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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 056726 0005 Rev. 00

Certificate Holder: **Diesse Diagnostica Senese SpA**
Strada dei Laghi 39
53035 Monteriggioni (SI)
ITALY

Certification Mark:

Scope of Certificate: **Design and Development, Manufacture, Installation and Servicing of In-Vitro Diagnostic Analyzers / Software, In-Vitro Diagnostic Medical Devices, In-Vitro Diagnostic Reagents, In-Vitro Diagnostic Test Kits used in the Diagnosis and Management of Autoimmune Status, Cancer, Endocrine Disorders, Infectious Disease Status, Immune Status, Prenatal Screening, Sexually Transmissible Agents, Transmissible Agents and In-Vitro Diagnostic Systems for Determination of ESR**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada USA FDA, MHLW / PMDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F003194**

Effective Date: **2022-06-06**

Expiry Date: **2025-05-17**

Date of Issue: 2022-06-15

(Renee Walker)
Manager, US Certification Body,
Medical and Health Services

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Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada
- Medical Device Regulations – Part 1- SOR 98/282

Japan
- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820
- 21 CFR Part 821

Facility(ies):

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

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

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

Date of Issue: 2022-06-15

(Renee Walker)
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C E R T I F I C A T E

No. QS6 056726 0005 Rev. 00

Facility Scopes:

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

Manufacture, Installation, Servicing and Distribution of In-Vitro Diagnostic Analyzers / Software; Distribution of In-Vitro Diagnostic Medical Devices, In-Vitro Diagnostic Reagents, In-Vitro Diagnostic Test Kits used in the Diagnosis and Management of Autoimmune Status, Cancer, Endocrine Disorders, Infectious Disease Status, Immune Status, Prenatal Screening, Sexually Transmissible Agents and Transmissible Agents; Manufacture and Distribution In-Vitro Diagnostic Systems for Determination of Erythrocyte Sedimentation Rate (ESR)
REPs Facility ID: F003194

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

Design and Development, Manufacture of In-Vitro Diagnostic Medical Devices, In-Vitro Diagnostic Reagents, In-Vitro Diagnostic Test Kits used in the Diagnosis and Management of Autoimmune Status, Cancer, Endocrine Disorders, Infectious Disease Status, Immune Status, Prenatal Screening, Sexually Transmissible Agents and Transmissible Agents
REPs Facility ID: F003194

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

Design and Development of In-Vitro Diagnostic Analyzers / Software, Manufacture of In-Vitro Diagnostic Medical Devices, In-Vitro Diagnostic Reagents, In-Vitro Diagnostic Test Kits used in the Diagnosis and Management of Autoimmune Status, Cancer, Endocrine Disorders, Infectious Disease Status, Immune Status, Prenatal Screening, Sexually Transmissible Agents, Transmissible Agents and In-Vitro Diagnostic Systems for Determination of Erythrocyte Sedimentation Rate (ESR)
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