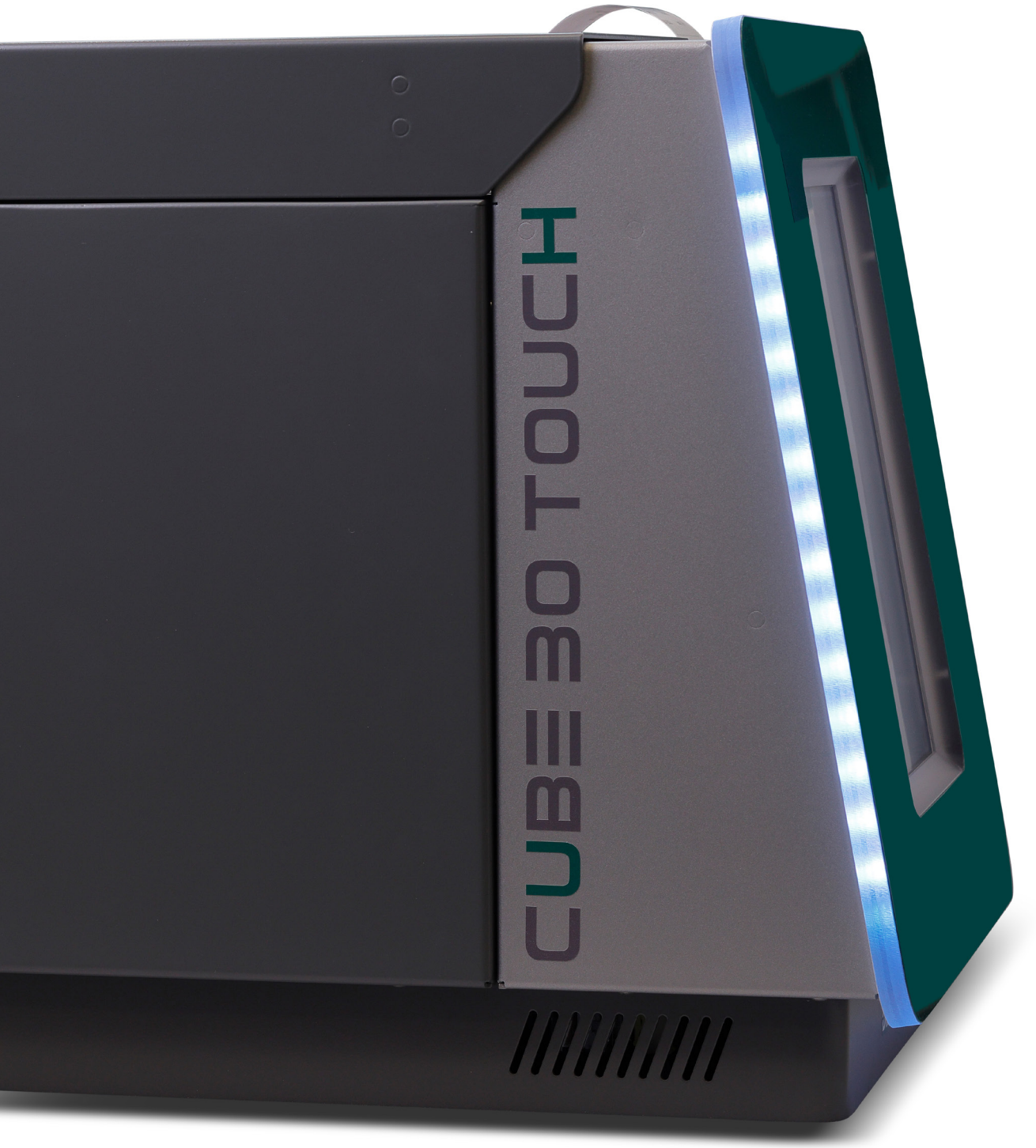
CUBE 30 TOUCH

SED-RATE SYSTEM

30 ESR RESULTS IN **25 MIN** WITH MODIFIED **WESTERGREN METHOD**

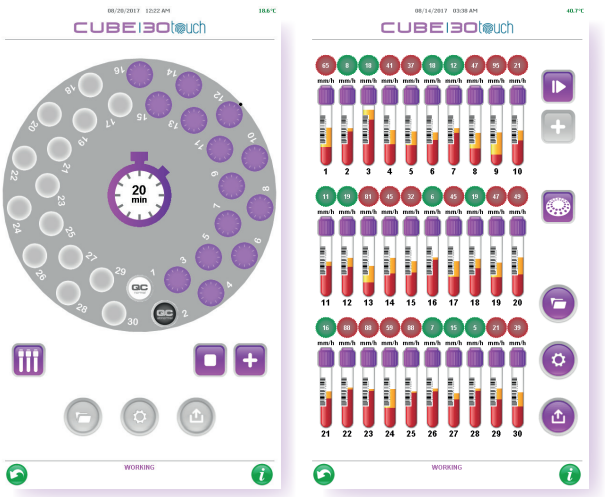


DIESSE

FEATURES

- BATCH / CONTINUOS WORKING MODE
- TOUCH SCREEN INTERFACE
- REDUCED SIZE
- NO SAMPLE CONSUMPTION
- NO WASTE FLUIDS
- SAFETY

Analyze different and **non-dedicated tubes**



Environmentally friendly

No production of waste materials, without extra-cost for liquid waste disposal.

DIESSE

Test performed on edta/cbc samples

The test is performed on blood samples collected in the same top lavender tubes used for full blood count.

USER FRIENDLY

- Up to 30 samples simultaneously
- Internal bar-code reader
- Ease of use
- Reduction of turn-around time Standardization
- Internal mixing of samples by complete inversion of the tubes
- 10.1 inches colour touch screen
- Innovative graphic interface
- Fast Turn-Around Time (TAT)
- 30 results in less than 25 minutes

DIESSE

2021_FL.0010 | REV.00

TECHNICAL CHARACTERISTICS

POWER SUPPLY
110 to 230 VAC (50 – 60Hz)

MIXING OF SAMPLES
in compliance with CLSI and ICSH requirements

ABSORBED ELECTRICAL POWER
max 100 W

DIMENSIONS
450 x 390 x 297 mm (w x h x d)

DISPLAY
10,1" wide vertical type

WEIGHT
14 Kg

NOISE LEVEL
< 80 Db

WORKING TEMPERATURE
+ 15° to + 35°C

BAR-CODE READER
Automatic internal

RELATIVE HUMIDITY
from 20% to 80% without condensation

INSTRUMENTS AND ACCESSORIES

CUBE 30 TOUCH	1	Ref. 10395
TEST DEVICE NEXT 500	500 tests	Ref. 10293
TEST DEVICE NEXT 1K	1000 tests	Ref. 10294
TEST DEVICE NEXT 5K	5000 tests	Ref. 10296
TEST DEVICE NEXT 10K	10.000 tests	Ref. 10297
ESR CONTROL CUBE	4 x 9 ml	Ref. 10435
ESR CONTROL CUBE	2 x 9 ml	Ref. 10436
EXTERNAL BAR-CODE READER	1	Ref. P20550510
THERMAL PAPER	1	Ref. 10403

DIESSE

www.diesse.it

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

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

EC DECLARATION OF CONFORMITY

MANUFACTURER:	DIESSE DIAGNOSTICA SENESE SPA STRADA DEI LAGHI 39 53035 MONTERIGGIONI (SI) ITALY
EUROPEAN REPRESENTATIVE:	//
GENERIC NAME	RFID TRANSPONDER DEVICES

PRODUCT AND CODE	
TEST DEVICE 10K	10290
TEST DEVICE 5K	10291
TEST DEVICE 1K	10292
TEST DEVICE NEXT 10K	10297
TEST DEVICE NEXT 5K	10296
TEST DEVICE NEXT 1K	10294
TEST DEVICE NEXT 500	10293
TEST DEVICE NEXT 50	10295
TEST DEVICE ORIGINAL 4K	10270

WE HEREWITH DECLARE THAT TEST DEVICE PRODUCTS COMPLY WITH DIRECTIVE 2014/53/EU AND THE RELEVANT APPLICABLE SECTOR STANDARDS LISTED BELOW, WHEN USED WITH THE ESR ANALYZERS PRODUCED BY DIESSE DIAGNOSTICA SENESE S.P.A.

ETSI EN 300 330 V2.1.1 (2016-11)	Short Range Devices (SRD); Radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
ETSI EN 301 489-1 V1.9.2 (2011-09)	Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
ETSI EN 301 489-3 V2.1.1 (2019-03)	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 246 GHz; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
EN 55035:2017+A11:2020	Electromagnetic compatibility of multimedia equipment. Immunity requirements
EN 61000-4-2:2009	Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test
EN 61000-4-3:2006 +A1:2008+A2:2010	Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test

START OF CE-MARKING:	NOVEMBER 2021
	EXCEPT:
2022:	TEST DEVICE ORIGINAL 4K
REVISION:	2
PLACE, DATE OF ISSUE:	MONTERIGGIONI, 03 OCTOBER 2022
EXPIRY DATE:	//

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, 03/10/2022

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 10436
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