



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,

A handwritten signature in black ink that reads "Giada Benvenuti".

Giada Benvenuti
Regulatory Affairs Specialist