ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

SCC Accredited CB-MS OCSM Accrédité CCN

America

CERTIFICATE

No. QS2 049539 0015 Rev. 00

Certificate Holder: **Diesse Diagnostica Senese SpA**
Via delle Rose 10
53035 Monteriggioni (SI)
ITALY

Certification Mark:

Scope of Certificate: **Design, Development, Manufacture and Distribution of In-Vitro Diagnostic Medical Devices used in the Diagnosis and Management of Immune Status, Autoimmune Status, Disease Status, Prenatal Screening, Donor Screening, Transmissible Agents, Sexually Transmissible Agents, Bacterial Disease, and Disposable In-Vitro Diagnostic Systems for the Determination of ESR**

Standard(s): **ISO 13485:2003**

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.: **ITA1210845**

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Expiry Date: **2019-02-28**

Date of Issue: 2018-12-14

(Arie Henkin)
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

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TÜV SÜD America

CERTIFICATE

No. QS2 049539 0015 Rev. 00

Facility(ies):

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

Facility Scopes:

Design and Development of In-Vitro Diagnostic Systems for Clinical Analysis, Manufacture of In-Vitro Diagnostic Medical Devices (Reagents) used in the Diagnosis and Management of Immune Status, Autoimmune Status, Disease Status, Prenatal Screening, Donor Screening, Transmissible Agents, Sexually Transmissible Agents, Bacterial Disease

Facility(ies):

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

Facility Scopes:

Manufacture of In-Vitro Diagnostic Medical Device (Reagents) used in the Diagnosis and Management of Immune Status, Autoimmune Status, Disease Status, Prenatal Screening, Donor Screening, Transmissible Agents, Sexually Transmissible Agents, Bacterial Disease

Facility(ies):

Diesse Diagnostica Senese SpA
Strada del Laghi 39, Loc. Rigoni, 53035 Monteriggioni (SI) ITALY

Facility Scopes:

Manufacture and Distribution of In-Vitro Diagnostic Medical Devices (Reagents) used in the Diagnosis and Management of Immune Status, Autoimmune Status, Disease Status, Prenatal Screening, Donor Screening, Transmissible Agents, Sexually Transmissible Agents, Bacterial Disease, and In-Vitro Diagnostic Systems for the Determination of ESR

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