



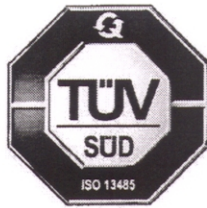
America

CERTIFICATE

No. QS1 17 07 49539 012

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 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.

TÜV SÜD America Inc. is a Health Canada CMDCAS Recognized Registrar.

Report No.: M2710
Effective Date: 2017-07-01
Expiry Date: 2018-12-31

Gary Minks
Vice President, Regulatory Affairs



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TÜV SÜD America Inc.
10 Centennial Drive
Peabody, MA 01960
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America

CERTIFICATE

No. QS1 17 07 49539 012

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

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

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

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

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

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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