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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 056726 0005 Rev. 02

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

Certification Mark:

Scope of Certificate: **Design and Development, Manufacture, Installation, Servicing and Distribution of In-Vitro Diagnostic Analyzers / Software; Design and Development, Manufacture, 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 of In-Vitro Diagnostic Systems for Determination of Erythrocyte Sedimentation Rate (ESR)**

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

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, Japan MHLW / PMDA, USA FDA. 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. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:QS6 056726 0005 Rev. 02
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

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(Renee Walker)
Director, US Certification Body, MHS

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C E R T I F I C A T E

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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. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

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

Japan
- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
- Japan PMD Act (as applicable)

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

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