

MANUFACTURER:

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

EUROPEAN REPRESENTATIVE:

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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:

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SIGNATURE:



CHIARA MUZZI
REGULATORY AFFAIRS MANAGER

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ISSUED: MONTERIGGIONI,

03/10/2022



MAGDALENA STOCZKO
REGULATORY SUPERVISOR



EC DECLARATION OF CONFORMITY

MANUFACTURER:

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

EUROPEAN REPRESENTATIVE:

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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

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