Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 049539 0014 Rev. 01

Manufacturer:

Diesse Diagnostica Senese SpA
Via delle Rose 10
53035 Monteriggioni (SI)
ITALY

Facility(ies):

Diesse Diagnostica Senese SpA
Via del Pozzo 5, 53035 Monteriggioni (SI), ITALY

Diesse Diagnostica Senese SpA
Strada dei Laghi 39, 53035 Monteriggioni (SI), ITALY

Diesse Diagnostica Senese SpA
Via delle Rose 10, 53035 Monteriggioni (SI), ITALY

Product Category(ies): **Reagents for determination of infection markers and detection of tumoral marker PSA**

Model(s):

ELISA reagents, kits, and controls for Rubella, Toxoplasma, CMV, and Chlamydia of: CHORUS product line, ENZYWELL product line
Complement Fixation Test reagents, kits, and controls for Rubella, Toxoplasma, CMV, and Chlamydia of: Manual procedure product line, SERAMAT product line
ELISA reagents, kits, and controls for detection of tumoral marker PSA of CHORUS product line

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. See also notes overleaf.

Report no.: ITA1033876

Valid from: 2019-09-20
Valid until: 2023-08-12

Date, 2019-09-20

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany