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.

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REGULATORY AFFAIRS MANAGER

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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:	//
PRODUCT: CODE:	ESR CONTROL CUBE 10435
CLASSIFICATION:	IVD NOT IN ANNEX II OR SELF-TESTING IVD
CONFORMITY ASSESSMENT ROUTE:	ANNEX APPLIED N° III

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