Monteriggioni, 16th February 2026

TO WHOM IT MAY CONCERN

We, DIESSE Diagnostica Senese S.p.A., manufacturer of in vitro diagnostic medical devices with manufacturing site in Strada dei Laghi 39, 53035 Monteriggioni (SI), Italy, unique manufacturer of:

- 10290 TEST DEVICE 10K
- 10291 TEST DEVICE 5K
- 10292 TEST DEVICE 1K
- 10293 TEST DEVICE NEXT 500
- 10294 TEST DEVICE NEXT 1K
- 10296 TEST DEVICE NEXT 5K
- 10297 TEST DEVICE NEXT 10K

considering that

all the products listed above are not:

- reagents or a reagent products
- a calibrator
- a control material
- a kit
- an instrument or an apparatus
- a piece of equipment
- a software or a system

used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens derived from the human body

hereby declare

that all these products cannot be classified as In Vitro Diagnostic Medical Device (IVDMD) according to REGULATION (EU) 2017/746. For this reason, the registration by the Health Authorities is not applicable to these devices.

Sincerely,

Digitally signed by Ceaicovschi Tudor
Date: 2026.07.24 11:49:55 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Giada Benvenuti
Regulatory Affairs Specialist

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

LISTA DISPOZITIVILOR MEDICALE *(2)*

+ Adăugați dispozitiv

Cod	Numărul de catalog	Denumirea
DM000890018	10435	CONTROL PENTRU DETERMINAREA VSH
DM000890019	10436	CONTROL PENTRU DETERMINAREA VSH

Crează Fișier

15 25 50 Tot